Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Thome, Nicole L. (Nikki); NIH guidelines
Cc: Biosafety; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Attention: Incident Reports
Date: Friday, April 17, 2020 3:24:32 PM

Dear Nikki Thome,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Thome, Nicole L. (Nikki) <Thome.Nicole@mayo.edu>
Sent: Thursday, March 26, 2020 5:33 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Biosafety <Biosafety@mayo.edu>; Thome, Nicole L. (Nikki) <Thome.Nicole@mayo.edu>
Subject: Attention: Incident Reports
Importance: High

Good afternoon,

Attached you will find an Incident Report for the Mayo Clinic – Rochester. If you require additional information, please do not hesitate to contact biosafety@mayo.edu.

Thank you,

Nikki L. Thome
Mayo Clinic
Biosafety Officer
Research Administrative Services
Phone: 507-293-3901 ~ Pager: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

Fax: 507-538-0051
Email: thome.nicole@mayo.edu

Mayo Clinic
200 First Street SW
Rochester, MN 55905
mayoclinic.org
facebook.com/MayoClinic
youtube.com/MayoClinic
twitter.com/MayoClinic

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Mayo Clinic - Rochester
Date of Report:	3/26/2020
Reporter name and position:	Nikki L. Thome Biosafety Officer
Telephone number:	507-293-3901
Email address:	thome.nicole@mayo.edu
Reporter mailing address:	200 First Street SW Rochester MN 55095
Date of incident:	2/10/2020 3/26/2020 – date of self-report to Biosafety Office
Name of Principal Investigator:	Stephen Russell, M.D., Ph.D.
Is this an NIH-funded project?	☐YES ☒NO Funding source was Mayo Clinic "base budget" allocated to PI. If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: Bios00000773 IBC reviewed application on: 3/26/2020
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section II-A. Risk Assessment Section III-D-1-a (rDNA in RG2 agent) Section III-D-3-a (Use of RG2 agents in TC) Appendix B-II-D. Risk Group 2 (RG2) - Viruses
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Recombinant Moraten strain measles vaccines with the following modifications: 1. Substitution of the surface F glycoprotein for the F glycoprotein of CDV 2. Substitution of the surface H glycoprotein for a

Obtained via FOIA by Judicial Watch Inc.

	SLAM-blind, Nectin4-blind, CD46-tropic measles H glycoprotein engineered for diminished (8-fold) susceptibility to neutralization by human measles-immune serum, or for a Nectin4-blind CDV H with CD46 tropism conferred by the C-terminal display of a single chain antibody to CD46. 3. Insertion (between the N and P genes) of a sequence coding for the neutrophil activating protein (NAP) fused to a sequence coding for the receptor binding domain (RBD) of the SARS-2-coronavirus spike glycoprotein. The RBD is considered sufficient to induce an immune response to the SARS spike and the NAP is a polymeric (dodecamer) scaffold to present the RBD to the immune system in a multivalent form.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted

Obtained via FOIA by Judicial Watch Inc.

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On February 1st, PI reached out to male postdoctoral scientist in his lab to look into the development of a Measles-based Coronavirus vaccine due to the genetic sequence availability released by China. The hope was that the laboratory could respond quickly to the growing outbreak due to product resulting from work on a previous research project and current facility capabilities.

In response to this request from PI, male postdoc ordered reagents and designed recombinant Moraten-based vaccine constructs with maximal chance to induce immunity to SARS-2-CoV. The rationale was to induce immunity to the RBD of the SARS-2-CoV spike (200 aminoacids, compared to 1250 aminoacids for the entire spike) since this was previously shown to be a good target for SARS-neutralizing antibodies. The RBD was fused to NAP to drive multivalent display of the antigen on a dodecameric scaffold (a measles virus encoding NAP is about to enter clinical trials at Mayo Clinic).

Male postdoc constructed recombinant viral genomes and rescued recombinant measles viruses in level 2 containment laboratory. Viruses were rescued but grew VERY slowly so postdoc nurtured them and eventually was able to harvest lysates of infected cells and corresponding supernatants to test (by Western blot) for expression of the NAP-RBD protein. Western blot was positive, so PI wishes to move construct forward for very rapid clinical translation.

Rationale is that recombinant measles virus vaccines have very poor efficacy in the face of antimeasles neutralizing antibodies. The system in question was developed to facilitate vaccination of infants before decay of transplacentally acquired maternal antimeasles antibody

Obtained via FOIA by Judicial Watch Inc.

titers (main barrier to measles eradication). Hence, this platform should be more effective than a recombinant Moraten vaccine with unmodified coat in normal measles-immune subjects. Also, Moraten history of low reactogenicity and high efficacy to protect against measles suggests this platform should have acceptable tolerability for population protection. Hence, we believe this is the best shot (across all vaccine platforms) for a broadly applicable, highly efficacious and highly tolerable, vaccine to protect unexposed individuals to SARS-2-CoV infection.

Given that this work was closely related to other work associated with laboratory, in particular the development of the resurfaced Moraten Measles Virus, in their haste and motivated by the growing pandemic, neither the PI nor the post doc confirmed prior approval of the proposed vaccine development work before onset of experimentation. As the pandemic has progressed and institutions saw an increase in interest associated with COVID19 work, the Mayo Clinic COVID-19 Research Task Force began to identify individuals tagged with the potential to perform such research. The Biosafety Office started to reach out to work with them through the registration process. At this time, the PI realized his error in registration and self-reported the violation. The IBC Chair asked that all work with on the project stop until a review was conducted and IBC approval was obtained.

Research Leadership and a COVID-19 Research Task Force were immediately notified of the breach in registration. All recognized the significance of the oversight and agreed that the swift action of pausing research till IBC approval was obtained was appropriate.

The laboratory has the proper facilities and procedures to handle work with the virus and it was confirmed that they were handling the virus as recommended by the IBC (in an approved BSL2/2+ tissue culture room, wearing laboratory coat and gloves, handling the virus inside of a BSC). Only a single postdoctoral scientist was involved in the design and execution of the studies.

After an evaluation of the incident, it was determined that staff was not at risk due to the onset of experimentation. No illness has been associated with the event.

The laboratory was audited by the Biosafety Office annually, most recently on September 3rd, 2019. No outstanding issues were found during the audit. The laboratory will be re-audited follow a release of the shelter at home order for Minnesota.

Workers have taken the appropriate Bloodborne Pathogen training and the PI has taken and passed the Investigator Responsibility training associated with working under the NIH Guidelines.

Given the nature of the report, there were no medical surveillance provided or recommended after the incident and no equipment failures.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO Incident and application were jointly reviewed at the March 26th, 2020 IBC meeting
Please describe the root cause of this incident:	Rapid response to the SARS-2-coronavirus pandemic. PI/laboratory did not confirm that they had obtained prior approval for working prior to experimental onset.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

1. The laboratory will suspend work on the project until appropriately registered and approved by the IBC – initial review to occur at March 26th, 2020 meeting
2. The Biosafety Office will audit the laboratory during immediately following a release of the Safe at Home MN shelter in place governor's order.
3. The Biosafety Office will retrain the laboratory via a virtual meeting regarding:
    a. The need for prior registration of projects falling under the *NIH Guidelines*
    b. How to access applications to determine which organisms have approval for use prior to the onset of an experiment
    c. The PI will supply a list of attendees and the date of retraining will be recorded.
4. The Biosafety Officer will communicate the need for registration of organisms/material falling under IBC purview prior to the onset of experimentation
5. Research Leadership and the COVID-19 Task Force will issue a joint statement that can be used to stress the need for registration with the IBC for all projects falling under the IBC purview even in the unstable COVID-19 environment. This statement will be distributed to the wider research community to promote regulatory compliance and continuity of practice.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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From: Thome, Nicole L. (Nikki)
To: NIH guidelines
Cc: Biosafety; Thome, Nicole L. (Nikki)
Subject: Attention: Incident Reports
Date: Thursday, March 26, 2020 5:32:56 PM
Attachments: Incident Reporting - Mayo Clinic to NIH OSP (3-26-2020).pdf
Importance: High

Good afternoon,

Attached you will find an Incident Report for the Mayo Clinic – Rochester. If you require additional information, please do not hesitate to contact biosafety@mayo.edu.

Thank you,

Nikki L. Thome
Mayo Clinic
Biosafety Officer
Research Administrative Services
Phone: 507-293-3901 ~ Pager: Redacted by agreement
Fax: 507-538-0051
Email: thome.nicole@mayo.edu

Mayo Clinic
200 First Street SW
Rochester, MN 55905
mayoclinic.org
facebook.com/MayoClinic
youtube.com/MayoClinic
twitter.com/MayoClinic

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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

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A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Mayo Clinic - Rochester
Date of Report:	3/26/2020
Reporter name and position:	Nikki L. Thome Biosafety Officer
Telephone number:	507-293-3901
Email address:	thome.nicole@mayo.edu
Reporter mailing address:	200 First Street SW Rochester MN 55095
Date of incident:	2/10/2020 3/26/2020 – date of self-report to Biosafety Office
Name of Principal Investigator:	Stephen Russell, M.D., Ph.D.
Is this an NIH-funded project?	☐YES ☒NO Funding source was Mayo Clinic "base budget" allocated to PI. If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
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Obtained via FOIA by Judicial Watch Inc.

	SLAM-blind, Nectin4-blind, CD46-tropic measles H glycoprotein engineered for diminished (8-fold) susceptibility to neutralization by human measles-immune serum, or for a Nectin4-blind CDV H with CD46 tropism conferred by the C-terminal display of a single chain antibody to CD46. 3. Insertion (between the N and P genes) of a sequence coding for the neutrophil activating protein (NAP) fused to a sequence coding for the receptor binding domain (RBD) of the SARS-2-coronavirus spike glycoprotein. The RBD is considered sufficient to induce an immune response to the SARS spike and the NAP is a polymeric (dodecamer) scaffold to present the RBD to the immune system in a multivalent form.

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- The training received by the individual(s) involved and the date(s) the training was conducted

Obtained via FOIA by Judicial Watch Inc.

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
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DESCRIPTION OF INCIDENT: (use additional space as necessary)

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Workers have taken the appropriate Bloodborne Pathogen training and the PI has taken and passed the Investigator Responsibility training associated with working under the NIH Guidelines.

Given the nature of the report, there were no medical surveillance provided or recommended after the incident and no equipment failures.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO Incident and application were jointly reviewed at the March 26th, 2020 IBC meeting
Please describe the root cause of this incident:	Rapid response to the SARS-2-coronavirus pandemic. PI/laboratory did not confirm that they had obtained prior approval for working prior to experimental onset.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

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    c. The PI will supply a list of attendees and the date of retraining will be recorded.
4. The Biosafety Officer will communicate the need for registration of organisms/material falling under IBC purview prior to the onset of experimentation
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- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, May 11, 2020 3:09 PM
To: glickmam@MSKCC.ORG; NIH guidelines
Cc: cottinge@mskcc.org; GibsonJ2@mskcc.org; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Violation report

Dear Dr. Michael Glickman,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: glickmam@MSKCC.ORG <glickmam@MSKCC.ORG>
Sent: Sunday, April 19, 2020 11:46 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: cottinge@mskcc.org; GibsonJ2@mskcc.org
Subject: Violation report

Hello,

Please find attached a report of a violation of the NIH recombinant DNA guidelines, and our response to this violation. I am available to answer any questions.

Sincerely,

Michael S. Glickman MD

Obtained via FOIA by Judicial Watch Inc.

Chairman, MSK IBC

Memorial Sloan Kettering Cancer Center
Z1504 MSKCC, New York, NY 10065
Lab Office: 646-888-2368
Assistant: Veronica Shields
Lab: 646-888-2360
Clinical: 212-639-3191
glickmam@mskcc.org

www.mskcc.org

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Please note that this e-mail and any files transmitted from Memorial Sloan Kettering Cancer Center may be privileged, confidential, and protected from disclosure under applicable law. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any reading, dissemination, distribution, copying, or other use of this communication or any of its attachments is strictly prohibited. If you have received this communication in error, please notify the sender immediately by replying to this message and deleting this message, any attachments, and all copies and backups from your computer.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: glickmam@MSKCC.ORG
Sent: Sunday, April 19, 2020 11:46 AM
To: NIH guidelines
Cc: cottinge@mskcc.org; GibsonJ2@mskcc.org
Subject: Violation report
Attachments: Violation NIH Guidelines-MSK.pdf

Hello,

Please find attached a report of a violation of the NIH recombinant DNA guidelines, and our response to this violation. I am available to answer any questions.

Sincerely,

Michael S. Glickman MD

Chairman, MSK IBC

Memorial Sloan Kettering Cancer Center
Z1504 MSKCC, New York, NY 10065
Lab Office: 646-888-2368
Assistant: Veronica Shields
Lab: 646-888-2360
Clinical: 212-639-3191
glickmam@mskcc.org

www.mskcc.org

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Please note that this e-mail and any files transmitted from
Memorial Sloan Kettering Cancer Center may be privileged, confidential,
and protected from disclosure under applicable law. If the reader of
this message is not the intended recipient, or an employee or agent
responsible for delivering this message to the intended recipient,
you are hereby notified that any reading, dissemination, distribution,
copying, or other use of this communication or any of its attachments
is strictly prohibited. If you have received this communication in
error, please notify the sender immediately by replying to this message
and deleting this message, any attachments, and all copies and backups
from your computer.

Obtained via FOIA by Judicial Watch Inc.

Memorial Sloan Kettering Cancer Center

April 17, 2020

NIH Office of Science Policy
Biosafety, Biosecurity, and Emerging Biotechnology
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
301-496-9838
NIHGuidelines@od.nih.gov

Re: Violation of the NIH Guidelines at Memorial Sloan Kettering Cancer Center (MSK)

In accordance with the NIH guidelines, this report is a follow up of an initial report submitted to the NIH Office of Science Policy via email to NIHGuidelines@od.nih.gov on 4/1/2020.

The MSK Institutional Biosafety Committee (IBC) was notified that an IBC registered investigator was constructing recombinant Modified Vaccinia Ankara (MVA) expressing spike proteins from SARS-COV-2 without IBC approval, a violation of Section III-D-1 of the NIH Guidelines. The objective of the project was to investigate vaccine efficacy using recombinant MVAΔE5R or MVAΔE5R-Flt3L-OX40L to express either the S1 subunit or full length of the SPIKE protein from SARS-CoV-2. Flt3L is a dendritic cell growth factor and OX40L is a T cell co-stimulator. MVA deleted for E5R induces higher levels of type I Interferon compared to its undeleted counterpart.

As the Chairman of the IBC, as soon as I learned of this activity, I directed the PI to halt the unapproved research immediately and initiated an investigation. Our investigation revealed that the recombinant viruses had been generated and the Investigator was awaiting sequence confirmation. It was determined that the viruses must be destroyed immediately. Dr. James Gibson, Interim Vice President, Environmental Health and Safety was tasked to oversee the destruction of the materials. The PI surrendered all the materials from the project and these materials were destroyed by autoclaving them at 121^0C for 60 minutes.

The next morning, the Biosafety Officer (BSO) met with the PI and the lab members to review the details of the violation and to audit of the laboratory. The BSO also performed a spot check of over 1000 frozen vials in the -80^0C freezer. No materials associated with the unapproved activity were found. In addition, the BSO conducted an audit of the PI's animals in the vivarium to determine if animals had been administered with the viruses. No evidence to suggest that any in vivo work had been carried out was discovered. This study was not supported by PHS funds.

Obtained via FOIA by Judicial Watch Inc.

The following steps have been implemented to promote adherence to the NIH Guidelines and to foster best practices:

1. The PI was retrained in the applicability of the NIH Guidelines and the obligations to comply with them.
2. A training session will be scheduled for the PI and the entire lab on biosafety practices and the NIH Guidelines for recombinant work.
3. Unannounced monthly lab inspections for a period of twelve months to ensure compliance with the NIH Guidelines and Institutional policies.

The details of this issue were discussed at the IBC meeting on March 31, 2020. The IBC agreed that the destruction of the materials and retraining/educational efforts were appropriate. Additionally, the IBC also recommended that a review of the group's flow cytometry experiments to determine if any cytometry had been conducted for the unapproved project. This investigation revealed that no sorting had been conducted for the unapproved project.

We believe we have taken the necessary steps to prevent recurrence of this issue. Please do not hesitate to contact me with any questions or if you need further information. I can be reached by telephone at 646-888-2368 or through email at: glickmam@mskcc.org.

Sincerely,

Redacted by agreement

Michael Glickman, MD
IBC Chairperson

Cc: Eric Cottington, Ph.D., Senior Vice President, Research and Technology Management

Institutional Biosafety Committee (IBC)
Research and Technology Management
RTMIBC@mskcc.org

600 Third Avenue, New York, NY 10016 T 646.888.1077 F 646.888.1120
www.mskcc.org

NCI-designated Comprehensive Cancer Center

Obtained via FOIA by Judicial Watch Inc.

Memorial Sloan Kettering
Cancer Center

April 1, 2020

To:
Office of Science Policy, NIH
NIHGuidelines@od.nih.gov

From:
Michael Glickman, MD
IBC Chairman
Memorial Sloan Kettering Cancer Center

We are writing with an initial report of a violation of the NIH Guidelines under section IV-B-2-b-(7). We are gathering the necessary information for a full report, which will follow.

Regards,

Redacted by agreement

Michael Glickman, MD
IBC Chairperson

Institutional Biosafety Committee (IBC)
Research and Technology Management
RTMIBC@mskcc.org

600 Third Avenue, New York, NY 10016 T 646.227-2180 F 646.888.1120
www.mskcc.org

NCI-designated Comprehensive Cancer Center

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: kumara1@mskcc.org
Sent: Wednesday, April 1, 2020 1:59 PM
To: NIH guidelines
Cc: glickmam@MSKCC.ORG; schalled@mskcc.org; cottinge@mskcc.org
Subject: Preliminary report
Attachments: MSKCC violation 4-1-2020.pdf

Good Afternoon,

Please see attached preliminary report of a violation of the NIH Guidelines that has occurred at our Institution, on behalf of the IBC Chairman, Dr. Michael Glickman.

Thank you.
Sincerely,
Asmita

Asmita Kumar, Ph.D.
Associate Director, Research Compliance (IBC and IACUC)
Research and Technology Management / Office of Research Outreach and Compliance

Memorial Sloan Kettering Cancer Center
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10016
646-227-2180; C Redacted by agreement
kumara1@mskcc.org

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Please note that this e-mail and any files transmitted from Memorial Sloan Kettering Cancer Center may be privileged, confidential, and protected from disclosure under applicable law. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any reading, dissemination, distribution, copying, or other use of this communication or any of its attachments is strictly prohibited. If you have received this communication in error, please notify the sender immediately by replying to this message and deleting this message, any attachments, and all copies and backups from your computer.

Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Jensen, Sandra; NIH guidelines
Cc: Nattinger, Ann; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report for Research subject to the NIH Guidelines - Medical College of Wisconsin
Date: Monday, May 11, 2020 3:00:45 PM

Dear Sandra Jensen,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Jensen, Sandra <sjensen@mcw.edu>
Sent: Thursday, April 30, 2020 8:36 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Nattinger, Ann <anatting@mcw.edu>
Subject: Incident Report for Research subject to the NIH Guidelines - Medical College of Wisconsin

Hello,

Attached please find an incident report from the Medical College of Wisconsin.

Respectfully,

Sandy

Sandra L. Jensen, M.S., RLATG, CPIA
IACUC & Research Safety Committee Manager, Office of Research
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226
Phone: (414) 955-8223
Fax: (414) 955-6565
Email: sjensen@mcw.edu

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	X YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Medical College of Wisconsin
Date of Report:	04/17/2020
Reporter name and position:	Ann B. Nattinger, MD, MPH, Associate Provost for Research and Institutional Official
Telephone number:	414-955-8495
Email address:	anatting@mcw.edu
Reporter mailing address:	Medical College of Wisconsin 8701 Watertown Plank Road Milwaukee, WI 53226
Date of incident:	4/16/2020
Name of Principal Investigator:	Joseph T. Barbieri, PhD
Is this an NIH-funded project?	☐YES X NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill X Other (please describe): Initiation of work without IBC review and approval
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES X NO If yes, date of approval:
What was the approved biosafety level of the research?	☐ BL1 ☐ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III D-2-a
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	This incident involved synthesizing recombinant protein coding for the Receptor Binding Domain (RBD) of SARS-CoV2 spike protein. The gene encoding RBD was subcloned into a pET vector, expressed and purified from *E. coli K-12*. This recombinant protein fragment is non-toxic.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Overview: The lab is working with a collaborator from another institution to test the potential vaccine candidacy of the Receptor Binding Domain of SARS-CoV-2 spike protein. This non-toxic recombinant protein was synthesized into pET vector, expressed and purified from *E. coli* K-12.

During the SARS-CoV-2 pandemic, the Medical College of Wisconsin (MCW) has put all research labs into hibernation, and PI's require approval from the Institutional Official (IO) in order to conduct any active research activities. The PI received IO permission for this project, and mistakenly believed that this approval meant that he could initiate work without first getting approval from the IBC. All recombinant work conducted at MCW requires IBC approval.

Furthermore, the PI believed this work would fall under *NIH Guidelines Section III-F-8; Appendix C-II*. However, because the source organism is RG3, this work would correctly fall under *NIH Guidelines Section III-D-2*, requiring review and approval from the IBC (per the *NIH Guidelines*).

On April 16, 2020, the Biological Safety Officer learned that the work had started on April 10, 2020. The Biological Safety Officer asked the PI to halt work pending IBC review and approval. The PI complied, and the IBC subsequently reviewed the application on April 17, 2020 and approved this work on April 22, 2020.

Incident location: The incident occurred in a BSL2 research lab.

Involved Individuals: PI and one study staff member (i.e. Research Associate)

Immediate Actions Taken: Investigator ceased work on this project until IBC could review. IBC reviewed the project the next day and approved the work the following week.

Training received by the individuals involved:

a. Principal Investigator:
   - OSHA Bloodborne Pathogen Training
     - Date: 12/12/2019
     - Expiration Date: 12/12/2020
   - rDNA Training for Researchers Training
     - Date: 6/20/2019
     - Expiration Date: 6/20/2020

b. Research Associate:
   - OSHA Bloodborne Pathogen Training
     - Date: 4/17/2020
     - Expiration Date: 4/17/2021
   - rDNA Training for Researchers Training
     - Date: 5/8/2019
     - Expiration Date: 5/8/2022

Related SOP's: NA

Obtained via FOIA by Judicial Watch Inc.

Deviations from SOP at time of exposure: NA

Personal Protective Equipment used at time of incident: Disposable nitrile gloves, lab coat and eye protection

Occupational Health Requirements for personnel involved in the incident: NA

Medical advice/treatment/surveillance provided or recommended after the incident: NA

Any injury or illness associated with the incident: There was no injury or illness as a result of this incident.

Medical surveillance results: Medical surveillance was not necessary.

Equipment failures: NA

Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	The PI interpreted the communication of institutional approval to conduct research during the hibernation period as indicating regulatory approval for the work.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The communication from the Institutional Official granting permission to conduct research during hibernation has been modified to explicitly indicate that approval from related research committees (i.e., IBC, IRB, IACUC) must be obtained prior to project initiation.

Also, the Biological Safety Officer will work with the IBC Office staff to determine whether any other PI's made this same error. MCW will immediately report any further breaches of compliance.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

From: Jensen, Sandra
To: NIH guidelines
Cc: Nattinger, Ann
Subject: Incident Report for Research subject to the NIH Guidelines - Medical College of Wisconsin
Date: Thursday, April 30, 2020 8:36:30 AM
Attachments: Medical College of Wisconsin Incident Report_04.17.2020.pdf

---

Hello,

Attached please find an incident report from the Medical College of Wisconsin.

Respectfully,

Sandy

Sandra L. Jensen, M.S., RLATG, CPIA
IACUC & Research Safety Committee Manager, Office of Research
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226
Phone: (414) 955-8223
Fax: (414) 955-6565
Email: sjensen@mcw.edu

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

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April, 2019

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Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	X YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Medical College of Wisconsin
Date of Report:	04/17/2020
Reporter name and position:	Ann B. Nattinger, MD, MPH, Associate Provost for Research and Institutional Official
Telephone number:	414-955-8495
Email address:	anatting@mcw.edu
Reporter mailing address:	Medical College of Wisconsin 8701 Watertown Plank Road Milwaukee, WI 53226
Date of incident:	4/16/2020
Name of Principal Investigator:	Joseph T. Barbieri, PhD
Is this an NIH-funded project?	☐YES X NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill X Other (please describe): Initiation of work without IBC review and approval
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES X NO If yes, date of approval:
What was the approved biosafety level of the research?	☐ BL1 ☐ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III D-2-a
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	This incident involved synthesizing recombinant protein coding for the Receptor Binding Domain (RBD) of SARS-CoV2 spike protein. The gene encoding RBD was subcloned into a pET vector, expressed and purified from *E. coli K-12*. This recombinant protein fragment is non-toxic.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Overview: The lab is working with a collaborator from another institution to test the potential vaccine candidacy of the Receptor Binding Domain of SARS-CoV-2 spike protein. This non-toxic recombinant protein was synthesized into pET vector, expressed and purified from *E. coli* K-12.

During the SARS-CoV-2 pandemic, the Medical College of Wisconsin (MCW) has put all research labs into hibernation, and PI's require approval from the Institutional Official (IO) in order to conduct any active research activities. The PI received IO permission for this project, and mistakenly believed that this approval meant that he could initiate work without first getting approval from the IBC. All recombinant work conducted at MCW requires IBC approval.

Furthermore, the PI believed this work would fall under *NIH Guidelines Section III-F-8; Appendix C-II*. However, because the source organism is RG3, this work would correctly fall under *NIH Guidelines Section III-D-2*, requiring review and approval from the IBC (per the *NIH Guidelines*).

On April 16, 2020, the Biological Safety Officer learned that the work had started on April 10, 2020. The Biological Safety Officer asked the PI to halt work pending IBC review and approval. The PI complied, and the IBC subsequently reviewed the application on April 17, 2020 and approved this work on April 22, 2020.

Incident location: The incident occurred in a BSL2 research lab.

Involved Individuals: PI and one study staff member (i.e. Research Associate)

Immediate Actions Taken: Investigator ceased work on this project until IBC could review. IBC reviewed the project the next day and approved the work the following week.

Training received by the individuals involved:

a. Principal Investigator:
   - OSHA Bloodborne Pathogen Training
     - Date: 12/12/2019
     - Expiration Date: 12/12/2020
   - rDNA Training for Researchers Training
     - Date: 6/20/2019
     - Expiration Date: 6/20/2020

b. Research Associate:
   - OSHA Bloodborne Pathogen Training
     - Date: 4/17/2020
     - Expiration Date: 4/17/2021
   - rDNA Training for Researchers Training
     - Date: 5/8/2019
     - Expiration Date: 5/8/2022

Related SOP's: NA

Obtained via FOIA by Judicial Watch Inc.

Deviations from SOP at time of exposure: NA

Personal Protective Equipment used at time of incident: Disposable nitrile gloves, lab coat and eye protection

Occupational Health Requirements for personnel involved in the incident: NA

Medical advice/treatment/surveillance provided or recommended after the incident: NA

Any injury or illness associated with the incident: There was no injury or illness as a result of this incident.

Medical surveillance results: Medical surveillance was not necessary.

Equipment failures: NA

Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	The PI interpreted the communication of institutional approval to conduct research during the hibernation period as indicating regulatory approval for the work.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The communication from the Institutional Official granting permission to conduct research during hibernation has been modified to explicitly indicate that approval from related research committees (i.e., IBC, IRB, IACUC) must be obtained prior to project initiation.

Also, the Biological Safety Officer will work with the IBC Office staff to determine whether any other PI's made this same error. MCW will immediately report any further breaches of compliance.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

From: Keaton, Jason
To: Harris, Kathryn (NIH/OD) [C]
Subject: Medical College of Wisconsin Report Coming
Date: Thursday, April 16, 2020 2:31:05 PM
Importance: High

Dear Dr. Harris,

I became aware this morning that we had a PI clone the SARS-CoV-2 spike protein gene into E.coli K-12 for protein purification without IBC approval.

I believe that this falls under Section III-D-2-a of the NIH Guidelines and not III-F-8/Appendix C-II because SARS-CoV-2 is a Risk Group 3 organism.

The PI has halted work pending IBC review and I will gather more information and submit a report in the next few days.

Best regards,

Jason

Jason M Keaton, MS, RBP, CBSP, CSP
Director of Environmental Health & Safety
P: (414) 955-8060 | **C**: Redacted by agreement

See an Unsafe Condition or Behavior?
Report a Close-Call and Prevent an Injury!

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Harris, Kathryn (NIH/OD) [C]
Sent: Monday, May 4, 2020 1:11 PM
To: Coulson, Garry Brian
Cc: Cyr, Douglas M.; Brennan, Catherine; Tucker, Jessica (NIH/OD) [E]; McKinney, Michelle (NIH/OD) [E] (michelle.mckinney@nih.gov); Stemmy, Erik (NIH/NIAID) [E]; Beanan, Maureen (NIH/NIAID) [E]; Lane, Chelsea (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: RE: NIH Incident Report _ FINAL

Dear Dr. Coulson:

Thank you for your April 21, and April 23, 2020 reports to the NIH Office of Science Policy (OSP) regarding an incident involving SARS-CoV-2 which occurred on April 21, 2020. We understand you have also notified the NIH program officers within NIAID and the local public health department about the incident.

From your reports, we understand that a researcher working in a Biosafety Level (BL) 3 laboratory at the University of North Carolina Chapel Hill (UNC) received a mouse bite from a mouse infected with recombinant SARS-CoV-2 virus adapted for growth in mice.

You state in your reports that the researcher followed the approved post-exposure procedures and was evaluated at the University Employee Occupational Health Clinic. The individual was placed on medical surveillance and was instructed to complete a 14-day self-quarantine at home plus actively self-monitor with temperature checks twice daily consistent with CDC guidance for medium/high-risk exposures in healthcare personnel (HCP).

Your report indicates that the researcher involved in the incident was appropriately trained, was wearing the required personal protective equipment, and was following established laboratory procedure for handling live animals. In response to this incident, you indicate the investigator will review safe methods for handling mice, including whether the use of restraining devices and bite resistant gloves might be employed to minimize the possibility of a reoccurrence of such an incident.

You indicate the UNC Institutional Biosafety Committee (IBC) will be reviewing the incident at its May 6, 2020 meeting. No further information regarding this incident is required at this time, but please advise NIH OSP of any additional pertinent information after the IBC concludes its review.

Regards,

Dr. Kathryn Harris

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Thursday, April 23, 2020 10:05 AM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>
Subject: RE: NIH Incident Report _ FINAL

Dear Dr. Harris,

Obtained via FOIA by Judicial Watch Inc.

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of the potential exposure to recombinant DNA that occurred in a laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

Confidentiality Notice:
This email and any transmitted documents contain private, privileged and confidential information belonging to the sender. The information therein is solely for the use of the addressee. If your receipt of this transmission has occurred as the result of an error, please immediately notify us so we can arrange for the return of the documents. In such circumstances, you are advised that you may not disclose copy, distribute, or take any other action in reliance on the information transmitted.

From: Coulson, Garry Brian
Sent: Wednesday, April 22, 2020 8:05 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>
Subject: RE: NIH Incident Report - Preliminary

Hi Dr. Harris,

We have a single, unified BSL-3 Laboratory Medical Surveillance SOP for our research program, which I have attached. The applicable exposure response procedure for exposure to SARS-CoV-2 ("2019-nCOV") can be found on page 13. The individual has been instructed to complete a 14 day self-quarantine at home and actively self-monitoring with temperature checks twice daily consistent with CDC guidance for medium/high-risk exposures in healthcare personnel (HCP). Of note, the individual was uncertain if the mouse bite actually broke the skin as no blood was observed upon inspection of their finger. However, given the uncertainty surrounding the exposure, we are treating this as a medium/high-risk exposure. The Orange County Health Department Medical Director is aware of the exposure and there are existing protocols in place with our academic medical center, including SARS-CoV-2 PCR testing, to ensure that the public and other patients are not at risk of exposure if the individual becomes symptomatic and requires medical evaluation and treatment.

Please don't hesitate to reach out to me if you have any further questions. If needed, my cell phone number is 919-869-5874.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP

Obtained via FOIA by Judicial Watch Inc.

Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722 (office)
Email | garry.coulson@ehs.unc.edu

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From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Wednesday, April 22, 2020 5:41 PM
To: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>
Subject: RE: NIH Incident Report - Preliminary

Dear Dr. Coulson:

Thank you for your preliminary report of an incident involving a potential exposure to a recombinant SARS-CoV-2 virus. In your email, you indicate the exposed researcher reported to the Occupational Health Clinic and has been placed on medical surveillance protocols as described in the standard operating procedure (SOP).

We understand you are still gathering information for your formal report, but in the meantime, please provide NIH OSP a copy of the post-exposure SOP for the laboratory, and indicate whether the CDC guidelines for exposure are being followed. Please also verify whether any applicable local and/or state public health notifications have been made.

In advance of your final report, please advise NIH OSP of any pertinent information/further developments as they occur (for example if the researcher develops symptoms or tests positive for SARS-CoV-2). Please do not identify any potentially exposed individuals by name in any correspondence to NIH OSP.

If the research is NIH-funded, the terms and conditions of the award may require notification to the program officer of any significant incidents occurring during the conduct of the research. In any event, we recommend notifying the program officer, if this has not already occurred.

Thanks again for your preliminary incident report, and we will await further information as it becomes available.

Regards,

Dr. Kathryn Harris

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Tuesday, April 21, 2020 5:49 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>
Subject: NIH Incident Report - Preliminary

Obtained via FOIA by Judicial Watch Inc.

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of a potential exposure to recombinant DNA involving a worker in a BSL-3 laboratory. Our initial investigation indicates a researcher received a mouse bite from a mouse infected with recombinant SARS-CoV-2 virus adapted for growth in mice. The Researcher has reported to the Occupational Health Clinic, and placed on medical surveillance protocols as described in the standard operating procedure (SOP).

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

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Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of North Carolina at Chapel Hill
Date of Report:	4/23/2020
Reporter name and position:	Garry Coulson, Biosafety Officer
Telephone number:	919.962.5722
Email address:	garry.coulson@ehs.unc.edu
Reporter mailing address:	Environment, Health and Safety 1120 Estes drive Campus Box 1650 Chapel Hill, NC 27599
Date of incident:	4/21/2020
Name of Principal Investigator:	Dr. Ralph Baric
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant number: U19AI100625 / U19AI142759 /* Task order 75N93020F00001 for contract HHSN272201700036I *NIH funding institute or center: NIAID* *NIH program officer (name, email address):Qian Liu / Maureen Beanan / Eric Stemmy and Chelsea Lane*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO Date approved: 4/3/2020
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☒BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☒State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	A molecular infectious clone for the SARS-CoV-2 Seattle strain was used to isolate a recombinant virus encoding two mutations in the S glycoprotein gene (SARS-CoV-2 2AA that promotes mACE2 binding and virus docking and entry into mice.

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Description of the incident:

At approximately 10:00 am on Tuesday, April 21, 2020 the Researcher was checking mouse weights with experimental unanesthetized mice when the incident occurred. Mice used in this experiment were BALB/c mice. These mice had previously been infected via intranasal administration with a recombinant SARS CoV-2 strain (SARS CoV-2 2AA) encoding two mutations in the spike (S) glycoprotein to promote binding of the virus to the murine ACE2 (mACE2) receptor on 04/20/2020. The Researcher was working within a biological safety cabinet (BSC) inside a BSL-3 laboratory. For personal protective equipment (PPE), the Researcher was wearing the required protection for the BSL-3 laboratory, which included scrubs, lab shoes, shoe covers, Tyvek suit, hood, purified air powered respirator (PAPR), apron and 2 pairs of gloves.

The mice used for this experiment have ear tags that identify them. Reading of the small ID numbers on each ear tag requires scruffing the mice. It was during this procedure that the mouse flipped in the Researchers hand and bit the Researcher on their right hand index finger. The bite penetrated through both gloves, but did not appear to break the skin as there was no evidence of blood.

The Researcher immediately returned the mouse to its cage and replaced the cage back on the rack. After removing both gloves, the Researcher immediately sprayed down their hands with 70% ethanol followed by thorough hand washing with soap and water for at least a minute. No blood was observed during the hand washing and disinfection procedure. The Researcher then deconned out of the lab as per SOP and returned to their lab space where they informed a senior co-worker of the incident. The Researcher reported to The University Employee Occupational Health Clinic (UEOHC) after calling ahead. At the UEOHC, the Researcher was evaluated by the medical staff and received medical care as indicated for the incident and as per BSL-3 Laboratory Medical Surveillance Standard Operating Procedure (SOP). The Department of Environment, Health, and Safety (EHS) was notified of the incident by the Medical Director at 3:32 pm on Tuesday, April 21, 2020.

The Researcher is an experienced BSL-3 worker and compliant with all required EHS training. Additionally, the Researcher had completed the required animal handling training provided by the Division of Comparative Medicine (DCM) and is experienced in handling animals.

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Has the IBC reviewed this incident?	☒YES ☐NO The IBC is aware of the incident and will discuss the incident at the next IBC meeting (5/6/2020).
Please describe the root cause of this incident:	Due to the inherent challenges of working with unpredictable live mice, a root cause cannot readily be assigned to this incident. The Researcher involved in the incident was appropriately trained in proper handling of the mice (including manual restraint), was wearing the appropriate PPE, and was acting according to the established procedures for the experiment. It is possible that the routine use of small ID ear tags requiring manual restrain of the mice to read the tag contributed to the incident.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As part of the corrective and preventative actions to be taken, an internal Incident Report will be submitted by the Department of Environment, Health and Safety (EHS) to the Principal Investigator (PI) detailing the incident and including recommendations for the lab to follow to mitigate future reoccurrence of the incident.

The affected Researcher was trained in animal handling, was performing all duties according to established laboratory procedures, and was wearing the appropriate PPE for the procedure. As part of the recommendations, the PI will be instructed to review this incident with their laboratory and discuss safe methods for handling and restraining mice, including review of the UNC Mouse Handling and Technique Guide that describes safe methods for handling mice. The guide also addresses the use of restraining devices that minimize the contact between the mouse and the researcher. Additionally, it will be recommended to the PI to review the biosafety practices with this and other related animal models, and evaluate whether bite resistant gloves and/or other restraining devices might be employed to minimize reoccurrence of the incident. Lastly, potential risk mitigation strategies may also include anesthesia for uncooperative or aggressive mice and evaluation of alternative means for tagging mice that don't require manual restraint ("scruffing") for mouse identification.

The expected date of completion for recommendations will be 5/8/2020.

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BSL-3 Laboratory Standard Operating Procedures
Medical Surveillance
UNC BSL-3 SOP # 001

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MEDICAL SURVEILLANCE PROGRAM FOR HIGH CONTAINMENT LABORATORY WORKERS

BSL-3 SOP #: 001	**SUPERCEDES: Version 6**
VERSION NO.: 7	**EFFECTIVE DATE: February 2020**
PREPARED BY: James Hill, MD MPH/ Jessica Poole	**LAST REVISED: February 2020**

APPROVALS

Approver's Name	Approver's Signature	Date
Responsible Official/Biological Safety Officer: Garry Coulson, Ph.D.	Redacted by agreement	2/11/2020
Associate Biological Safety Officer/ARO: Jessica Poole, M.S.		2/11/2020
UEOHC: James Hill, MD, MPH		2/18/2020
IBC Chair: Douglas Cyr, Ph.D.		2/11/2020
Principal Investigators:		
Ralph Baric, Ph.D.		2/12/20
Miriam Braunstein, Ph.D.		2/11/20
William Goldman, Ph.D.		2/11/20
Mark Heise, Ph.D.		2/25/2020
Virginia Miller, Ph.D.		2/11/20

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Change History

Changes	Reason	Date	Version
Approvals page 2	New IBC Chair Name	6-18-2015	1
Throughout the document – the term high containment has been added	Clarity	6-18-2015	1
New responsibilities page 4	Clarity	6-18-2015	1
Removal of Contract language	Clarity	6-18-2015	1
Page numbers added	Clarity	6-18-2015	1
Remove Dr. Dittmer and his MEJ BSL-3 laboratory	Dr. Dittmer is no longer working at BSL-3.	6-23-2016	2
Added Appendix I and J, added *M. tuberculosis* and Chikunguyna Virus to Appendix B, added Garry Coulson as BSO, added table of contents	Yearly Review	11-07-2017	3
Added information to the SOP that was in the individual BSL-3 lab SOPs to make an inclusive Medical Surveillance SOP	Yearly Review	6/8/2018	4
Moved Change History to front of document; added annual review page; updated forms to reflect forms currently used by clinic	Yearly Review	9/18/2019	5
Added 2019-nCoV; added all agents to Appendix A	Additional Agent	2/10/2020	6

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ANNUAL REVIEW VERIFICATION IF NO CHANGES ARE REQUIRED DURING THE YEAR

VERIFICATION DATE	SIGNATURE
2021	
2022	
2023	
2024	
2025	
2026	
2027	
2028	
2029	
2030	
2031	
2032	

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Table of Contents

Section	Title	Page
	Change History	3
	Annual Review	4
	Table of Contents	5
1	Purpose	6
2	Responsibilities	6
3	Addition of New Lab Workers to Medical Surveillance Program	7
4	Physical Exams	7
5	Immunizations/Tests Required for Entry	9
6	Medical Evaluations	10
7	Exposure Procedures	10
8	Illness Surveillance and Management	14
9	Protocol for Emergency Department Arrival	15
10	Notification to Regulatory/Public Health Agencies	16
Appendix A	High Containment Labs	17
Appendix B	Request for Services	18
Appendix C	Hazard Information	19
Appendix D	Medical Surveillance Requirements	25
Appendix E	Quick Reference Table: Medical Surveillance Requirements	26
Appendix F	BSL-3 Medical Evaluation Questionnaire	27
Appendix G	Occupational Medical Clearance	30
Appendix H	Research Animal Handlers/Caretakers Questionnaire	31
Appendix I	Tuberculosis Screening Questionnaire	33
Appendix J	OSHA Respirator Medical Evaluation Questionnaire	34
Appendix K	Annual Clearance for Respirators	38
Appendix L	Medical Information Sheets	39
Appendix M	Incident Report Form 19	44
Appendix N	Employee's Accident Report Form	46
Appendix O	UNC-CH Supervisor's Incident Report Form	47
Appendix P	Medical Monitoring Form	48
Appendix Q	Checklist for Home Quarantine	49

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SECTION 1: PURPOSE

The Medical Surveillance Program ("MSP") of the University of North Carolina at Chapel Hill ("University") has been developed to ensure that work in the University's High Containment Biosafety Level 3 Laboratories ("Labs") is performed in the safest and most responsible manner possible. The MSP is in place to protect the health and safety of High Containment Lab Workers ("Lab Workers"). The MSP applies to all University and Non-University Lab Workers who work in a University High Containment Laboratory. The High Containment Laboratories are unique areas designed to accommodate the safe manipulation of select agents, toxins, organisms and materials that may be required for vaccine development and/or basic research on emerging diseases posing a potential threat to human, animal and plant life. The University's High Containment Labs are listed in Appendix A.

SECTION 2: RESPONSIBILITIES

EHS Director is responsible for oversight of the UNC MSP. The Biological Safety Officer or Associate Biological Safety Officer will report notification of non-compliance by individuals covered by this policy to the Director.

Medical Director ("Medical Director") of the University Employee Occupational Health Clinic ("UEOHC") is responsible for providing occupational medical services as required by the MSP.

Biological Safety Officer ("BSO") is responsible for compliance of this MSP and staff requirements.

Associate Biological Safety Officer ("ABSO") is responsible for the overall management of the MSP. The ABSO is responsible for the day-to-day operations of the applicable labs, including: developing and enforcing standard operating procedures ("SOPs") pertaining to the specific organisms; maintaining documentation for Lab Workers; providing training to Lab Workers; monitoring laboratory activities; conducting laboratory surveys; and record-keeping. The ABSO is also responsible for making laboratory access determinations for Lab Workers.

Responsible Official ("RO") and Alternate Responsible Official ("ARO") are responsible for ensuring facility compliance with the code of federal regulations for the possession and use of select agents and toxins. The Select Agent program consists of a facility Responsible Official and Alternate Responsible Official(s). The RO and ARO(s) are the centralized point persons for the dissemination of information and forms. They are also the only conduits of action to and from the Centers for Disease Control Select Agent Program.

Principal Investigator ("PI") is responsible for ensuring and documenting that all High Containment Lab Workers working in his/her BSL-3 laboratory are trained and proficient in the skills and aptitudes required by the agent-specific work being conducted within a BSL-3 facility. Additionally, the PI is responsible for hazardous materials communication and registering all BSL-3 work with EHS. All PIs working with select agents and toxins must register the facility.

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SECTION 3: ADDITION OF LAB WORKERS TO MEDICAL SURVEILLANCE PROGRAM

New personnel must be added to the medical surveillance program before they can begin work in the lab.

Laboratory Worker Registration Form:

The Principal Investigator is responsible for making sure the individual is designated as a BSL-3 worker on the Laboratory Worker Registration Form. This will enable EHS to flag the Lab Worker for the BSL-3 medical surveillance and respiratory protection programs in the HASMIS Database. BSL-2 Select Agent Lab Workers are not flagged for the respiratory protection program. Lab workers will be contacted once they have been added to the medical surveillance and respiratory protection programs and provided with additional instructions on scheduling an appointment at the University Employee Occupational Health Center (UEOHC) for medical evaluation and respiratory clearance/fit testing.

Special Immunizations:

If a Lab Worker needs to receive a special immunization related to his/her research, he/she needs to fill out a "Request for Services" form (Appendix B) and submit it to EHS. EHS will verify the need for the immunization by reviewing the applicable Laboratory Safety Plan. EHS will send the completed form to the UEOHC. Once the form has been received by the UEOHC, EHS will contact the Lab Worker and let him/her know that they can schedule an appointment.

Emergency Medical Cards:

EHS provides all High Containment Lab Workers medical carry cards prior to starting work in the lab. If a laboratory worker becomes ill while traveling outside of Chapel Hill, the worker should present this card to the medical provider. This card contains the names of the agents the Lab Worker may be exposed to, the symptoms of the illnesses caused, and the contact information for the PI, UEOHC and EHS.

SECTION 4: PHYSICAL EXAMS

Initial Physical Exams:

Medical evaluations are required for all Lab Workers prior to starting work in a lab to help identify medical conditions that may impair the Lab Worker's judgement, concentration, agility, or endurance. Examples of potentially disqualifying conditions that could disqualify or defer medical clearance include, but are not limited to: inadequately controlled metabolic, neurologic, cardiopulmonary, or other major organ system disease; the use of medications or substances that impair the Lab Worker's judgment or concentration; and providing false or misleading medical information.

Lab Workers must make an appointment with the UEOHC to complete a Medical Clearance Evaluation and to be fit tested for an N95 (if applicable). If a Non-University Lab Worker has

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received medical clearance from an outside agency to work in a University High Containment lab, the Medical Director will review the provided documentation to ensure compliance with the MSP. Any deficiencies in the outside medical clearance must be corrected before University High Containment access is given. In the event of a substantive difference between the UEOHC's medical protocols and the medical protocols of an outside institution, the UEOHC's protocols will be the controlling protocols.

The complexity of the evaluation is tailored to the agents present in the Lab (Appendix C) and the Lab Worker's essential job functions. A summary of requirements is provided in Appendices D and E. Select Agent BSL-2 only workers will be treated as a BSL-3 worker regarding annual BSL-3 physical but will not have respiratory clearance conducted as part of their initial/annual physical. BSL-3 Physical Forms are provided in Appendices F-K.

Once the medical evaluation and requirements are completed, the medical provider will complete a Medical Evaluation specifying the agent(s) or for which the Lab Worker is cleared (Appendix F). A clearance notification will be maintained in the Lab Worker's occupational health records. Once a Lab Worker is medically cleared for work in a lab, he/she will be evaluated at least annually and after any adverse events (Refer to Section 6).

If the Medical Director determines that a Lab Worker is not medically qualified to work in a High Containment Lab, the Medical Director will do the following:

1. Promptly notify the ABSO, who will in turn notify the Lab Worker's supervisor that the Lab Worker has not been cleared to work in a High Containment lab;
2. The Lab Worker will be informed that he/she has not been cleared to access the High Containment lab and referred to his/her personal healthcare provider for further evaluation and treatment, as needed.
3. The Lab Worker may return at an appropriate time with copies of relevant medical records for confidential review by the Medical Director; and
4. The Medical Director reviews the personal medical records in accordance with established UEOHC policies to ensure that the condition has been appropriately addressed and resolved before access to the High Containment lab is authorized.

Annual Physical Exams:

Annual medical evaluations are required for all High Containment Lab Workers. Access to the lab will be terminated by the ABSO for Lab Workers that are out of compliance. The annual medical evaluation includes:

1. A review of the relevant agents or toxins with which the High Containment Lab Worker is currently working and relevant immunizations;
2. An update of the Lab Worker's medical history from the last evaluation to identify changes in health status or potential immune compromising conditions;
3. Clinical testing and the provision of immunization, as clinically indicated;
4. A medical clearance determination and notification to the ABSO.

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Exit Physical Exams:

Access to the lab will be terminated two (2) weeks prior to the Lab Worker's scheduled last day at the High Containment facility in instances where the individual is leaving University employment or transferring to a non-BSL-3 position within the University. An exit physical is required for all Lab Workers during this two-week period.

SECTION 5: IMMUNIZATIONS/TESTS REQUIRED FOR ENTRY

Baric Lab Members:

Annual flu vaccinations which include (if possible) H1N1 in their formulation are required for lab personnel unless medically contraindicated.

Laboratory personnel who are unable to take the appropriate agent-specific post-exposure treatment will not be allowed to work in the laboratory.

Storage of baseline serum samples from individuals working with Reconstructed 1918 Influenza strains or SARS-CoV is required.

Heise Lab Members:

Annual flu vaccinations are required for lab personnel unless medically contraindicated.

JEV immunization:

Immunization is recommended for all laboratory personnel unless medically contraindicated and is required for all personnel working with JEV. Only immunized individuals may enter a room where JEV work is ongoing. "Ongoing work" includes manipulations within a BSC and infectious materials in an incubator or centrifuge. Ongoing work does not include infected mice in unopened cages or infectious materials stored in a freezer. Non-vaccinated individuals may continue to work in the BSL-3 laboratory while JEV is in use but may not handle infected materials or work in the same room while JEV is being used. Mice infected with JEV will be housed in cages marked "JEV – DO NOT OPEN" to ensure that they are only handled by vaccinated personnel.

Immunization consists of two doses of inactivated Vero cell culture-derived vaccine (IXIARO) at least 28 days apart, followed by a booster 1 year later and additional boosters every 5 years.

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Miller/Goldman Lab Members:

1. Baseline TB symptom review and testing (two-step TST or IGRA)
2. Optional biannual TB symptom review and testing (TST or IGRA) if requested by the employee.

Braunstein Lab Members (including DCM personnel):

1. Baseline TB symptom review and testing (two-step TST or IGRA)
2. Biannual TB symptom review and testing (TST or IGRA)

.

SECTION 6: MEDICAL EVALUATIONS

Immediate medical treatment and evaluation is provided following any exposure to an agent (e.g., by percutaneous injury, splash, inhalation, or ingestion) or when a Lab Worker develops symptoms suggestive of a laboratory-acquired infection. In these circumstances, the Lab Worker initiates first aid measures and notifies the PI, EHS and the UEOHC as outlined in Section 7. The UEOHC will evaluate the Lab Worker and determine follow-up care. The Medical Director or EHS will notify any regulatory/public health agencies (refer to section 10). UNC will abide by any requirements set forth by the public health departments regarding surveillance and management of illness.

Specific life events may also trigger a medical evaluation of the Lab Worker's fitness to continue to work in a High Containment lab. Examples of such events include, but are not limited to, the following: in-patient or out-patient care for substance abuse issues; performance or conduct issues suspected to result from a medical condition; injuries, illnesses and/or new medications that might impair the Lab Worker's judgement; and inability to wear personal protective equipment for prolonged periods. The PI, in consultation with the Medical Director, BSO and ABSO, may request a medical evaluation of the Lab Worker if the PI becomes aware of any behaviors or health concerns that may put the Lab Worker or his/her co-workers at risk. In this event, the Lab Worker's access to the High Containment lab will be suspended until medical clearance has been received.

Non-University High Containment Lab Workers are covered under medical surveillance program. In the event of an exposure or illness, the Non-University High Containment Lab Worker will initially be treated by the UEOHC. Costs will be billed back to the Non-University Lab Worker's sponsoring employer for reimbursement to the University.

SECTION 7: EXPOSURE PROCEDURES

Potential Exposure:

A potential exposure occurs when an incident occurs in which a lab worker is potentially exposed to a biological agent. Examples include:

a. Failure of personal protective equipment with no known aerosol or direct contact with infectious materials

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b. spills, needle stick or cut with object not known to be contaminated
c. animal bite or scratch from uninfected animal. Loss of containment with a spill constitutes a potential exposure to lab laboratory and building occupants.

After a potential exposure, employees must follow the following steps:

a. Decontaminate exposure site if applicable
    a. Percutaneous exposure (needle sticks, cuts, animal bites or scratches):
        i. Remove contaminated gloves and if possible, allow the wound to bleed freely for a minute.
        ii. Wash the wound with soap and water for 5 minutes
        iii. Apply sterile gauze or a bandage if necessary
        iv. Put on a new pair of gloves
    b. Mucous membrane exposure:
        i. Rinse tissue surface with copious amounts of water.
        ii. Eyes will be irrigated for at least 5 minutes using the emergency eye wash station.
b. Secure all infectious agents for lab exit
c. Exit laboratory using standard exit protocols (refer to Section 7 of Lab SOPs)
d. Report immediately to PI/Lab Manager and EHS.
e. EHS will contact the Medical Director. The Medical Director and EHS will determine if the employee needs to be evaluated (UEOHC or UNC Emergency Department).
f. EHS or the Medical Director will follow-up with the employee and provide any additional instructions. If the lab worker is instructed to go to the UEOHC or Emergency Department he/she should take the applicable "Medical Information Sheet (Appendix L) with him/her.
g. The employee will complete a Form 19 (Appendix M) and an "Employee's Accident Report Form" (Appendix N).
h. The employee's supervisor will complete the "UNC-CH Supervisor's Incident Report Form" (Appendix O).
i. EHS will complete a report on how the incident was addressed and recommendations/corrective steps to prevent it from happening in the future.
j. The RO/ARO will contact any regulatory agencies and appropriate local authorities.

Overt Exposure:

An overt exposure occurs when an incident occurs in which a lab worker has been exposed to a biological agent. Examples include:

a. A needle stick or cut with contaminated material
b. animal bites or scratches from infected animals,
c. splash to unprotected face,
d. direct contact of contaminated materials with mucous membranes or broken skin
e. failure of respiratory protection with aerosol generating event outside of the BSC.

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After an overt exposure, employees must follow the following steps:

a. Decontaminate exposure site
    a. Percutaneous exposure (needle sticks, cuts, animal bites or scratches):
        i. Remove contaminated gloves and if possible, allow the wound to bleed freely for a minute.
        ii. Wash the wound with soap and water for 5 minutes
        iii. Apply sterile gauze or a bandage if necessary
        iv. Put on a new pair of gloves
    b. Mucous membrane exposure:
        i. Rinse tissue surface with copious amounts of water.
        ii. Eyes will be irrigated for at least 5 minutes using the emergency eye wash station.
b. Secure all infectious agents for lab exit
c. Exit laboratory using standard exit protocols (refer to Section 7 of Lab SOPs)
d. Report immediately to PI/Lab Manager and EHS.
e. The employee will be directed to go to the UEOHC if the incident occurs during work hours (8:30 a.m. to 4:30 p.m. Monday through Friday) and the UNC Emergency Department (refer to Section 9) if the incident occurs after work hours. The lab worker should take the applicable "Medical Information Sheet" (Appendix L) with him/her.
f. EHS will contact the Medical Director.
g. The employee will complete a Form 19 (Appendix M) and an "Employee's Accident Report Form" (Appendix N).
h. The employee's supervisor will complete the "UNC-CH Supervisor's Incident Report Form" (Appendix O).
i. EHS will complete a report on how the incident was addressed and recommendations/corrective steps to prevent it from happening in the future.
j. The RO/ARO will contact any regulatory agencies and appropriate local authorities.

VEEV/CHIK/WNV/JEV/SLEV/POWV/ZIKV/USUV Exposure Procedures:

Initial/Follow-Up Tests: A serum draw will be taken at the initial visit to test for antibodies. A second serum draw will be taken 14 days later (4 weeks for VEE) to test for a rise in antibody titer.

Sign/Symptom Surveillance: Lab Workers will take their temperature and monitor for symptoms twice daily and report this information to the UEOHC once a day for 14 days following the exposure.

Additional Information: The lab worker will be presumed viremic and take steps to minimize potential interactions with mosquito vectors (avoid spending time outdoors, wear DEET-containing insect repellent) for 14 days.

Obtained via FOIA by Judicial Watch Inc.

SARS-CoV/MERS-CoV/2019 n-CoV/1918 Influenza Exposure Procedures:

Initial/Follow-Up Tests: A serum draw will be taken at the initial visit to test for virus specific antibodies. A second serum draw will be taken 4 weeks later to test for a rise in antibody titer. In the event of an exposure to virus containing genes from 1918 H1N1 influenza, specimens will be sent to the CDC for testing.

Sign/Symptom Surveillance: Lab workers will take temperature and monitor for symptoms twice a day and report this information to the UEOHC once a day for 10 days (14 days for 2019 nCoV) following the exposure. If there is a change in symptoms, he/she must immediately contact the UEOHC.

Self-Quarantine: Lab workers will be required to remain out of work for a minimum of 10 days (14 days for 2019 nCoV) after an exposure. They must self-quarantine in a location determined by the Medical Director in conjunction with the local health department. The self-quarantine checklist will be used (Appendix Q). Lab workers must have an oral thermometer and surgical mask at home.

Chemoprophylaxis: Pre-exposure prophylaxis is not recommended. Post-exposure prophylaxis is available for influenza.

Additional Information: Lab Workers have been informed of the potential for secondary transmission and the possibility that they may be put into isolation if person-to-person transmission could result as a consequence of the exposure.

Yersinia pestis Exposure Procedures:

Sign/Symptom Surveillance: Lab workers will take temperature and monitor for symptoms twice a day and report this information to the UEOHC once a day for 7 days following the exposure.

Chemoprophylaxis: Doxycycline (100 mg) for 7 days

Mycobacterium tuberculosis Exposure Procedures:

Initial/Follow-up Tests: A TST will be completed at the time of exposure. A second TST will be conducted 12 weeks after the exposure.

Sign/Symptom Surveillance: Lab workers will take temperature and monitor for symptoms twice a day and report this information to the UEOHC once a day for 7 days following the exposure.

Treatment: Per current recommendations from the NC TB Control Program.

Obtained via FOIA by Judicial Watch Inc.

HIV Exposure Procedures:

Employees working with HIV infected macrophages will follow the protocol for HIV surveillance.

Recommended HIV postexposure prophylaxis for percutaneous injuries and mucosal exposures to infected cell lines:

1) Exposures generally NOT requiring PEP
   a. Contaminated cell line exposure on intact skin
2) Exposures for which PEP is recommended
   a. Percutaneous exposure to contaminated cell lines
   b. Exposure of non-intact skin or mucous membranes to contaminated cell lines

Recommended PEP – IN ORDER OF PREFERENCE

1) Truvada (emtricitabine 200 mg and tenofovir 300 mg) - one tablet PO 1x/day plus Raltegravir (400 mg PO 2x/day)
2) If Raltegravir is contra-indicated provide: Truvada (emtricitabine 200 mg and tenofovir 300 mg) one tablet PO 1x/day plus Kaletra (lopinavir 200 mg/ritonavir 50 mg tablets) two tablets PO 2x/day
3) If Truvada is contra-indicated provide Combivir (lamivudine 150 mg and zidovudine 300 mg) one tablet PO 2x/day plus Raltegravir (400 mg PO 2x/day)
4) Alternatively, at the Family Medicine attending or ID discretion the following regimen can be used: Truvada (emtricitabine 200 mg and tenofovir 300 mg) one tablet PO 1x/day plus Ritonavir (100 mg PO 1x/day) and Darunavir (800 mg PO 1x/day)

SECTION 8: ILLNESS SURVEILLANCE AND MANAGEMENT

Employees experiencing any of the symptoms associated with exposure to an agent present in the lab (outlined in Section 1: Hazard Information of the Lab SOPs) and have been in the lab within the last 14 days (Baric lab=10 days) must immediately report to the PI, Biological Safety and the UEOHC. The UEOHC will be informed that the individual works in a High Containment Lab and she/he is to be evaluated for potential exposure using the Medical Monitoring Form (Appendix P). The lab worker should take the applicable Medical Information Sheet (Appendix L) to the UEOHC with him/her. The UEOHC will provide the ABSO with information regarding any reporting requirements, sign/symptom monitoring, and when the lab worker can come back to work. The ABSO will supply this information to the lab manager and inform him/her when the lab worker is allowed to come back to work.

Braunstein Lab:

Employees working with HIV infected macrophage will call the UEOHC to report the following symptoms if they have worked with macrophages containing HIV within the previous three weeks: fever, rash, headache, swollen lymph nodes, night sweats, malaise, fatigue, myalgia and sore throat.

Obtained via FOIA by Judicial Watch Inc.

Baric Lab:

Lab workers who develop respiratory symptoms within 10 days of being in the lab (14 days for 2019 nCoV) with no known exposure shall do as follows:

a. The employee notifies their supervisor, the PI and the ABSO within 12 hours of the start of symptoms and/or at the time they document an oral temperature of at least 100°F.
b. The ABSO confirms that the Lab Worker has access to a thermometer and surgical masks. If supplies are not available, this will be coordinated with the UEOHC staff.
c. The employee will remain away from work for a minimum of 72 hours after developing fever or symptoms. Employee will be advised to self-quarantine and take precautions to minimize droplet generation.
d. The Lab Worker will call UEOHC daily to report temperature (taken and recorded at least twice daily, in AM and PM, but need to report only once per 24 hours) and symptoms.
e. If temperature and symptoms are resolved within 72 hours of appearance, the UEOHC will consult with the lab worker to provide final approval to return to work. The UEOHC will contact the ABSO when the approval is given. The ABSO will contact the lab manager and inform him/her that the lab worker is cleared to come back to work.
f. If the symptoms have not improved by day three, the worker will be contacted by the UEOHC to arrange for a medical evaluation including imaging at UNC Healthcare. This evaluation will be done adhering to UNC Hospitals Highly Communicable Disease protocols. The worker will need to present to the clinic by private transportation and wearing a surgical mask. Workers with symptoms/fever for more than three days will be out of work for 10 days from the end of their last documented fever. Orange County Health Department will be notified of any case with symptoms/fever lasting more than 2 days.

SECTION 9: PROTOCOL FOR EMERGENCY DEPARTMENT ARRIVAL

If it is determined that a Lab Worker needs to go to the Emergency Department, the Medical Director will call the Emergency Department to activate the respiratory disease protocol. The preferred location for medical evaluation of symptomatic BSL-3 workers is the Emergency Department, UNC Hospitals, which is located on main campus off Emergency Room Drive. The Medical Director must have a direct provider-to physician conversation with the responsible admitting physician (i.e. ED attending or MICU attending for direct admit).

Hospital Epidemiology/Infection Prevention will be notified immediately by the ED attending or MICU attending that a patient requiring Special Airborne Precautions is in route.

The lab worker will arrive at the emergency room in his/her own vehicle, wearing a surgical mask (If the lab worker needs a ride, transportation can be arranged). Do not use valet parking.

Obtained via FOIA by Judicial Watch Inc.

Hospital Admission:

Emergency Department Admission:

The ED attending will be informed of the diagnosis of concern and the status of the patient. The ED attending or designee will be contacted directly when the lab worker is 5 minutes out from the facility. The ED attending or designee should confirm and document that the patient is wearing a surgical mask or is intubated prior to entry to a UNC Hospital facility. The route of entry to UNC Hospitals should be documented in the physician note. The patient will be taken to a negative-pressure room by predetermined route.

MICU admission:

The MICU attending will be informed of the diagnosis of concern and the status of the patient. The MICU attending or designee will be contacted directly when the lab worker is 5 minutes out from the facility. The MICU attending or designee should confirm and document that the patient is wearing a surgical mask or is intubated prior to entry to a UNC Hospital facility. The route of entry to UNC Hospitals should be documented in the physician note. The patient will be taken to an airborne isolation room by predetermined route.

****Life-threating emergencies are to be taken to the nearest appropriate emergency facility with the PI, Biological Safety and the Medical Director notified <u>after</u> addressing the lab worker's acute medical needs****

SECTION 10: NOTIFICATION TO REGULATORY/PUBLIC HEALTH AGENCIES

EHS will notify the Institutional Biosafety Committee and NIH/OSP if the exposure event involves an agent that results from recombinant DNA technology.

EHS will notify the CDC of any occupational exposure or illness associated with Select Agents.

EHS will notify local and state public health departments within 24 hours of any confirmed laboratory acquired illness from these agents.

EHS will notify the Orange County Health Department and the UEOHC immediately of any occupational exposure or illness associated with agents present in the labs. If the exposure is due to a known accident and occurs after hours, EHS will contact the Orange County Health Director and page the UNC Infection Control Pager.

If a lab worker reports to the Emergency Department after hours with symptoms, EHS will contact the Orange County Health Director. The Orange County Health Department will then make a report to the NC State Health Department if necessary.

Obtained via FOIA by Judicial Watch Inc.

Appendix A – High Containment Labs

Principal Investigator	Department	Lab Location	Agent	Select Agent	BSL
Dr. Ralph Baric	Epidemiology	Redacted by agreement	Severe Acute Respiratory Syndrome (SARS) Coronavirus Middle East Respiratory Syndrome (MERS) Coronavirus 2019 Novel Human Betacoronavirus (2019-nCoV) Reconstructed 1918 Influenza Virus Influenza Virus A H1N1	Yes	3
Dr. Ralph Baric	Epidemiology		Severe Acute Respiratory Syndrome (SARS) Coronavirus Middle East Respiratory Syndrome (MERS) Coronavirus 2019 Novel Human Betacoronavirus (2019-nCoV) Reconstructed 1918 Influenza Virus Influenza Virus A H1N1	Yes	3
Dr. Ralph Baric	Epidemiology		SARS-CoV RNA	Yes	2
Dr. Miriam Braunstein	Microbiology		*Mycobacterium tuberculosis* *Mycobacterium bovis* *Mycobacterium avium* Human Immunodeficiency Virus	No	3
Dr. Miriam Braunstein	Microbiology		*Mycobacterium tuberculosis* *Mycobacterium bovis* *Mycobacterium avium*	No	3
Dr. Virginia Miller	Microbiology		*Yersinia pestis* *Klebsiella pneumoniae* *Bordetella pertussis* *Yersinia pseudotuberculosis* *Yersinia enterocolitica*	Yes	3
Dr. Mark Heise	Genetics		Venezuelan Equine Encephalitis Virus Saint Louis Encephalitis Virus Japanese Encephalitis Virus Chikungunya Virus West Nile Virus Powassan Virus Ross River Virus Mayaro Virus O'nyong-nyong Virus Sindbis Virus Dengue Virus Usutu Virus Zika Virus Influenza Virus A H1N1	Yes	3

Obtained via FOIA by Judicial Watch Inc.

APPENDIX B: REQUEST FOR SERVICES FORM

UNC ENVIRONMENT, HEALTH & SAFETY

University Employee Occupational Health Clinic – UEOHC

Request for Services (i.e. evaluation, vaccination(s), etc.) under UNC Medical Surveillance Program

Complete all information and fax to EHS at 919-962-0227. EHS will review services requested. This form constitutes authorization for vaccination(s) or other services required for job duties.

A. EMPLOYEE INFORMATION

Name: PID:

Job Title: Telephone:

Department: CB#:

Authorized Department Representative:

Chartfield String

Note: Cannot use Grants/OSR funding.

Unit: Fund: Source: Account: Dept:

B. JOB DUTIES AT UNC

- ☐ Healthcare Worker (defined as employees whose position has them entering facilities where patient care is provided, whether in a patient care area or in an administration wing)
- ☐ Research:
  - ☐ BSL3 ☐ Bloodborne Pathogens ☐ Other:
- ☐ DLAM
- ☐ TEACCH
- ☐ Frank Porter Graham
- ☐ Dental School
- ☐ Other:

C. BRIEF DESCRIPTION OF TASKS OR DUTIES THAT INDICATE NEED FOR VACCINATION(S) OR OTHER SERVICES:

D. THE FOLLOWING MUST BE COMPLETED BY AUTHORIZED DEPARTMENT REPRESENTATIVE:

_____ I verify that the above individual is an employee of the University of North Carolina – Chapel Hill.
Initials

_____ I grant authorization for the above employee to have the requested services and understand that the department will be billed for these services.
Initials

_____ _____
Department Representative Title

_____ _____
Signature Date

Obtained via FOIA by Judicial Watch Inc.

Appendix C: Hazard Information

Chikungunya Virus

PATHOGENICITY: CHIKV infection has an abrupt onset, characterized by fever, and severe arthralgia, which is seen in 70% of cases. The fever rises quickly, often reaching 39 to 40 °C and is accompanied by intermittent shaking chills. The arthralgias are polyarticular, migratory and predominantly affect the small joints of the hands, wrists, ankles, and feet. Cutaneous manifestations are typical with many patients presenting a flush over the face and trunk. This is usually followed by a maculopapular rash, involving most commonly the trunk, and limbs, but the face, palms and soles can also show lesions. Other symptoms of CHIKV include myalgia, nausea, vomiting, headaches, nasal discharge, conjunctivitis, retrobulbar pain, photophobia, and lymphadenopathy.

HOST RANGE: Humans, non-human primates, rodents, and birds.

INFECTIOUS DOSE: Unknown.

MODE OF TRANSMISSION: CHIKV is transmitted to humans from infected non-human primates and other humans by the bite of *Aedes* mosquitoes. Evidence exists that CHIKV can also be passed from an infected mother to a developing fetus. Furthermore, inhalation of aerosolized CHIKV in a laboratory setting may lead to CHIKV infection.

INCUBATION PERIOD: Usually 2 to 3 days, with a range of 1 to 10 days.

DRUG SUSCEPTIBILITY: No antivirals are currently available.

SUSCEPTIBILITY TO DISINFECTANTS: No information specific to CHIKV; however, most lipid enveloped viruses are sensitive to 70% (v/v) ethanol, sodium hypochlorite, formaldehyde, glutaraldehyde, phenolics, iodophors, and quaternary ammonium compounds.

PHYSICAL INACTIVATION: Inactivated by desiccation and temperatures above 58°C.

SURVIVAL OUTSIDE HOST: Unknown.

EPIDEMIOLOGY: CHIKV was first recognized in Tanzania in 1953 during an epidemic of dengue-like illness. Between the 1960s and 1990s, the virus was isolated repeatedly from numerous countries in Central and Southern Africa. CHIKV has also been isolated in Western African countries. In Southeast Asia, frequent outbreaks were reported from the 1960s through to 2003 in India, Malaysia, Indonesia, Cambodia, Vietnam, Myanmar, Pakistan, and Thailand. Numerous cities, including Bangkok and Calcutta have been identified as particularly active sites of transmission and disease. Cases have also been reported in Europe (United Kingdom, Belgium, Germany, Czech Republic, Norway, Italy, Spain and France), Hong Kong, Canada, Taiwan, Sri Lanka and United States; however, these were directly associated with the return of tourists from India and the affected islands of the Indian Ocean. At Present, CHIKV is endemic in 23 countries and phylogenetic analysis of viral sequences has identified 3 distinct clades: West African, Central/East African and Asian.
There are 2 epidemiological transmission cycles of CHIK fever: a sylvatic cycle, occurring primarily in Africa mainly between wild primates and arboreal Aedes mosquitoes, where humans are accidental hosts; and an urban human-mosquito-human transmission cycle that typically occurs in cities in Asia.

Obtained via FOIA by Judicial Watch Inc.

Mycobacterium tuberculosis

PATHOGENICITY: Primary tuberculosis may be asymptomatic and only be recognized by a positive skin test. In 90-95% of the cases, the host immune response generated against the bacteria limits its growth and multiplication, leading to a latent infection. If the disease becomes progressive (5-10% of cases), symptoms include cough, weight loss, night sweats, low-grade fever, dyspnea, lymphadenopathy, chest pain, and pneumonia or phthisis. Extrapulmonary tuberculosis may affect any organ system and may cause cervical lymphadenitis, pleuritis, pericarditis, synovitis, meningitis, and infections of the skin, joint or bones. Milliary tuberculosis is characterized by high and sustained fever, night sweats, dry cough, malaise, splenomegaly, and skin lesions. Meningitis (high fever, cranial nerve deficits, and psychic changes) develops in 50% of the cases with a high mortality rate, if left untreated.

HOST RANGE: Monkeys, humans, parrots, cattle, sheep, goats, dogs and cats.

INFECTIOUS DOSE: Very low infectious dose. The ID_{50} is estimated to be <10 bacilli in humans.

MODE OF TRANSMISSION: Transmission can be nosocomial, airborne, exposure to autopsy material, venereal transmission, and percutaneous transmission. Infected animals can spread the infection to laboratory workers through aerosols, fomites, and bites.

INCUBATION PERIOD: 4-6 weeks. For latent TB infections, 5% of patients develop an active infection within 2 years and 5% develop an infection within their lifetime.

DRUG SUSCEPTIBILITY: isoniazid, ethambutol, rifampin, and pyrazinamide

DRUG RESISTANCE: Multiple drug resistant TB (MDR-TB) strains are resistant to at least isoniazid and rifampin. Extremely drug resistant TB (XDR-TB) is caused by strains which are resistant to isoniazid and rifampin, but also show resistance to fluroquinolones and at least one of three injectable second line anti-tubercular drugs (amikacin, kanamycin, and/or capreomycin).

SUSCEPTIBILITY TO DISINFECTANTS: Amphyl and other phenol soap mixtures and 0.05 % to 0.5% sodium hypochlorite can be used for surface disinfection. Susceptible to N-dodecyl-1,3-propanediamine supplemented with sodium hydroxide, ethylene oxide, a mixture 7.5% hydrogen peroxide and 0.85% phosphoric acid, phenolics, 0.35% peracetic acid, orthophthaldehyde and superoxidized water. Higher concentrations of chlorine. A 2% solution of aqueous glutaraldehyde requires 10-20 minutes of contact time at room temperature. A 2% solution of alkaline glutaraldehyde has slower action against *M. tuberculosis*.

PHYSICAL INACTIVATION: Susceptible to UV light, moist heat (121°C for at least 15 min) or heat (> 65 °C for at least 30 min).

SURVIVAL OUTSIDE HOST: *M. tuberculosis* can survive for months on dry inanimate surfaces.

EPIDEMIOLOGY: Tuberculosis is a major health problem worldwide. The greatest risk factor for TB progression from a latent infection to an active one is HIV infection. World Health Organization (WHO) reported that in 2008, there were an estimated 8.9–9.9 million incident cases and 9.6–13.3 million prevalent cases of TB, worldwide. TB infections resulted in 1.1–1.7 million deaths among HIV-negative people and an additional 0.45–0.62 million deaths among HIV-positive people. The number of reported cases appears to be decreasing in the western hemisphere (3% of the total cases in North America: prevalence of 24 cases/100,000) owing to effective strategies to prevent, detect, and treat the infection, implemented by these countries. An estimated 0.5 million cases of MDR-TB (Multiple drug resistant TB) occurred worldwide in 2007, with most cases being reported from India and China. WHO also reported an increase in the number of Extensively Drug Resistant TB strains (XDR-TB) cases in the year 2009.

Obtained via FOIA by Judicial Watch Inc.

Reconstructed 1918 Influenza Virus

PATHOGENICITY: Normal flu symptoms of fever, nausea, aches and diarrhea. Many individuals develop a severe pneumonia or pulmonary edema. Dark spots may appear on the checks and the person may turn blue, suffocating from a lack of oxygen.

HOST RANGE: Birds and possibly pigs.

INFECTIOUS DOSE: Unknown for humans but severe infections have been induced in non-human primates at 7 X 10^6 PFU.

MODE OF TRANSMISSION: Person-to-person contact (direct mucous membrane contact (eyes, nose and mouth) with infectious respiratory droplets and/or direct contact with infected body fluids) and/or through exposure to fomites. Other possible modes of transmission include through blood transfusions, or by sharps injuries.

INCUBATION PERIOD: The incubation period for 1918 influenza is short - 1 to 3 days.
DRUG SUSCEPTIBILITY: Two types of antiviral drugs, rimantadine (Flumadine) and oseltamivir (Tamiflu), have been shown to be effective against influenza viruses like the 1918 virus. Vaccines containing the 1918 HA or other subtype H1 HA proteins were effective in protecting mice against the 1918 virus. In fact, the current influenza vaccine provided some level of protection against the 1918 virus in mice.[1]

DRUG RESISTANCE: Unknown

SUSCEPTIBILITY TO DISINFECTANTS: Inactivated by a 5-minute contact of household bleach, ice-cold acetone, ice-cold acetone/methanol mixture (40:60), 70% ethanol (10 minutes), 100% ethanol (5 minutes) paraformaldehyde, and glutaraldehyde.

PHYSICAL INACTIVATION: Susceptible to moist heat at 121°C for 20 minutes or dry heat at 170°C for 1 hour, 160°C for 2 hours, or 121°C for at least 16 hours.

SURVIVAL OUTSIDE HOST: Unknown but Influenza A virus can survive for 24 to 48 hours on hard, nonporous surfaces such as stainless steel and plastic and for approximately 8 to 12 hours on cloth, paper and tissues.

EPIDEMIOLOGY: The origin of the 1918 influenza pandemic remains elusive. The causes for its transmissibility, virulence, and unique age pattern remain inadequately understood. In less than 2 years, the pandemic killed >675,000 people in the United States and 40-100 million worldwide, with the majority of deaths occurring among those <45 years old.

Obtained via FOIA by Judicial Watch Inc.

SARS-CoV/MERS-CoV

PATHOGENICITY: Initial symptoms include a fever greater than 38°C (100.4°F), accompanied by myalgia, malaise, chills, a non-productive cough, and rigor. After 2 to 7 days, this is followed by respiratory symptoms such as a dry cough, shortness of breath, difficulty breathing or hypoxia. In some cases, the respiratory symptoms become increasingly severe, and patients require oxygen support and mechanical ventilation. The case-fatality rate is 9.6%; however, in patients over 65 years of age this rate exceeds 50%.

HOST RANGE: Natural hosts include humans, Himalayan palm civets (*Paguma larvata*), racoon dogs (*Nyctereutes procyonoides*), Chinese ferret badgers (*Melogale moschata*), cats, and pigs. Experimental hosts include non-human primates, ferrets, golden hamsters, guinea pigs, mice, and rats.

INFECTIOUS DOSE: Unknown

MODE OF TRANSMISSION: Person-to-person contact (direct mucous membrane contact (eyes, nose and mouth) with infectious respiratory droplets and/or direct contact with infected body fluids) and/or through exposure to fomites. Other possible modes of transmission include through blood transfusions, or by sharps injuries.

INCUBATION PERIOD: The incubation period for SARS/MERS ranges from 2 to 14 days.

DRUG SUSCEPTIBILITY: Unknown

DRUG RESISTANCE: Unknown

SUSCEPTIBILITY TO DISINFECTANTS: Inactivated by a 5-minute contact of household bleach, ice-cold acetone, ice-cold acetone/methanol mixture (40:60), 70% ethanol (10 minutes), 100% ethanol (5 minutes) paraformaldehyde, and glutaraldehyde.

PHYSICAL INACTIVATION: Sensitive to heat (60° for 30 minutes) and UV irradiation.

SURVIVAL OUTSIDE HOST: Can survive for 4 days in diarrheal stool samples with an alkaline pH, more than 7 days in respiratory secretions at room temperature, for at least 4 days in undiluted urine and human serum at room temperature, up to 9 days in suspension, 60 hours in soil/water, more than a day on hard surfaces such as glass and metal, and 6 days in dried state.

EPIDEMIOLOGY: SARS-CoV/MERS is a novel virus. The earliest known cases were identified in mid-November 2002 in the Guangdong Province of South-East China. The index case was reported in Foshan, a city 24 km from Guangzhou. Retrospective analysis revealed severe cases of the disease in 5 cities around Guangzhou over a period of 2 months, with many of the cases having had epidemiological links to the live-animal market trade. After its introduction to Hong Kong in mid-February 2003, the virus spread to Vietnam, Singapore, Canada, the Philippines, the United Kingdom, the United States, and then back again to China. By the end of July 2003, SARS had spread to affect a reported 8,098 people in over 30 countries, across 5 continents, killing 774 people.

Obtained via FOIA by Judicial Watch Inc.

Venezuelan equine encephalitis virus

PATHOGENICITY/TOXICITY: Flu-like symptoms such as headache, myalgia, fatigue, vomiting, nausea, diarrhea, pharyngitis and fever appear abruptly, 2 to 5 days after exposure to the virus. The VEE virus can also cause retro-orbital and occipital headaches as well as leucopenia and tachycardia.

INFECTIOUS DOSE: 1 viral infectious particle injected subcutaneously is enough to infect an individual with the VEE virus.

MODE OF TRANSMISSION: The VEE virus is most often transmitted by infected mosquito bites, although, it is also very contagious through aerosols. Subcutaneous injection, nasal instillation, and contact with broken skin or contaminated animal bedding are other ways to spread the virus, particularly in a laboratory setting.

INCUBATION PERIOD: The incubation period is usually about 2 to 6 days after exposure to the virus but can be as short as 24 hours.

DRUG SUSCEPTIBILITY: No drug susceptibilities have been determined to date.

SUSCEPTIBILITY TO DISINFECTANTS: VEE virus is susceptible to 1% sodium hypochlorite, 4% formaldehyde, 2% glutaraldehyde, 70% ethanol, 3-6% hydrogen peroxide, 2% and peracetic acid.

PHYSICAL INACTIVATION: Microbial inactivation is possible using moist or dry heat. Togaviruses can be inactivated by 15 minutes of heat at 65 °C.

SURVIVAL OUTSIDE HOST: The virus is stable in blood and exudates as well as in freeze dried materials (aerosols).

EPIDEMIOLOGY: The epizootic and enzootic strains of the VEE virus range from northern Argentina to Florida and parts of the Rocky Mountains; however, it is most prevalent in northern South America.

Obtained via FOIA by Judicial Watch Inc.

Yersinia pestis

PATHOGENICITY: Zoonotic disease; bubonic plague with lymphadenitis in nodes receiving drainage from site of flea bite, occurring in lymph nodes and inguinal areas, if untreated; may progress to septicemic plague with dissemination by blood to meninges; secondary pneumonic plague with pneumonia, mediastinitis, and pleural effusion; untreated pneumonic and septicemic are fatal.

HOST RANGE: Humans,> 200 mammalian species

INFECTIOUS DOSE: Unknown

MODE OF TRANSMISSION: Result of human intrusion into zoonotic (sylvatic) cycle or by entry of rodents or infected fleas into human's habitat and bite of infected fleas; handling of infected tissues; airborne droplets from humans or pets with plague pneumonia; careless manipulation of laboratory cultures; person-to-person transmission by human fleas.

INCUBATION PERIOD: From 2 to 6 days; may be a few days longer in vaccinated individuals; for primary plague pneumonia, 1 to 6 days, usually short.

DRUG SUSCEPTIBILITY: Sensitive to streptomycin, tetracycline, chloramphenicol (for cases of plague meningitis), kanamycin (for neonates).

DRUG RESISTANCE: Generally, not a concern; a multi-drug resistant strain (MDR) mediated by transferrable plasmid has been isolated.

SUSCEPTIBILITY TO DISINFECTANTS: Susceptible 1% sodium hypochlorite, 70% ethanol, 2% glutaraldehyde, iodines, phenolics, formaldehyde.

PHYSICAL INACTIVATION: Sensitive to moist heat (121° C for at least 15 min) and dry heat (160-170° C for at least 1 hour).
SURVIVAL OUTSIDE HOST: Blood - 100 days; human bodies - up to 270 days

EPIDEMIOLOGY: Wild rodent plague in North America, South America, Africa, Near and Middle East, Central and Southeast Asia, Indonesia; Endemic in Burma and Vietnam; sporadic cases in North and South America following exposure to wild rodents or their fleas (no human-to-human transmission in USA since 1925).

Obtained via FOIA by Judicial Watch Inc.

APPENDIX D: MEDICAL SURVEILLANCE REQUIREMENTS

A. BSL-3 Researchers and Lab Personnel

a. BSL-3 entrance physical
b. Baseline TB testing required only for Miller, Goldman and Braunstein labs
c. Annual BSL-3 physical
d. Semi-annual TB testing required for Braunstein lab and optional for the Miller and Goldman labs
e. BSL-3 exit physical
f. Symptom monitoring
g. Annual Influenza vaccination required for Heise and Baric labs
h. Serum Storage required only for Baric lab

B. DCM (BSL-3 TB colony) Personnel

a. BSL-3 entrance physical
b. Baseline TB testing
c. Annual BSL-3 physical
d. Semi-annual TB testing
e. BSL-3 exit physical
f. Symptom monitoring

C. DCM (general and emergency back-up) Personnel

a. BSL-3 entrance physical
b. Baseline TB testing
c. Annual BSL-3 physical
d. Ongoing TB testing per DCM policy
e. BSL-3 exit physical
f. Symptom monitoring

D. EHS Emergency Response Personnel

a. BSL-3 entrance physical
b. Baseline TB testing
c. Annual BSL-3 physical
d. Annual TB Symptom Review
e. BSL-3 exit physical
f. Symptom monitoring
g. Annual influenza vaccination

E. EHS Biological Safety Personnel and Responsible Official

a. BSL-3 entrance physical
b. Baseline TB testing
c. Annual BSL-3 physical
d. Annual TB Symptom Review
e. BSL-3 exit physical
f. Symptom monitoring
g. Annual influenza vaccination

F. BSL-3 Facilities Entry Team Personnel

a. BSL-3 entrance physical
b. Baseline TB testing
c. Annual BSL-3 physical
d. Annual TB Symptom Review
e. BSL-3 exit physical
f. Symptom monitoring
g. Annual influenza vaccination

G. Vendors

a. Must submit paperwork to show they are part of an occupational health program
b. Must submit paperwork to show they have respiratory training and clearance
c. Symptom monitoring

Obtained via FOIA by Judicial Watch Inc.

APPENDIX E: QUICK REFERENCE TABLE: MEDICAL SURVEILLANCE

	Entrance Physical	Annual BSL-3 Physical	Exit Physical	Symptom Monitoring (Note 1)	Baseline TB testing	Ongoing TB testing	Annual Influenza vaccination	Serum Storage (Note 4)
BSL-3 Daily Lab Personnel								
BSL-3 researchers/lab personnel	YES	YES	YES	YES	Miller, Goldman and Braunstein labs	Braunstein: semi-annual Miller/Goldman: optional semi-annual	Heise and Baric labs	Baric Lab
DCM (TB colony)	YES	YES	YES	YES	YES	semi-annual	NO	NO
BSL-3 Support Personnel								
DCM (general)	YES	YES	YES	YES	YES	Per DCM policy	NO	NO
EHS Biological Safety and Responsible Official	YES	YES	YES	YES	YES	ANNUAL SYMPTOM REVIEW (Note 3)	YES	NO
EHS Emergency Response	YES	YES	YES	YES	YES	ANNUAL SYMPTOM REVIEW (Note 3)	YES	NO
BSL-3 Facilities Entry Team	YES	YES	YES	YES	YES	ANNUAL SYMPTOM REVIEW (Note 3)	YES	NO
Vendors (Note 2)	NO	NO	NO	YES	NO	NO	NO	NO

Note 1: Personnel need to be aware of symptoms suggestive of a laboratory-acquired infection after each entry into a live BSL-3 lab. Immediate medical treatment and evaluation is provided following any exposure to an agent as outlined in the specific BSL-3 SOP or when personnel develop symptoms suggestive of a laboratory-acquired infection of contamination.

Note 2: Must show paperwork to prove they are part of an occupational health program and have respiratory clearance

Note 3: UNC-CH TB Policy

Note 4: Serum storage per BMBL recommendations.

Obtained via FOIA by Judicial Watch Inc.

APPENDIX F: BSL-3 MEDICAL EVALUATION QUESTIONNAIRE

UNC FINANCE AND OPERATIONS Environment, Health and Safety

Today's Date _____

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
UNIVERSITY EMPLOYEE OCCUPATIONAL HEALTH CLINIC
North Carolina Area Health Education Center | Suite 201 | Campus Box 1649
145 North Medical Drive | Chapel Hill, NC 27599-1649
Phone: 919-966-9119 | Fax: 919-966-6337

BSL3 Medical Evaluation Questionnaire

Employee Information

Employee Name (First, MI, Last) _____ PID # _____

Position Title _____ Date of Birth _____

Department _____ Sex (M/F) _____

Home Street Address _____ Phone Number _____

City / State / Zip code _____ Emergency Contact _____

Occupational History

What are your current job duties? _____

Previous work experience in BSL2+ or BSL3 setting: _____

Do you work with, or have you been immunized against any of the following?

	Works With	Immunized		Works With	Immunized
1918 Influenza	☐ Yes	☐	Japanese Encephalitis	☐ Yes	☐
Avian Flu	☐ Yes	N/A	Malaria	☐ Yes	☐
Bacillus anthracis (Anthrax)	☐ Yes	☐	MERS	☐ Yes	N/A
Brucella species	☐ Yes	N/A	Monkey Pox	☐ Yes	N/A
Burkholderia species	☐ Yes	N/A	Other	☐ Yes	☐
Chemotherapeutic agents	☐ Yes	N/A	Radio-isotopes	☐ Yes	N/A
Chikungunya	☐ Yes	N/A	Rift Valley Virus	☐ Yes	N/A
Chimeric particles	☐ Yes	N/A	SARS	☐ Yes	N/A
Clostridium botulinum	☐ Yes	☐	Toxoplasma gondii	☐ Yes	N/A
Dengue	☐ Yes	N/A	Vaccinia	☐ Yes	☐
Eastern Equine Encephalitis	☐ Yes	N/A	Venezuela Equine Encephalitis	☐ Yes	☐
Francisella tularensis	☐ Yes	N/A	West Nile	☐ Yes	N/A
H2N2	☐ Yes	☐	Yellow Fever	☐ Yes	☐
Human Retroviruses	☐ Yes	N/A	Yersinia pestis (Plague)	☐ Yes	N/A

Obtained via FOIA by Judicial Watch Inc.

UNC FINANCE AND OPERATIONS Environment, Health and Safety

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BSL3 Medical Evaluation Questionnaire

Medical History *(if "YES" to any of the following, please explain in the comment section)*

Do you have any condition that weakens the immune system such as HIV/AIDS, leukemia, cancer, aplastic anemia, sickle cell, agammaglobulinemia?	☐ YES	☐ NO
Do you have a severe autoimmune disease such as systemic lupus erythematosus, rheumatoid arthritis, or Grave's disease that may significantly depress the immune system?	☐ YES	☐ NO
Are you currently taking immunosuppressive drugs like oral steroids (e.g. Prednisone) to treat an autoimmune disease or as the result of an organ transplant?	☐ YES	☐ NO
Are you currently receiving cancer treatment with drugs and/or radiation?	☐ YES	☐ NO
Do you have a chronic medical condition such as renal failure, liver disease, hepatic insufficiency, hepatitis, diabetes, or chronic heart or lung disease?	☐ YES	☐ NO
Have you been diagnosed with nephritic syndrome, renal insufficiency, or uremia?	☐ YES	☐ NO
Do you have sarcoidosis?	☐ YES	☐ NO
Do you have myasthenia gravis?	☐ YES	☐ NO
Have you had your spleen removed or have congenital asplenia (absence of your spleen)?	☐ YES	☐ NO
Are you currently or trying to get pregnant?	☐ YES	☐ NO
Do you suffer from alcoholism?	☐ YES	☐ NO
Are you presently taking disease-modifying anti-rheumatic drugs (DMARDs)?	☐ YES	☐ NO
Do you suffer from malnutrition?	☐ YES	☐ NO
Foreign travel in the past year?	☐ YES	☐ NO
History of allergic rhinitis, conjunctivitis, or hay fever?	☐ YES	☐ NO
Asthma	☐ YES	☐ NO
Chronic cough	☐ YES	☐ NO
Eczema/urticaria/hives	☐ YES	☐ NO
Family history of allergic disease (please explain)	☐ YES	☐ NO
Chronic skin conditions	☐ YES	☐ NO
Seizure disorders	☐ YES	☐ NO
Chromosomal abnormalities	☐ YES	☐ NO
Other	☐ YES	☐ NO

Comments:

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BSL3 Medical Evaluation Questionnaire

Primary / Secondary Immunodeficiency Screening

Two or more new ear infections within 1 year	☐ YES	☐ NO
Two or more new sinus infections within 1 year (not attributed to animal or seasonal allergies)	☐ YES	☐ NO
One pneumonia diagnosis per year for more than 1 year	☐ YES	☐ NO
Chronic diarrhea with weight loss.	☐ YES	☐ NO
Recurrent viral infections (e.g. colds, herpes, warts, condyloma)	☐ YES	☐ NO
Recurrent need for intravenous antibiotics to clear infections	☐ YES	☐ NO
Recurrent, deep abscesses of the skin or internal organs	☐ YES	☐ NO
Persistent thrush (e.g. whitish, velvety lesions on your tongue or in your mouth), fungal infection on skin or elsewhere	☐ YES	☐ NO
Infection with normally harmless tuberculosis-like bacteria	☐ YES	☐ NO
A family or childhood history of primary immunodeficiency	☐ YES	☐ NO

I certify that I fully understand all requests for information contained on this form and I certify that the information supplied by me on this form is complete and correct to the best of my knowledge.

Employee Signature: _____ **Date:** _____

UEOHC Medical Provider Only

Recommended Post Prophylaxis (PEP): _____

Contraindications to PEP? ☐ Yes ☐ No

Details: _____

Alternative Agent: ☐ Yes ☐ No List: _____

☐ No medical restrictions for work in this BSL2+/BSL3 setting per SOP

☐ Temporary restrictions pending risk assessment.

☐ Restrictions: _____

☐ Unable to work in this BSL2+ / BSL3 setting per SOP

I have reviewed the information provided.

UEOHC Medical Provider Signature: _____ **Date:** _____

Comments: _____

Obtained via FOIA by Judicial Watch Inc.

APPENDIX G: OCCUPATIONAL MEDICAL CLEARANCE

Date: _____

Demographics: _____year old _____-handed employee employed as _____ for _____# of weeks/months/years.

Past Medical/Surgical History:

_____
_____
_____
_____

Medications:

_____
_____
_____

Drug Allergies: _____ **Other Allergies:** _____

Immunizations: _____

Psychosocial History: Non-smoker Smoker Quit _____

Alcohol use: rare, seldom, occasional, social, never, quit? _____

Exercise: regular, moderate, vigorous; # of times /week? _____

Seatbelt use: all the time, most of the times, some of the times, no use _____

Occupational History: Employee's job duties include; _____
_____
_____
_____

Health concerns:

_____

Physical Exam: Ht: _____ inches Wt: _____ pounds BMI: _____ BP: _____ Pulse: _____

General: _____
Lungs: _____

CV: _____

Ext: _____

Assessment and Plan: Required forms were completed by employee and reviewed by examiner.

Cleared for Fit Testing

_____

UEOHC Provider Signature **Date**

Obtained via FOIA by Judicial Watch Inc.

APPENDIX H: RESEARCH ANIMAL HANDLERS/CARETAKERS QUESTIONNAIRE

Principal Investigator/Supervisor: Work phone/pager:
Job Title: Today's date:
Date you began this job:

Animal Exposure:

Which animal(s) are you *exposed to at work* and what is your *extent of contact*?
Please note: "exposed to" includes animals that are in the room you work in even if you do not have direct contact with those animals.

Animal: _____ Days/week: _____ Hours/day: _____

Animal: _____ Days/week: _____ Hours/day: _____

Animal: _____ Days/week: _____ Hours/day: _____

Immunization History:

Date of last tetanus booster: _____ ☐ unknown
Tetanus boosters are recommended every 10 years. If you are due, please call University Employee Occupational Health (966-9119) to schedule.

You may skip to the next section (Hazard Exposure), *IF* you do *NOT* work with non-human primates or if your work does not involve possible exposure to Tuberculosis or human bloodborne pathogens.

Tuberculosis (TB)
Date of last TB skin test: _____ ☐ unknown **Result:** ☐positive ☐negative ☐unknown
History of TB treatment:

Measles/Rubeola (old fashioned, red)
Date of last booster: _____ ☐ unknown History of disease: ☐ Yes ☐ No

Hepatitis B
☐ Never vaccinated ☐ History of disease
☐ Previously vaccinated: Date last dose received: _____ Number of Hep B vaccine doses received: _____

Hazard Exposure:

Do you work with **formaldehyde**? ☐ **Yes** ☐ **No**
Do you work with **non-fixed human blood or tissue?** ☐ **Yes** ☐ **No**
Do you work with any **infectious agents?** ☐ **Yes** ☐ **No**
If yes, what type(s)? _____

Please list **any other hazardous agent(s)** you are currently working with:

Allergy History:

Do you currently have, or have had, a history of allergies? ☐ **Yes** ☐ **No**
If **Yes**, please check all that apply:
☐ hayfever ☐ allergic skin problems ☐ eczema ☐ latex allergy ☐ asthma
☐ other allergies, please describe: _____

Are you allergic to household pets? ☐ **Yes** ☐ **No** If **Yes**, what type(s)? _____

Have you ever changed jobs/work habits because of symptoms from handling animals? ☐ Yes ☐ No
If **Yes,** please explain:

Continue to page 2→

Obtained via FOIA by Judicial Watch Inc.

Indicate below any symptoms you experience in your CURRENT work with LAB ANIMALS:

If you experience NO symptoms, check here → ☐

SYMPTOM	FREQUENCY	SEVERITY	ANIMAL(S) CAUSING PROBLEM(S)
☐ sneezing spells	☐every time ☐most times ☐sometimes ☐rarely	☐ Mild ☐ Moderate ☐ Severe	
☐ watery/itchy eyes	☐every time ☐most times ☐sometimes ☐rarely	☐ Mild ☐ Moderate ☐ Severe	
☐ shortness of breath	☐every time ☐most times ☐sometimes ☐rarely	☐ Mild ☐ Moderate ☐ Severe	
☐ wheezing	☐every time ☐most times ☐sometimes ☐rarely	☐ Mild ☐ Moderate ☐ Severe	
☐ coughing spells	☐every time ☐most times ☐sometimes ☐rarely	☐ Mild ☐ Moderate ☐ Severe	
☐ other: *please specify:*	☐every time ☐most times ☐sometimes ☐rarely	☐ Mild ☐ Moderate ☐ Severe	

Training:

Have you received adequate training to safely perform your job duties? ☐**Yes** ☐**No**

(Examples of safety training include: the proper use of gloves, gowns, masks, shoe covers & goggles/glasses; the importance of handwashing & showering/changing clothes after work; handling animals safely; handling hazardous agents; infection control; general lab safety; precautions when pregnant, ill, or immunosuppressed.)

If you answered NO, please arrange for training as follows:

1) If you need training on handling animals safely, go to the **Institutional Animal Care & Use Committee's** training site at www.med.unc.edu/iacuc/ or call 966-5569.
2) If you need any other training, go to **Environment, Health & Safety's** training site at www.ehs.unc.edu or call 962-5507.

Work Health:

Do you have any health problems that you feel may be **related to your work**? ☐ **Yes** ☐ **No**

If **Yes**, please specify: _____

Do you have any concerns with work safety? ☐ **Yes** ☐ **No**

If **Yes,** please specify: _____

If you answered **YES**, please call the University Employee Occupational Health Clinic to schedule an appointment for evaluation of possible work injury or illness.

_____

Employee Signature Date

UEOHC review/comments

Symptom score:_____

_____ _____

UEOHC Medical Provider Signature Date

Obtained via FOIA by Judicial Watch Inc.

APPENDIX I: TUBERCULOSIS SCREENING QUESTIONNAIRE

UNC FINANCE AND OPERATIONS Environment, Health and Safety

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
UNIVERSITY EMPLOYEE OCCUPATIONAL HEALTH CLINIC
North Carolina Area Health Education Center | Suite 201 | Campus Box 1649
145 North Medical Drive | Chapel Hill, NC 27599-1649
Phone: 919-966-9119 | Fax: 919-966-6337

Tuberculosis Screening Questionnaire and Symptom Review

Name (First, MI, Last): _____ **Date of Birth:** _____

PID #: _____ **Medical Records #:** _____

Contact Number: _____ **Email Address:** _____

Department: _____ **Position Title:** _____

Have you ever experienced any of the following symptoms in the past month?

Chills	☐ YES	☐ NO	Shortness of Breath	☐ YES	☐ NO
Night Sweats	☐ YES	☐ NO	Unexplained Fever	☐ YES	☐ NO
Sputum Production	☐ YES	☐ NO	Unexplained Weight Loss ≥ 10 lbs.	☐ YES	☐ NO
Blood in Sputum	☐ YES	☐ NO	Unexplained cough > 3 Weeks	☐ YES	☐ NO

If yes to any of the above, please explain: _____

Have you ever had a 2-Step TB test placed?

☐ YES ☐ NO

If yes, please provide the following: Date (Month/Year): _____ Results: _____

Have you ever had an IGRA blood test for TB?

☐ YES ☐ NO

If yes, please provide the following: Date (Month/Year): _____ Results: _____

Have you ever received BCG (Bacillus Calmette - Guérin)?

☐ YES ☐ NO

If yes, please provide the following: Date (Month/Year): _____ Date (Month/Year): _____

Have you ever had a positive TB skin test or treatment for TB?

☐ YES ☐ NO

If yes, please provide the following: Date (Month/Year): _____ Location: _____

mm duration: _____ Result of X-ray: _____ # of months on treatment: _____

TB Treatment Medications: _____

Step 1 Placement — UEOHC Medical Provider Only

Date: ____/____/____ Time: ____:____ AM PM | Lot #: _____ Exp. Date: ____/____ | ☐ Left Forearm ☐ Right Forearm

UEOHC Medical Provider's Signature: _____

Step 1 Reading — UEOHC Medical Provider Only

Date: ____/____/____ Time: ____:____ AM PM | mm induration: _____ ☐ Positive ☐ Negative | ☐ Routine ☐ Travel ☐ Exposure ☐ New Employee

☐ HASMIS

UEOHC Medical Provider's Signature: _____ INITIAL

Step 2 Placement — UEOHC Medical Provider Only

Date: ____/____/____ Time: ____:____ AM PM | Lot #: _____ Exp. Date: ____/____ | ☐ Left Forearm ☐ Right Forearm

UEOHC Medical Provider's Signature: _____

Step 2 Reading — UEOHC Medical Provider Only

Date: ____/____/____ Time: ____:____ AM PM | mm induration: _____ ☐ Positive ☐ Negative | ☐ Routine ☐ Travel ☐ Exposure ☐ New Employee

☐ HASMIS

INITIAL

Comments: _____

UEOHC Medical Provider's Signature: _____ **Date:** ____/____/____

TB SCREENING QUESTIONNAIRE / REVISED FEBRUARY 2019 1

I understand my employment at UNC at Chapel Hill requires and/or recommends that I complete this TB screening questionnaire annually to comply with the N.C. regulations for TB assessment for employees in health care settings

Obtained via FOIA by Judicial Watch Inc.

APPENDIX J: OSHA RESPIRATOR MEDICAL EVALUATION QUESTIONNAIRE

Today's Date _____

UNC FINANCE AND OPERATIONS Environment, Health and Safety

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
UNIVERSITY EMPLOYEE OCCUPATIONAL HEALTH CLINIC
North Carolina Area Health Education Center | Suite 201 | Campus Box 1649
145 North Medical Drive | Chapel Hill, NC 27599-1649
Phone: 919-966-9119 |Fax: 919-966-6337

OSHA Respirator Medical Evaluation Questionnaire

Note: Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the healthcare professional who will review it.

PART A Section 1 Mandatory

The following information & questions must be provided by every employee who has been selected to use any type of respirator.

Name	_____	Today's Date	_____
PID #	_____	Date of Birth	_____
Age:	_____	Sex	_____
Height	_____	Weight	_____
Department	_____	Position Title	_____
Phone Number	_____	Best Contact Time	_____

Check the type of respirator you will use (check all that apply):

☐ N, R, or P disposable respirator (filter-mask, non-cartridge type only)

☐ Other type (i.e. half or full-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus)

Have you received training in use and limitation of respirator? ☐ YES ☐ NO

If yes, what type: _____

PART A Section 2 Mandatory

Do currently smoke tobacco or have you smoke tobacco in the last month? ☐ YES ☐ NO

Have you ever had any of the following conditions?

Seizures (fits)	☐ YES	☐ NO
Diabetes (sugar disease)	☐ YES	☐ NO
Allergic reactions that interfere with your breathing	☐ YES	☐ NO
Claustrophobia (fear of closed-in places)	☐ YES	☐ NO
Trouble smelling odors	☐ YES	☐ NO

Have you ever had any of the following pulmonary or lung problems?

Asbestosis	☐ YES	☐ NO
Asthma	☐ YES	☐ NO
Chronic Bronchitis	☐ YES	☐ NO
Emphysema	☐ YES	☐ NO
Pneumonia	☐ YES	☐ NO
Tuberculosis	☐ YES	☐ NO
Silicosis	☐ YES	☐ NO
Pneumothorax (collapsed lung) Lung Cancer	☐ YES	☐ NO
Lung Cancer	☐ YES	☐ NO
Broken Ribs	☐ YES	☐ NO
Any chest injuries/surgeries or lung problems you've been told about	☐ YES	☐ NO

Obtained via FOIA by Judicial Watch Inc.

UNC FINANCE AND OPERATIONS Environment, Health and Safety

Today's Date _____

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Do you currently have any of the following symptoms of pulmonary or lung disease?

Shortness of breath	☐ YES	☐ NO
Shortness of breath when walking fast on level ground or walking up a slight hill or incline	☐ YES	☐ NO
Shortness of breath when walking with other people at an ordinary pace on level ground	☐ YES	☐ NO
Shortness of breath that interferes with your job	☐ YES	☐ NO
Must stop for breath when walking at your own pace on level ground	☐ YES	☐ NO
Shortness of breath when washing or dressing yourself	☐ YES	☐ NO
Coughing that produces phlegm (thick sputum)	☐ YES	☐ NO
Coughing that wakes you early in the morning	☐ YES	☐ NO
Coughing that occurs mostly when you're lying down	☐ YES	☐ NO
Coughing up blood in the last month	☐ YES	☐ NO
Wheezing	☐ YES	☐ NO
Wheezing that interferes with your job	☐ YES	☐ NO
Wheezing that interferes with your job	☐ YES	☐ NO
Any other symptoms that you think may be related to lung problems	☐ YES	☐ NO

Have you ever had any of the following cardiovascular or heart *problems?*

Heart Attack	☐ YES	☐ NO
Stroke	☐ YES	☐ NO
Angina	☐ YES	☐ NO
Heart Failure	☐ YES	☐ NO
Swelling in your legs or feet (not caused by walking)	☐ YES	☐ NO
Heart arrhythmia (heart beating irregularly)	☐ YES	☐ NO
High Blood Pressure	☐ YES	☐ NO
Any other heart problem that you've been told about	☐ YES	☐ NO

Obtained via FOIA by Judicial Watch Inc.

UNC FINANCE AND OPERATIONS Environment, Health and Safety

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Have you ever had any of the following cardiovascular or heart *symptoms?*

Frequent pain or tightness in your chest	☐ YES	☐ NO
Pain or tightness in your chest during physical activity	☐ YES	☐ NO
Pain or tightness in your chest that interferes with your job	☐ YES	☐ NO
In the past 2 years, have you noticed your heart skipping or missing a beat	☐ YES	☐ NO
Heartburn or indigestion that is not related to eating	☐ YES	☐ NO
Any other symptoms that you think may be related to heart or circulation problems	☐ YES	☐ NO
Frequent pain or tightness in your chest	☐ YES	☐ NO
Pain or tightness in your chest during physical activity	☐ YES	☐ NO

Do you currently take medication for any of the following problems?

Breathing or lung problems	☐ YES	☐ NO
Heart Trouble	☐ YES	☐ NO
Blood Pressure	☐ YES	☐ NO
Seizures (fits)	☐ YES	☐ NO

If you've used respirator, have you ever had any of the following problems?

Eye irritation	☐ YES	☐ NO
Skin allergies or rashes	☐ YES	☐ NO
Anxiety	☐ YES	☐ NO
General weakness or fatigues	☐ YES	☐ NO
Any other problem that interferes with your use of a respirator	☐ YES	☐ NO

Obtained via FOIA by Judicial Watch Inc.

UNC FINANCE AND OPERATIONS Environment, Health and Safety

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Full-facepiece/SCBA Mandatory — *Other respirator types: answering these questions is voluntary*

Do you currently have any of the following vision problems?		
Wear contact lenses	☐ YES	☐ NO
Wear glasses	☐ YES	☐ NO
Color Blind	☐ YES	☐ NO
Any other eye or vision problems	☐ YES	☐ NO
Do you currently have any of the following hearing problems?		
Difficulty hearing	☐ YES	☐ NO
Wear a hearing aid	☐ YES	☐ NO
Any other hearing or ear problem	☐ YES	☐ NO
Have you ever had an injury to your ears, including broken eardrum	☐ YES	☐ NO
Do you currently have any of the following musculoskeletal problems?		
Weakness in any of your arm, hands, legs, or feet	☐ YES	☐ NO
Back pain	☐ YES	☐ NO
Difficulty fully moving your arms and legs	☐ YES	☐ NO
Pain or stiffness when you lean forward or backward at the waist	☐ YES	☐ NO
Difficulty fully moving your head up or down	☐ YES	☐ NO
Difficulty fully moving your head side to side	☐ YES	☐ NO
Difficulty bending at your knees	☐ YES	☐ NO
Difficulty squatting to the ground	☐ YES	☐ NO
Climbing a flight of stairs or a ladder carrying more than 25 lbs.	☐ YES	☐ NO
Have you ever had a back injury	☐ YES	☐ NO
Would you like to discuss your answers with the healthcare professional?	☐ YES	☐ NO

Employee's Signature _____ Date _____

Obtained via FOIA by Judicial Watch Inc.

APPENDIX K: ANNUAL CLEARANCE FOR RESPIRATOR

Today's Date _____

UNC FINANCE AND OPERATIONS Environment, Health and Safety

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North Carolina Area Health Education Center | Suite 201 | Campus Box 1649
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Phone: 919-966-9119 | Fax: 919-966-6337

Annual Clearance Respirator Form

Employee Information

Employee Name (First, MI, Last) _____ PID # _____

Department _____ Date of Birth _____

Position Title _____ Work/Pager Phone Number _____

Work Type & Respirator Necessity

Type of work performed: _____

Substance(s) necessitating respirator use: _____

Type(s) of Respirator(s) Used (check all that apply)

- ☐ **N95** (filtering face-piece)
- ☐ **SCBA**
- ☐ **Full Face**
  - Filter: _____
  - Chemical Cartridge: Gas _____
  - Mask Canister: _____
- ☐ **Half Mask**
  - Filter: _____
  - Chemical Cartridge: _____
- ☐ **PAPR**
  - Hood Filter Cartridge: _____
  - ½ Mask Filter Cartridge: _____
  - Full Face: _____

Respiratory Use

Level of work effort while wearing respirator: ☐ Light ☐ Moderate ☐ Heavy

Extent of respiratory use: ☐ Daily ☐ Weekly ☐ Monthly ☐ Rarely

Estimate length of respirator uses per session: Avg. Minutes _____ Avg. Hours _____ Max Minutes _____ Max Hours _____

Special Work Consideration While Wearing Respirator

- ☐ Special need for visual or auditory acuity
- ☐ High Places
- ☐ Confined Space
- ☐ Exposure to highly toxic materials, IDLH
- ☐ High Temperature/Humidity
- ☐ Additional protective equip/clothing
- ☐ Estimate weight of protective equip/clothing: ____
- ☐ Possibility of emergency/rescue use

Other: _____

Training

Have you received training in use and limitation of respirator? ☐ Yes ☐ No

Employee Signature: _____ **Date:** _____

Medical Clearance for Respirator Use Under Work Conditions Described Above *UEOHC Medical Provider Only*

☐ No Restrictions ☐ No Use Permitted ☐ Temporary Specific Restrictions*

Medical Clearance By: _____ **Date:** _____

**Temporary Specific Restrictions may be indicated when an employee has medical condition that if properly treated could permit the employee to be later cleared for respirator usage. The employee will be reevaluated within 6 months to determine if their medical condition has changed. If still not medically fit to use a respiratory on re-evaluation, employee would be removed from the Respiratory Protection Program.*

Obtained via FOIA by Judicial Watch Inc.

APPENDIX L: MEDICAL INFORMATION SHEETS

Agent	Chikungunya
Mode(s) of transmission	**Breaks in skin** (i.e. sharps, animal bites, mosquito bites if working with them, direct contact of a wound or mucous membrane with infective material) **Inhalation**
Chikungunya virus infection Incubation period:	One to twelve days.
Signs/Symptoms:	Fever (>100° F), arthritis/arthralgia, maculopapular rash, myalgia, nausea and vomiting. Acute Chikungunya fever typically lasts a few days to a few weeks, but as with dengue, West Nile fever and other arboviral fevers, some patients have prolonged fatigue lasting several weeks. Additionally, some patients have reported incapacitating joint pain, or arthritis which may last for weeks or months
Actual Exposure: Needle stick or cuts with contaminated material, animal bites or scratches from infected animals, splash to unprotected face, direct contact of contaminated materials with mucous membranes, direct contact of contaminated materials with broken skin, failure of respiratory protection with aerosol generating event outside of cabinet. **Did patient perform the procedures below:**	
Percutaneous exposure: 1. Remove contaminated gloves and, if possible, allow the wound to bleed freely for a minute. 2. If there is reason to believe the inner glove was not compromised, it can be kept and filled with water to observe for leaks. 3. Wash wound with soap and water for 5 minutes; apply sterile dressing if necessary. 4. Put on fresh gloves for securing agents and waste and decontamination before exiting the lab. 5. Exit lab per egress protocols and proceed to UEOHC or UNC ED. **Mucous membrane exposure**: 1. (EYES) Flush eyes for at least 5 minutes using the eye wash station 2. (Other tissues) Rinse exposed tissue with copious amounts of water 3. Exit lab per egress protocols and proceed to UEOHC or UNC ED. **Inhalation exposure**: 1. Exit lab per egress protocols and proceed to UEOHC or UNC ED.	
Potential Exposure: Failure of PPE with no known aerosol or direct contact with infections materials, spills, needle stick or cut with object not known to be contaminated, animal bite or scratch from an uninfected animal. Loss of containment with spill constitutes a potential exposure to lab and building occupants.	
Did patient perform the procedures below: 1. Decontaminate exposure site, if applicable, 2. Secure agents and exit lab per exit protocols 3. Report to PI. If after work hours, employee is to contact PI and EHS who will facilitate medical care.	
Initial test(s)	Serum draw to test for virus specific antibodies
Follow Up test(s)	Second serum draw at 14 days to test for rise in antibody titer.
Signs/Symptoms Surveillance	Monitor for 14 days (see SOP #001, Section 8 and Appendix P, Medical Monitoring Form)
Chemoprophylaxis	Treatment is supportive, attempting to deal with problems such as swelling of the brain, loss of the automatic breathing activity of the brain and other treatable complications like bacterial pneumonia.
EHS Contact Information: Jessica Poole, Associate Biological Safety Officer: 919-962-5726 (O), 919-883-7020 (Cell), 704-267-6684 (Cell), 919-216-3963 (Pager).	

Obtained via FOIA by Judicial Watch Inc.

Agent	*Mycobacterium tuberculosis*
Mode(s) of transmission	**Breaks in skin** (i.e. sharps, animal bites, direct contact of a wound or mucous membrane with infective material) **Inhalation, Ingestion**
Tuberculosis: Incubation period:	2-12 weeks. Greater than 12 weeks is possible
Signs/Symptoms:	Severe cough that lasts 3 weeks or longer - pain in the chest - coughing up blood or sputum - weakness or fatigue - weight loss - no appetite - chills - fever - sweating at night
Latent Tb Infection: Incubation period:	
Signs/Symptoms:	Typically does not exhibit any symptom but does have positive Tuberculin Skin Test.
Actual Exposure: Needle stick or cuts with contaminated material, animal bites or scratches from infected animals, splash to unprotected face, direct contact of contaminated materials with mucous membranes, direct contact of contaminated materials with broken skin, failure of respiratory protection with aerosol generating event outside of cabinet. **Did patient perform the procedures below:**	
Percutaneous exposure: 1. Remove contaminated gloves and, if possible, allow the wound to bleed freely for a minute. 2. If there is reason to believe the inner glove was not compromised, it can be kept and filled with water to observe for leaks. 3. Wash wound with soap and water for 5 minutes; apply sterile dressing if necessary. 4. Put on fresh gloves for securing agents and waste and decontamination before exiting the lab. 5. Exit lab per egress protocols and proceed to UEOHC or UNC ED. **Mucous membrane exposure**: 1. (EYES) Flush eyes for at least 5 minutes using the eye wash station 2. (Other tissues) Rinse exposed tissue with copious amounts of water 3. Exit lab per egress protocols and proceed to UEOHC or UNC ED. **Inhalation exposure**: 1.Exit lab per egress protocols and proceed to UEOHC.	
Potential Exposure: Failure of PPE with no known aerosol or direct contact with infections materials, spills, needle stick or cut with object not known to be contaminated, animal bite or scratch from an uninfected animal. Loss of containment with spill constitutes a potential exposure to lab and building occupants.	
Did patient perform the procedures below: 1. Decontaminate exposure site, if applicable, 2. Secure agents and exit lab per exit protocols 3. Report to PI. If after work hours, employee is to contact PI and EHS who will facilitate medical care.	
Initial test(s)	TST at time of exposure
Follow Up test(s)	TST 12 weeks following exposure
Signs/Symptoms Surveillance	Monitor for 7 days (see SOP #001, Section 8 and Appendix P, Medical Monitoring Form)
Chemoprophylaxis	No post-exposure prophylaxis. Patients with documented conversion of their TST or positive IGRA will be treated per NC TB Control Manual.
EHS Contact Information: Jessica Poole, Associate Biological Safety Officer: 919-962-5726 (O), 919-883-7020 (Cell), 919-216-3963 (Pager).	

Obtained via FOIA by Judicial Watch Inc.

Agent	SARS/MERS Coronavirus, 2019 n-CoV, 1918 Flu
Mode(s) of transmission	**Breaks in skin** (i.e. sharps, animal bites, direct contact of a wound or mucous membrane with infective material) **Inhalation** **Ingestion**
Severe Acute Respiratory Syndrome (SARS) Incubation period:	One to twelve days.
Signs/Symptoms:	Elevated temperature (>100˚F) Respiratory symptoms-dry cough, sneezing, runny nose Headaches, body aches Pneumonia Diarrhea – 10 – 20%
Actual Exposure: Needle stick or cuts with contaminated material, animal bites or scratches from infected animals, splash to unprotected face, direct contact of contaminated materials with mucous membranes, direct contact of contaminated materials with broken skin, failure of respiratory protection with aerosol generating event outside of cabinet. **Did patient perform the procedures below:**	
Percutaneous exposure: 1. Remove contaminated gloves and, if possible, allow the wound to bleed freely for a minute. 2. If there is reason to believe the inner glove was not compromised, it can be kept and filled with water to observe for leaks. 3. Wash wound with soap and water for 5 minutes; apply sterile dressing if necessary. 4. Put on fresh gloves for securing agents and waste and decontamination before exiting the lab. 5. Exit lab per egress protocols and proceed to UEOHC or UNC ED. **Mucous membrane exposure**: 1. (EYES) Flush eyes for at least 5 minutes using the eye wash station 2. (Other tissues) Rinse exposed tissue with copious amounts of water 3. Exit lab per egress protocols and proceed to UEOHC or UNC ED. **Inhalation exposure**: 1. Exit lab per egress protocols and call EHS Biosafety from the anteroom to report an exposure. Wait on instructions from EHS Biosafety	
Potential Exposure: Failure of PPE with no known aerosol or direct contact with infections materials, spills, needle stick or cut with object not known to be contaminated, animal bite or scratch from an uninfected animal. Loss of containment with spill constitutes a potential exposure to lab and building occupants.	
Did patient perform the procedures below: 1. Decontaminate exposure site, if applicable, 2. Secure agents and exit lab per exit protocols 3. Report to PI. If after work hours, employee is to contact PI and EHS who will facilitate medical care.	
Initial test(s)	Serum draw to test for virus specific antibodies
Follow Up test(s)	Second serum draw at 4 weeks to test for rise in antibody titer.
Signs/Symptoms Surveillance Known Respiratory Exposure	Monitor for 10 days (see SOP #001, Section 8 and Appendix P, Medical Monitoring Form) The employee will remain away from work for a minimum of 72 hours after developing fever or symptoms. Employee will be advised to self-quarantine (i.e. minimize contacts) and take precautions to minimize droplet generation including covering nose and mouth when coughing or sneezing. If symptoms and fever are not gone after 72 hours, worker will continue to monitor his/her condition and will report results to UEOHC daily. Employee will be advised when/if arrangements for clinical evaluation after hours will be needed.
Chemoprophylaxis	Treatment is supportive, attempting to deal with problems such as pneumonia and fever.
EHS Contact Information: Jessica Poole, Associate Biological Safety Officer: 919-962-5726 (O), 919-883-7020 (Cell), 919-216-3963 (Pager)	

Obtained via FOIA by Judicial Watch Inc.

Agent	Venezuelan Equine Encephalitis
Mode(s) of transmission	**Breaks in skin** (i.e. sharps, animal/mosquito bites, direct contact of a wound or mucous membrane with infective material) **Inhalation**
Mild VEE infection Incubation period:	Two to six days.
Signs/Symptoms:	Abrupt onset of severe headache, chills, fever, myalgia, retro-orbital pain, nausea and diarrhea. Generally lasts for 3-5 days.
Encephalitis: Signs/Symptoms:	Some cases have diphasic fever, CNS involvement, encephalitis with disorientation, convulsions, paralysis, coma and death
Actual Exposure: Needle stick or cuts with contaminated material, animal bites or scratches from infected animals, splash to unprotected face, direct contact of contaminated materials with mucous membranes, direct contact of contaminated materials with broken skin, failure of respiratory protection with aerosol generating event outside of cabinet. **Did patient perform the procedures below:**	
Percutaneous exposure: 1. Remove contaminated gloves and, if possible, allow the wound to bleed freely for a minute. 2. If there is reason to believe the inner glove was not compromised, it can be kept and filled with water to observe for leaks. 3. Wash wound with soap and water for 5 minutes; apply sterile dressing if necessary. 4. Put on fresh gloves for securing agents and waste and decontamination before exiting the lab. **Mucous membrane exposure:** 1. (EYES) Flush eyes for at least 5 minutes using the eye wash station 2. (Other tissues) Rinse exposed tissue with copious amounts of water **Inhalation exposure:** 1. Exit lab per egress protocols and proceed to UEOHC or UNC ED.	
Potential Exposure: Failure of PPE with no known aerosol or direct contact with infections materials, spills, needle stick or cut with object not known to be contaminated, animal bite or scratch from an uninfected animal. Loss of containment with spill constitutes a potential exposure to lab and building occupants.	
Did patient perform the procedures below: 1. Decontaminate exposure site, if applicable, 2. Secure agents and exit lab per exit protocols 3. Report to PI. If after work hours, employee is to contact PI and EHS who will facilitate medical care.	
Initial test(s)	Serum draw to test for antibodies
Follow Up test(s)	Second serum draw at 4 weeks to test for rise in antibody titer.
Signs/Symptoms Surveillance	Monitor for 14 days (see SOP #001, Section 8 and Appendix P, Medical Monitoring Form)
Chemoprophylaxis	Treatment is supportive, attempting to deal with problems such as swelling of the brain, loss of the automatic breathing activity of the brain and other treatable complications like bacterial pneumonia.
EHS Contact Information: Jessica Poole, Associate Biological Safety Officer: 919-962-5726 (O), 919-883-7020 (Cell), 704-267-6684 (Cell), 919-216-3963 (Pager).	

Obtained via FOIA by Judicial Watch Inc.

Agent	*Yersinia pestis*
Mode(s) of transmission	**Breaks in skin** (i.e. sharps, animal/flea bites, direct contact of a wound or mucous membrane with infective material) **Inhalation**
Bubonic Plague:	
Incubation period:	2-8 days.
Signs/Symptoms:	Sudden onset of fever, (≥100.4F), chills, weakness, headache and painful lymphadenopathy (bubo).
Primary Pneumonic Plague:	
Incubation period:	< 1day – 4 days
Signs/Symptoms:	Cough, chest pain, hemoptysis w/ or w/o bubo. Chest X-ray: patchy, bronchopneumonia, cavities or confluent consolidation.
Septicemic Plague:	
Signs/Symptoms:	Fever, hypotension w/o bubo. Can affect other parts of the body, including meninges, and cause endotoxic shock and DIC. **Meningitis** associated w/ plague includes fever, nuchal rigidity, usually w/ bubo; it typically occurs ≥ 1 week after inadequate treatment of bubonic plague.
Cutaneous Plague:	
Signs/Symptoms:	Pustule, eschar, carbuncle or ecthyma gangrenosum, (necrotic ulcers) usually w/ bubo.
Actual Exposure: Needle stick or cuts with contaminated material, animal bites or scratches from infected animals, splash to unprotected face, direct contact of contaminated materials with mucous membranes, direct contact of contaminated materials with broken skin, failure of respiratory protection with aerosol generating event outside of cabinet. **Did patient perform the procedures below:**	
Percutaneous exposure: 1. Remove contaminated gloves and, if possible, allow the wound to bleed freely for a minute. 2. If there is reason to believe the inner glove was not compromised, it can be kept and filled with water to observe for leaks. 2. Wash wound with soap and water for 5 minutes; apply sterile dressing if necessary. 3. Put on fresh gloves for securing agents and waste and decontamination before exiting the lab. **Mucous membrane exposure**: 1. (EYES) Flush eyes for at least 5 minutes using the eye wash station 2. (Other tissues) Rinse exposed tissue with copious amounts of water **Inhalation exposure**: 1. Exit lab per egress protocols and proceed to UEOHC or UNC ED.	
Potential Exposure: Failure of PPE with no known aerosol or direct contact with infections materials, spills, needle stick or cut with object not known to be contaminated, animal bite or scratch from an uninfected animal. Loss of containment with spill constitutes a potential exposure to lab and building occupants.	
Did patient perform the procedures below: 1. Decontaminate exposure site, if applicable, 2. Secure agents and exit lab per exit protocols 3. Report to PI. If after work hours, employee is to contact PI and EHS who will facilitate medical care.	
Initial test(s)	n/a
Follow Up test(s)	n/a
Signs/Symptoms Surveillance	Monitor for 7 days (see SOP #001, Section 8 and Appendix P, Medical Monitoring Form)
Chemoprophylaxis	X 7 days (usually Doxycycline, 100 mg orally)
EHS Contact Information: Jessica Poole, Associate Biological Safety Officer: 919-962-5726 (O), 919-883-7020 (Cell), 919-216-3963 (Pager).	

Obtained via FOIA by Judicial Watch Inc.

APPENDIX M: INCIDENT REPORT FORM 19

North Carolina Industrial Commission

EMPLOYER'S REPORT OF EMPLOYEE'S INJURY OR OCCUPATIONAL DISEASE TO THE INDUSTRIAL COMMISSION

IC File #
*Emp Code #
*Carrier Code #
Employer FEIN
Carrier File #
*Required Information

The I.C. File # is the unique identifier for this injury. It will be provided by return letter and is to be referenced in all future correspondence.

To the Employer:
A copy of this Form 19 accompanied by a blank Form 18 must be given to the employee. It does not satisfy the employee's obligation to file a claim. The filing of this report is required by law.
This form MUST be transmitted to the Industrial Commission through your Insurance Carrier.

To the Employee:
This Form 19 is not your claim for workers' compensation benefits. To make a claim, you must complete and sign the enclosed **Form 18** and mail it to Claims Administration, N.C. Industrial Commission, 4335 Mail Service Center, Raleigh, NC 27699-4335 within two years of the date of your injury or last payment of medical compensation. For occupational diseases, the claim must be filed within two years of the date of disability or the date your doctor told you that you have a work-related disease, whichever is later.

The use of this form is required under the provisions of the Workers' Compensation Act

Employee's Name	Employer's Name		( ) - Telephone Number
Address	Employer's Address	City State Zip	
City State Zip	Insurance Carrier	Policy Number	
( ) - Home Telephone	( ) - Work Telephone	Carrier's Address	City State Zip
- - Social Security Number	☐ M ☐ F Sex / / Date of Birth	( ) - Carrier's Telephone Number	( ) - Fax Number

Employer	1	Give nature of employer's business
Time And Place	2	Location of plant where injury occurred County Department State if employer's premises
	3	Date of injury / / 4 Day of week Hour of day ☐ A.M. ☐ P.M.
	5	Was employee paid for entire day 6 Date disability began / / ☐ A.M. ☐ P.M.
	7	Date you or the supervisor first knew of injury / / 8 Name of supervisor
Person Injured	9	Occupation when injured
	10	(a) Time employed by you (b) Wages per hour $
	11	(a) No. hours worked per day (b) Wages per day $ (c) No. of days worked per week (d) Avg. weekly wages w/ overtime $ (e) If board, lodging, fuel or other advantages were furnished in addition to wages, estimated value per day, week or month $ per
Cause And Nature Of Injury	12	Describe fully how injury occurred and what employee was doing when injured (Statement made without prejudice and without vouching for correctness of information)
	13	List all injuries and specify body part involved (e.g. right hand or left hand)
	14	Date & hour returned to work / / at M. 15 If so, at what wages $ per
	16	At what occupation 17 Employee's salary continued in full?
	18	Was employee treated by a physician
Fatal Cases	19	Has injured employee died 20 If so, give date of death (Submit Form 29) / /

Employer name Date Completed / /
Signed by Official Title

OSHA 301 Information:

Case Number from Log	Date Hired / /	Time Employee began work on date of incident ☐ A.M. ☐ P.M.	If off-site medical treatment provided, answer entire next line	
Name of facility		Address Street/City/Zip/Telephone	ER visit? ☐ Yes ☐ No	Overnight stay? ☐ Yes ☐ No

Attention: This form contains information relating to employee health and must be used in a manner that protects the confidentiality of employees to the extent possible while the information is being used for occupational safety and health purposes.

FORM 19
8/1/08
PAGE 1 OF 2

FOR IC USE ONLY
RESEARCHER
CC
FC
DATA ENTRY

FORM 19

SELF-INSURED EMPLOYER OR CARRIER MAIL TO:

NCIC - CLAIMS ADMINISTRATION
4335 MAIL SERVICE CENTER
RALEIGH, NORTH CAROLINA 27699-4335
MAIN TELEPHONE: (919) 807-2500
HELPLINE: (800) 688-8349
WEBSITE: HTTP://WWW.IC.NC.GOV/

Obtained via FOIA by Judicial Watch Inc.

IMPORTANT INFORMATION FOR EMPLOYER

Employer must furnish a copy of this form, as completed, to the employee or the employee's representative when submitted to the Insurance Carrier or Claims Administrator for transmission to the Commission. Every question must be answered. This Form 19 must be transmitted to the Commission through your insurance carrier/claims administrator, and is required by law to be filed within 5 days after knowledge of accident. Employer must also give employee a blank Form 18.

IMPORTANT INFORMATION FOR EMPLOYEE

Reporting an Injury

If you do not agree with the description or time of the accident given on this form, you should make a written report of injury to the employer within thirty (30) days of the injury.

Making A Claim

To be sure you have filed a claim, complete a Form 18, Notice of Accident, within two years of the date of the injury and send a copy to the Industrial Commission and to your employer. The employer is required by law to file this Form 19, but the filing of the Form 19 does not satisfy the employee's obligation to file a claim. The employee must file a Form 18 even though the employer may be paying compensation without an agreement, or the Commission may have opened a file on this claim. A claim may also be made by a letter describing the date and nature of the injury or occupational disease. This letter must be signed and sent to the Industrial Commission and to your employer.

FOR ASSISTANCE OR TO OBTAIN A FORM 18 FROM THE INDUSTRIAL COMMISSION, YOU MAY CALL (800) 688-8349

USE YOUR I.C. FILE NUMBER (IF KNOWN) OR SOCIAL SECURITY NUMBER ON ALL FUTURE CORRESPONDENCE WITH THE COMMISSION

[SPANISH TRANSLATION]

INFORMACIÓN IMPORTANTE PARA LOS EMPLEADOS

Reporte de una Lesión (Reporting an Injury)

Si usted no está de acuerdo con la descripción o la hora del accidente que aparece en el formulario, debe hacer un reporte de la lesión por escrito y dárselo a su empleador dentro de un periodo de treinta (30) días a partir de la fecha de la lesión.

Cómo Presentar una Reclamación (Making a Claim)

Para cerciorarse de que ha presentado una reclamación, complete el Formulario 18 Notificación de Accidente dentro de un periodo de dos años a partir de la fecha de la lesión y envíe una copia a la Comisión Industrial y una copia a su empleador. Por ley, el empleador debe presentar el Formulario 19, sin embargo, el presentar el Formulario 19 no cumple con la obligación que tiene el empleado de presentar una reclamación. El empleado debe presentar el Formulario 18 aunque el empleador esté pagando compensación sin tener un acuerdo o si la Comisión ha creado un expediente con respecto a esta reclamación. También se puede presentar una reclamación por medio de una carta explicando la fecha y la naturaleza de la lesión o la enfermedad ocupacional. Esta carta se debe firmar y enviar a la Comisión Industrial así como al empleador.

PARA RECIBIR ASISTENCIA O PARA OBTENER EL FORMULARIO 18 DE LA COMISIÓN INDUSTRIAL, USTED PUEDE HABLAR AL (800) 688-8349

EN TODA LA CORRESPONDENCIA QUE ENVÍE A LA COMISIÓN INDUSTRIAL POR FAVOR ESCRIBA EL NÚMERO DE CASO DESIGNADO POR LA COMISIÓN *[I.C. FILE NUMBER]* (SI LO SABE) O SU NÚMERO DE SEGURO SOCIAL

FORM 19

SELF-INSURED EMPLOYER OR CARRIER MAIL TO:

NCIC - CLAIMS ADMINISTRATION
4335 MAIL SERVICE CENTER
RALEIGH, NORTH CAROLINA 27699-4335
MAIN TELEPHONE: (919) 807-2500
HELPLINE: (800) 688-8349
WEBSITE: HTTP://WWW.IC.NC.GOV/

Obtained via FOIA by Judicial Watch Inc.

APPENDIX N: EMPLOYEE'S ACCIDENT REPORT FORM
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

THIS FORM IS TO BE COMPLETED BY THE EMPLOYEE AND FORWARDED TO THE HEALTH AND SAFETY OFFICE AS SOON AS PRACTICABLE AFTER THE INJURY. (SEE HUMAN RESOURCES MANUAL)

ACCIDENT DATE

1. **NAME OF EMPLOYEE:**
2. **DATE AND TIME OF INJURY:**
3. **DESCRIBE HOW THE INJURY OCCURRED:**
4. **DESCRIBE WHAT JOB DUTY YOU WERE DOING AT THE TIME OF YOUR INJURY:**
5. **DESCRIBE WHAT PART OF YOUR BODY WAS INJURED:**
6. **DESCRIBE WHAT YOU WOULD RECOMMEND TO PREVENT A REOCCURRENCE:**
7. **FURTHER INFORMATION YOU WOULD LIKE TO INCLUDE REGARDING YOUR INJURY:**

EMPLOYEE SIGNATURE **DATE**

Obtained via FOIA by Judicial Watch Inc.

APPENDIX O: UNC–CH SUPERVISOR'S INCIDENT REPORT FORM

This form is to be completed by the Supervisor and forwarded to the Department of Environment, Health and Safety along with a copy of the North Carolina Industrial Commission Form 19 (Workers' Compensation Form) as soon as practicable. All incidents involving serious bodily injury or death must be reported to the Department of Environment, Health and Safety immediately.

General Info.	Injury/Illness Near Miss		Location of Incident	
	Time of Incident : AM PM	Date Incident Occurred / /		Date Incident Reported / /
Personnel Info	Name: (Last) (First) (MI)		Occupation of Injured Worker	
	Length of Employment Years Months	Length in Present Job Years Months	Shift 1st 2nd 3rd	Overtime Yes No
Incident Description	Injury Type (i.e. cut/strain)	Body Part Affected	Cause of injury	
	Describe events leading to incident:			
Witnesses	Name of Witness	Phone #	Before/During/Afterwards	
Immediate Cause	What acts or conditions contributed directly to the incident?			
Basic Cause	What personal and/or job factors contributed to the incident?			
PPE	What Personal Protective Equipment was required for this job? Was it in use? _____ yes _____ no			
Risk Assmnt.	Probability of event recurring Likely Possible Unlikely	Severity Potential Major Serious Minor	Exposure Frequency Frequent Occasional Rare	
Prevention	Temporary Fix – What immediate corrective action has been taken to prevent a recurrence?	Permanent Solution – What correction action has been or will be taken to eliminate the basic causes?		
Treatment Data	Medical Treatment None UEOHC ER (life threatening)	Treatment Status None Medical only Lost Time (medical note)		
Investigated by	Name	Date of Investigation		
	Signature			

Obtained via FOIA by Judicial Watch Inc.

APPENDIX P: MEDICAL MONITORING FORM

NAME _____ MRN _____

Category of monitoring:

Exposure event: Date and time of event: _____

Description of event: _____

Potential exposure event: Date and time of event: _____

Description of event: _____

Symptoms with no recognized exposure: Date of onset: _____

Medical history:

Any chronic medical conditions, esp. DM, CA, lung disorders (asthma, chronic bronchitis, emphysema), kidney, liver, heart disease: _____

Allergies: _____

Current medications: _____

DAILY MONITORING LOG *(Worker will be asked if they have experienced the following symptoms in the last 24 hours. Indicate "Y" for "yes" or "N" for "no". Additional comments, including discussion of any "yes", should be entered on a RECORD SHEET)*

DATE→										
Medicines taken today*										
Feeling "feverish"										
Highest Temp in last 24 hrs.										
Chills +/- shivering										
Muscle aches										
Malaise **										
H/A										
Diarrhea										
Dry cough										
Prod cough										
Dyspnea / SOB										
Nasal congestion/discharge										
Sore throat										
Wheezing										
Sneezing										
Rash										
N/V										

**List "medications taken today" on attached RECORD SHEET. Be sure to include aspirin, Tylenol, NSAIDs, or steroids.*

***"Malaise" is described as: general feeling of being unwell, tired, fatigued, low appetite, &/or lack of energy.*

Obtained via FOIA by Judicial Watch Inc.

APPENDIX Q: CHECKLIST FOR HOME QUARANTINE

INFRASTRUCTURE	PRESENT	SPECIFICS
Functioning telephone	Yes/No	Cell Phone Land line
Electricity	Yes/No	
Heat Source	Yes/No	Furnace Space heater Kerosene/propane heater
Potable Water	Yes/No	Well City Supplied
Bathroom with commode and sink	Yes/No	Private Shared
Waste and sewage disposal	Yes/No	Septic tank Community sewage line Trash Pick up
ACCOMODATIONS		
Separate bedroom for patient	Yes/No	
Accessible bathroom in the residence	Yes/No	Can be designated for use by patient Must be shared with other residents
RESOURCES FOR CARE AND SUPPORT		
Caregiver who can remain in residence	Yes/No	High risk for complications from SARS/MERS/1918 Not high risk for complications from SARS/MERS/1918
Meal Preparation	Yes/No	Patient Caregiver
Laundry	Yes/No	Patient Caregiver
Banking	Yes/No	Patient Caregiver
Essential Shopping	Yes/No	Patient Caregiver
Social Diversion	Yes/No	Television Radio Internet access Reading materials
Medical Supplies	Yes/No	Surgical Masks Thermometer Tissues Hand-hygiene products Anti-viral medications

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Thursday, April 23, 2020 10:05 AM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Cyr, Douglas M.; Brennan, Catherine; Tucker, Jessica (NIH/OD) [E]
Subject: RE: NIH Incident Report _ FINAL
Attachments: NIH_Report_04232020-FINAL.pdf

Dear Dr. Harris,

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of the potential exposure to recombinant DNA that occurred in a laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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From: Coulson, Garry Brian
Sent: Wednesday, April 22, 2020 8:05 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>
Subject: RE: NIH Incident Report - Preliminary

Hi Dr. Harris,

We have a single, unified BSL-3 Laboratory Medical Surveillance SOP for our research program, which I have attached. The applicable exposure response procedure for exposure to SARS-CoV-2 ("2019-nCOV") can be found on page 13. The individual has been instructed to complete a 14 day self-quarantine at home and actively self-monitoring with temperature checks twice daily consistent with CDC guidance for medium/high-risk exposures in healthcare personnel (HCP). Of note, the individual was uncertain if the mouse bite actually broke the skin as no blood was observed upon

Obtained via FOIA by Judicial Watch Inc.

inspection of their finger. However, given the uncertainty surrounding the exposure, we are treating this as a medium/high-risk exposure. The Orange County Health Department Medical Director is aware of the exposure and there are existing protocols in place with our academic medical center, including SARS-CoV-2 PCR testing, to ensure that the public and other patients are not at risk of exposure if the individual becomes symptomatic and requires medical evaluation and treatment.

Please don't hesitate to reach out to me if you have any further questions. If needed, my cell phone number is 919-869-5874.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722 (office)
Email | garry.coulson@ehs.unc.edu

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From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Wednesday, April 22, 2020 5:41 PM
To: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>
Subject: RE: NIH Incident Report - Preliminary

Dear Dr. Coulson:

Thank you for your preliminary report of an incident involving a potential exposure to a recombinant SARS-CoV-2 virus. In your email, you indicate the exposed researcher reported to the Occupational Health Clinic and has been placed on medical surveillance protocols as described in the standard operating procedure (SOP).

We understand you are still gathering information for your formal report, but in the meantime, please provide NIH OSP a copy of the post-exposure SOP for the laboratory, and indicate whether the CDC guidelines for exposure are being followed. Please also verify whether any applicable local and/or state public health notifications have been made.

In advance of your final report, please advise NIH OSP of any pertinent information/further developments as they occur (for example if the researcher develops symptoms or tests positive for SARS-CoV-2). Please do not identify any potentially exposed individuals by name in any correspondence to NIH OSP.

If the research is NIH-funded, the terms and conditions of the award may require notification to the program officer of any significant incidents occurring during the conduct of the research. In any event, we recommend notifying the program officer, if this has not already occurred.

Obtained via FOIA by Judicial Watch Inc.

Thanks again for your preliminary incident report, and we will await further information as it becomes available.

Regards,

Dr. Kathryn Harris

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Tuesday, April 21, 2020 5:49 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of a potential exposure to recombinant DNA involving a worker in a BSL-3 laboratory. Our initial investigation indicates a researcher received a mouse bite from a mouse infected with recombinant SARS-CoV-2 virus adapted for growth in mice. The Researcher has reported to the Occupational Health Clinic, and placed on medical surveillance protocols as described in the standard operating procedure (SOP).

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Hunter, Renee (NIH/OD) [C]

From: Harris, Kathryn (NIH/OD) [C]
Sent: Wednesday, April 22, 2020 5:41 PM
To: Coulson, Garry Brian
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Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Wednesday, April 22, 2020 8:05 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Cyr, Douglas M.; Brennan, Catherine; Tucker, Jessica (NIH/OD) [E]
Subject: RE: NIH Incident Report - Preliminary
Attachments: Signed 2020 Medical Surveillance SOP.pdf

Hi Dr. Harris,

We have a single, unified BSL-3 Laboratory Medical Surveillance SOP for our research program, which I have attached. The applicable exposure response procedure for exposure to SARS-CoV-2 ("2019-nCOV") can be found on page 13. The individual has been instructed to complete a 14 day self-quarantine at home and actively self-monitoring with temperature checks twice daily consistent with CDC guidance for medium/high-risk exposures in healthcare personnel (HCP). Of note, the individual was uncertain if the mouse bite actually broke the skin as no blood was observed upon inspection of their finger. However, given the uncertainty surrounding the exposure, we are treating this as a medium/high-risk exposure. The Orange County Health Department Medical Director is aware of the exposure and there are existing protocols in place with our academic medical center, including SARS-CoV-2 PCR testing, to ensure that the public and other patients are not at risk of exposure if the individual becomes symptomatic and requires medical evaluation and treatment.

Please don't hesitate to reach out to me if you have any further questions. If needed, my cell phone number is 919-869-5874.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722 (office)
Email | garry.coulson@ehs.unc.edu

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Thanks again for your preliminary incident report, and we will await further information as it becomes available.

Regards,

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We wanted to notify you of a potential exposure to recombinant DNA involving a worker in a BSL-3 laboratory. Our initial investigation indicates a researcher received a mouse bite from a mouse infected with recombinant SARS-CoV-2 virus adapted for growth in mice. The Researcher has reported to the Occupational Health Clinic, and placed on medical surveillance protocols as described in the standard operating procedure (SOP).

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Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, May 15, 2020 1:54 PM
To: Gregory Park; NIH guidelines
Cc: Chris Cramer; Masato Yamamoto; Frances Lawrenz; Fang Li; Jakub Tolar; Laura Molgaard; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Guidelines-related incident report from U of MN

Dear Dr. Gregory Park,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. However, we note that this incident involved failure to obtain IBC approval before initiating research subject to the *NIH Guidelines* that spanned the course of several years which went unnoticed until publication of a manuscript. We recommend that the university consider conducting a broad education campaign to remind all investigators and laboratory personnel of the requirements for IBC registration and approval under the *NIH Guidelines* and also identify any institutional oversight gaps that should be addressed to prevent future occurrences in this and other laboratories. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Gregory Park <parkx479@umn.edu>
Sent: Thursday, April 30, 2020 12:00 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chris Cramer <cramer@umn.edu>; Masato Yamamoto <yamam016@umn.edu>; Frances Lawrenz <lawrenz@umn.edu>; Fang Li <lifang@umn.edu>; Jakub Tolar <tolar003@umn.edu>; Laura Molgaard <molga001@umn.edu>
Subject: NIH Guidelines-related incident report from U of MN

Dear NIH-OSP,
Please find attached a cover letter with an NIH incident report. Do not hesitate to contact me if you have any further questions.
Regards,
Greg Park

Obtained via FOIA by Judicial Watch Inc.

--

**Please note, the OBAO is currently working remotely
. The best way to contact the office is to send email to ibc@umn.edu. If you need to contact me directly, my contact information is below:

Gregory Park, PhD
parkx479@umn.edu
Redacted by agreement (mobile)
(home)

Associate Director
Office of Biotechnology Activities Oversight
https://research.umn.edu/units/obao
Office of the Vice President for Research

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Sent: Thursday, April 30, 2020 12:00 PM
To: NIH guidelines
Cc: Chris Cramer; Masato Yamamoto; Frances Lawrenz; Fang Li; Jakub Tolar; Laura Molgaard
Subject: NIH Guidelines-related incident report from U of MN
Attachments: UMN NIH Incident 20200430.pdf

Dear NIH-OSP,
Please find attached a cover letter with an NIH incident report. Do not hesitate to contact me if you have any further questions.
Regards,
Greg Park

--
**Please note, the OBAO is currently working remotely
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Associate Director
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https://research.umn.edu/units/obao
Office of the Vice President for Research

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UNIVERSITY OF MINNESOTA

Office of the Vice President for Research
Institutional Biosafety Committee

420 Delaware ST SE
D192 Mayo MMC 820
Minneapolis, MN 55455

E-mail: ibc@umn.edu
Main line: 612-626-2161
Fax: 612-626-6061 (shared)

April 30, 2020

Attention: Incident Reports
NIH Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20817
Phone: 301-496-9838
Email: NIHGuidelines@od.nih.gov

Dear NIH OSP Representative,

Please find attached an incident report from the University of Minnesota. The Incident Reporting Template has been completed.

The reported incident involved a failure to seek IBC approval for research activities subject to the NIH Guidelines.

If you have any questions about this information, please contact Gregory Park, Assistant Director of the Institutional Biosafety Committee Administration at 612-625-9153.
Thank you.

Sincerely,

Redacted by agreement

Christopher J. Cramer, Ph.D.
Vice President for Research
Institutional Official

c: Lara Molgaard, Interim Dean, College of Veterinary Medicine
Frances Lawrenz, Associate VP for Research
Gregory Park, Assistant Director, Office of Biotechnology Activities Oversight
Jakub Tolar, Dean of Medical School, VP for Clinical Affairs
Masato Yamamoto, Director, Division of Basic and Translational Research

Enc: NIH-OSP Final Incident Report

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Minnesota
Date of Report:	04/30/2020
Reporter name and position:	Christopher J. Cramer, Vice President for Research, Institutional Official
Telephone number:	612-624-5054
Email address:	cramer@umn.edu
Reporter mailing address:	101 Pleasant ST SE 419 Johnston Hall Minneapolis, MN 55455
Date of incident:	03-30-2020
Name of Principal Investigator:	Fang Li
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number: R01AI089728, R01AI110700* *NIH funding institute or center: NIAID* *NIH program officer (name, email address):unknown*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☒NO If yes, date of approval: 3/25/2020 (some was approved)
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☒BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-b, III-D-2-a, III-E
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	genes: SARS-CoV-2 spike, RaTG13 spike, bat ACE2 viral vector: HIV-based viral vector from pNL4-3.LucR-E-

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On 3/30/20, it was noticed that Dr. Fang Li published an article in *Nature* that described research activities subject to the NIH Guidelines that were not approved by the IBC prior to initiation. Dr. Li had approval for work with two recombinant viral vector platforms (vaccinia virus and VSV-pseudotyped HIV) for the recombinant expression of NL63 coronavirus spike (RG2), SARS-CoV spike (RG3), and human ACE2 (SARS-CoV entry receptor), and he had approval for recombinant expression via a baculovirus expression system. However, Dr. Li did not have approval for use of SARS-CoV-2 spike, RaTG13 spike (a bat coronavirus), nor bat ACE2 in his experimentation. In addition, Dr. Li's paper describes his use of a HIV-based pseudovirus system (pNL4-3.LucR-E-) that he also did not have approval for. The lentivirus system disclosed in his IBC application is a 3rd generation system, but the one he reports in his paper is a 1st generation system (full genome with frame shift mutations to make VPR and Env non-functional). The descriptions above are a summary of the recombinant material that was not approved by the IBC before it was used. The following is a description and timeline as a result of the investigation into the non-compliance incident.

In the investigation into the timing of the unapproved research, Dr. Li wrote that the research for the paper began around 1/15/20 and involved two post-doctoral researchers in his BSL2 laboratory using the procedures for a VSV-SARS-CoV pseudovirus that had been approved by the IBC on 4/22/19 requiring BSL2 containment and procedures with enhanced PPE. On 3/10/20, Dr. Li submitted an amendment to his activities to include most of the specifics of the genetic material he used in his *Natur*e paper, and he received approval from the IBC on 3/25/20 for his amended experimentation. On 3/30/20, after the paper was released, the associate director of the IBC administration (AD) sent Dr. Li an email to inform him that he had failed to receive IBC approval before performing experimentation, and Dr. Li requested that the IBC discuss whether the incident was non-compliance at its meeting on 4/20/20.

Prior to the meeting and upon further investigation into the methods described in Dr. Li's Nature paper, it was discovered that Dr. Li was also using a MERS-CoV HIV-based lentivirus that was not disclosed in his IBC application. Additionally, this MERS-CoV HIV-based lentivirus was part of experimentation reported in a paper (published 8/26/14) suggesting experimental use at least prior to the submitted manuscript date of 3/29/14. IBC records at that time show that Dr. Li had IBC approval only for recombinant expression of coronavirus spike proteins from transfection of expression plasmids into insect cells. Thus, it appeared Dr. Li had been performing

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experimentation with a pseudotyped HIV-based lentivirus system for over 6 years without IBC approval.

At the IBC meeting on 4/20/20, the IBC agreed with the initial assessment of the AD and chair, agreed with the submission of the NIH incident report, and the IBC discussed and approved measures to bring Dr. Li back into compliance with the NIH Guidelines as well as the relevant policies of the University of Minnesota. These measures included: (1) Dr. Li must immediately stop all work not covered by his approved IBC application and seek approval; (2) Dr. Li must discuss the incident with the IBC chair; (3) Dr. Li and his staff must have the required training set out by the IBC; and (4) Dr. Li must inform the IBC of a plan for how he will ensure compliance with University policies and the NIH Guidelines related to his research. Depending on the actions of Dr. Li to return to compliance, the IBC also discussed further actions of (1) disciplinary action due to the severity of the violation; and (2) requesting Dr. Li meet with the IBC to discuss non-compliance.

After the IBC meeting, the chair of the IBC discussed with Dr. Li the non-compliance incident. Dr. Li has stated that he halted his pseudovirus studies, and IBC records show he has submitted an amendment for IBC review for use of the relevant viral vector. Overall, the unapproved activities included generation and use of the HIV-based lentivirus pseudotyped with risk group 3 viral proteins and generation of genetically engineered cells lines. These activities are subject to the NIH Guidelines sections III-D-1-b, III-D-2-a, and III-E. As mentioned above, the work with other viral vectors pseudotyped with coronavirus spike proteins have been approved by the IBC in BSL2 containment and practices with enhanced PPE, and this is the expectation for Dr. Li's amendment currently in review.

To finalize the AD's investigation, a former graduate student of Dr. Li responded to questions and indicated that work with the viral vector in question began approximately 11/20/2013. Over the course of the period of non-compliance, work involved two graduate research assistants and two post-doctoral researchers. The former graduate student reported that personnel received biosafety trainings and lab specific safety training for working with the pseudovirus annually. Further, work was reported with descriptions of standard BSL2 containment, PPE, and procedures used, and solid and liquid waste was disposed of via standard university procedures. Finally, information provided by University inspection staff show that the facilities where the work occurred were appropriate and had been inspected at least in 2015 and 2017. During the time period in question, there have been no reported injuries, illnesses, or equipment failures to the IBC from Dr. Li's lab.

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Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Dr. Li did not have IBC approval prior to initiating his experimentation subject to the NIH Guidelines.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Please see above for the measures taken by the University of Minnesota IBC to mitigate the problems identified. The amendment to include the viral vector is currently in review, and the PI will receive comments and requests by 5/6/20. For the PI to continue studies, the Dr. Li must respond to the requests. The requests will include (1) completion of the required training set out by the IBC by the PI and all staff; and (2) Dr. Li must inform the IBC of a plan for how he will ensure compliance with University policies and the NIH Guidelines related to his research.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, June 1, 2020 9:07 AM
To: O'Meara, Helen; NIH guidelines
Cc: Williams, Marshall; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Guideline incident report from the Ohio State University

Dear Helen O'Meara,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: O'Meara, Helen <omeara.15@osu.edu>
Sent: Tuesday, May 19, 2020 7:49 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Williams, Marshall <williams.70@osu.edu>
Subject: NIH Guideline incident report from the Ohio State University

Attached is an incident report from the IBC Chair at The Ohio State University. This involved work that was conducted by an investigator prior to IBC approval.
Please let me know if you have any questions.
Best,
Helen O'Meara



Helen O'Meara, MS, CPIA
Associate Director, IACUC/IBC
Office of Research, Office of Responsible Research Practices
303 Research Administration Building, 1960 Kenny Road, Columbus, OH 43210
614-292-0830 Office

Obtained via FOIA by Judicial Watch Inc.

omeara.15@osu.edu orrp.osu.edu

COVID-19 and Animal Research: Click Here

COVID-19 and Biosafety Reviews: Click Here

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	The Ohio State University
Date of Report:	05/12/2020
Reporter name and position:	Marshall V. Williams, JR., PhD Chair, Institutional Biosafety Committee
Telephone number:	614-293-6175
Email address:	Williams.70@osu.edu
Reporter mailing address:	300 Research Administration 1960 Kenny Rd Columbus, Ohio 43210-1063
Date of incident:	April 2020
Name of Principal Investigator:	Shan-Lu Liu
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐YES ☒NO If yes, date of approval:
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4 BSL2+ will be the containment level once approved
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D1
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Lentiviral pseudotypes bearing the SARS-CoV-2 spike protein were produced and used to develop an assay for the detection of neutralizing antibodies to SARS-CoV-2 in COVID-19 patients.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

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On April 30, information was received by the IBC regarding work that had been conducted to produce a pseudotyped lentivirus containing the gene encoding the SARS CoV-2 S protein. This pseudotyped virus is being used as a surrogate in infection assays for testing neutralizing antibodies in COVID-19 clinical samples. The PI has an approved IBC protocol to conduct similar work with a variety of other viral genes.

The production of pseudotyped lentivirus containing the SARS-CoV-2 spike protein had not yet been approved by the IBC. While the unapproved work was being conducted, appropriate containment procedures were followed and there is no evidence of a potential release or exposure. The PI was notified by the IBC Chair in an email dated 05.01.2020 that the conduct of the work was in violation of the NIH regulations and could not continue until his amendment is approved.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Public pressure to quickly develop and advance methodology to combat the COVID-19 pandemic.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The PI has ceased work relating to the development of this assay until approval is obtained from the IBC. The amendment for adding the SARS-CoV-2 S protein-pseudotyped lentivirus was reviewed by the full committee of the IBC on May 5, 2020 and approved on May 7, 2020.

Communication from the IBC Chair regarding the incident and the need for IBC approval has been sent to Senior Leadership at the University and the Medical Center. The requirement for IBC approval particularly before initiating any studies related to SARS-CoV-2 has been reiterated to leaders and investigators. This information has also been posted on the COVID-19 Research Information site maintained by the Office of Research.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: O'Meara, Helen <omeara.15@osu.edu>
Sent: Wednesday, May 6, 2020 10:49 AM
To: NIH guidelines
Subject: question on the need to report an incident

Good morning
I have reviewed your FAQs on reporting incidents and wonder if we need to report the following violation:
A PI has an IBC protocol for research that falls under NIH Guidelines and has approval to create pseudotyped viruses that carry viral envelopes for several different viruses. The PI submitted an amendment to add SARS-CoV-2 genes but initiated experiments prior to approval for these specific genes.
Trying to clarify whether any violation of the guidelines requires a report or only if considered significant.
Thank you for any information that you can provide regarding the need to submit a report.
Helen O'Meara

THE OHIO STATE UNIVERSITY

Helen O'Meara, MS, CPIA
Associate Director, IACUC/IBC
Office of Research, Office of Responsible Research Practices
303 Research Administration Building, 1960 Kenny Road, Columbus, OH 43210
614-292-0830 Office

omeara.15@osu.edu orrp.osu.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, June 1, 2020 9:05 AM
To: Cavallaro, David; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: University of Connecticut Spill/Exposure Report

Dear David Cavallaro,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Cavallaro, David <david.cavallaro@uconn.edu>
Sent: Thursday, May 21, 2020 5:00 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: University of Connecticut Spill/Exposure Report

Attached is a report of the incident that occurred on 5/20/20. Please let me know if you need any additional information.
Thank you
David

From: Cavallaro, David
Sent: Wednesday, May 20, 2020 5:00 PM
To: NIHGuidelines@od.nih.gov
Subject: University of Connecticut Spill/Exposure Report

To Whom It May Concern
I am writing to notify you of a spill and exposure incident involving recombinant/synthetic nucleic acid research. While cleaning up broken flasks containing recombinant E. coli (DH5a), a male Graduate student noticed a small cut to his thumb. I will file a more complete report after meeting with the Graduate student on 5/21. Please let me know if you have questions.
Thank you

Obtained via FOIA by Judicial Watch Inc.

David J. Cavallaro, MS, CBSP
Biological Health and Safety Manager

Environmental Health and Safety
UConn | Division of Public Safety
3102 HORSEBARN HILL RD, U-4097
STORRS, CT 06269-4097
PHONE: 860-486-3180
CELL: Redacted by agreement
FAX: 860-486-1106
ehs.uconn.edu

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	XYES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Connecticut
Date of Report:	5/20/2020
Reporter name and position:	David J. Cavallaro Biological Health and Safety Manager
Telephone number:	Cell: 860-208-6392
Email address:	David.cavallaro@uconn.edu
Reporter mailing address:	3102 Horsebarn Hill Rd Unit 4097 Storrs CT, 06269
Date of incident:	5/20/2020
Name of Principal Investigator:	Paulo Verardi
Is this an NIH-funded project?	☐YES X NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal X Personnel exposure X Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ X YES ☐NO If yes, date of approval: 04/22/2020
What was the approved biosafety level of the research?	☐ BL1 X BL2 X BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-2 III-D-3
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	**Bacteria:** *E. coli* (DH5α) **Plasmids:** • **psPAX2** (10,703 bp, 2nd generation lentiviral packaging plasmid from Trono lab expressing Gag, Pol, Rev, and Tat; can be used with 2nd and 3rd generation transfer plasmids) • **pMC406** (8033 bp, phCMV1- SARS-CoV-2 Spike Protein modified: GSAS_PP_ΔTM)

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
    - Biosafety level 2 laboratory
- Who was involved in the incident/violation, including others present at the incident location?
    - A male Graduate student
    - Dr. Verardi and a female Graduate student assisted after the incident
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
    - Injury was washed with soap and water for 15 minutes, antiseptic and bandage was applied
- The training received by the individual(s) involved and the date(s) the training was conducted
    - Training and dates for the male Graduate student:
    - Biosafety General Training 01/02/2018
    - Biological Safety in Animal Research 09/26/2018
    - Biological Waste 09/24/2018
    - Bloodborne Pathogens Retraining 11/11/2019
    - Lab Specific Training Checklist 08/27/2018 & 01/08/2019
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
    - General spill clean-up guidance can be found in the Biosafety Manual http://media.ehs.uconn.edu/Biological/BiologicalSafetyManual.pdf
    - Lab specific spill clean-up procedure is attached.
    - There was no deviation from these procedures.
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
    - No deviation from IBC approved containment level or other approval conditions
    - Other IBC approval conditions (enhancements) did not apply to this part of the research project. All work with inactivated RG3 and RG4 materials must occur in the biosafety cabinet.
- The personal protective equipment in use at the time of the incident/violation
    - Lab coat, gloves, goggles

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- The occupational health requirements for laboratory personnel involved in the research
    - No requirements for this research.

- Any medical surveillance provided or recommended after the incident
    - Recommended that the Graduate Student seek medical advice if wound conditions change to include redness or swelling.

- Any injury or illness associated with the incident
    - Small cut injury to left thumb.

- Equipment failures
- Equipment was functioning normally. See root cause description below.

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

Three flasks were placed in an orbital shaking incubator on Tuesday May 19 for an overnight incubation of E. coli cultures transformed with plasmids pxPAX2 and pMC406. It is believed that sometime during the night, while the lab was unoccupied, one flask became loose from its holder and collided with another flask. The contents of both flasks, approximately 600 ml, was released into the incubator with some leaking onto the floor. The male Graduate student entered the lab on Wednesday May 20 and discovered the broken flasks. The culture liquids had dried on the glassware, incubator and floor. Following the attached procedure, he donned the appropriate PPE and began using a dustpan and brush to remove the broken glass from the incubator. At approximately 11:00 a.m. the male Graduate student saw blood on the glove at his left thumb. He removed his gloves, immediately washed the cut with soap and warm water for 15 minutes, cleaned the wound with an alcohol wipe, and bandaged it. Upon reporting the injury to, Dr. Verardi, he was advised to wash the wound again and cover with a new bandage after applying Neosporin.
The Graduate student reported that the cut itself is approximately 1/8th of an inch on the tip of his left thumb. It is not a deep cut, but it did bleed for several minutes after it occurred.
Dr. Verardi, the Graduate student and a female Graduate student worked together to finish the cleanup procedure.

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Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	A new holder was installed in the incubator platform to accommodate a third flask. The new holder included a spare tension spring in its base. The Graduate student did not remove this spring. The presence of this spring likely prevented the flask from contacting the platform giving it the opportunity to come loose over time while shaking.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The PI reviewed the use of the holders and set up of the platform with the Graduate student. The PI reviewed the lab specific spill clean-up procedure with all other lab members (retraining).

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Biological Agent Small Spill Response



1. ACT immediately and warn others in the laboratory.
2. Hang warning sign on door:
3. Wear personal protective equipment (PPE):
   a. Lab coat
   b. DOUBLE gloves
   c. Face / eye protection (safety glasses, goggles, or face shield)
4. Mechanically remove (with tongs, forceps, or a disposable dustpan and broom) any broken glass or other sharps (if present) and place in sharps biomedical waste container.
5. Cover spill with paper towels.
6. Soak paper towels with disinfectant (a 10% solution of bleach or LYSOL® disinfectant spray). Let stand ***at least*** **10 minutes**.
7. Remove these materials with tongs and place in regular (solid) biomedical waste container.
8. Repeat steps 5 to 7 as necessary.
9. Cover area with LYSOL® disinfectant spray. Let stand ***at least*** **10 minutes** to air dry and wipe up with paper towels.
10. Discard all materials as biomedical waste. Disinfect tongs or forceps in a 10% solution of bleach for 30 min. Dispose of dustpan and broom as sharps medical waste.
11. Inspect your clothing and exposed skin for contamination.
12. Remove gloves and wash hands with soap thoroughly.

Redacted by agreement

IMMEDITELY Report Incident To PI (Dr. Verardi)

FOR LARGE SPILLS CALL 911

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Cavallaro, David <david.cavallaro@uconn.edu>
Sent: Thursday, May 21, 2020 5:00 PM
To: NIH guidelines
Subject: University of Connecticut Spill/Exposure Report
Attachments: 052020 Potential Exposure.pdf

Attached is a report of the incident that occurred on 5/20/20. Please let me know if you need any additional information.
Thank you
David

From: Cavallaro, David
Sent: Wednesday, May 20, 2020 5:00 PM
To: NIHGuidelines@od.nih.gov
Subject: University of Connecticut Spill/Exposure Report

To Whom It May Concern
I am writing to notify you of a spill and exposure incident involving recombinant/synthetic nucleic acid research. While cleaning up broken flasks containing recombinant E. coli (DH5a), a male Graduate student noticed a small cut to his thumb. I will file a more complete report after meeting with the Graduate student on 5/21. Please let me know if you have questions.
Thank you

David J. Cavallaro, MS, CBSP
Biological Health and Safety Manager

Environmental Health and Safety
UConn | Division of Public Safety
3102 HORSEBARN HILL RD, U-4097
STORRS, CT 06269-4097
PHONE: 860-486-3180
CELL: Redacted by agreement
FAX: 860-486-1106
ehs.uconn.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Cavallaro, David <david.cavallaro@uconn.edu>
Sent: Wednesday, May 20, 2020 5:00 PM
To: NIH guidelines
Subject: University of Connecticut Spill/Exposure Report

To Whom It May Concern
I am writing to notify you of a spill and exposure incident involving recombinant/synthetic nucleic acid research. While cleaning up broken flasks containing recombinant E. coli (DH5a), a male Graduate student noticed a small cut to his thumb. I will file a more complete report after meeting with the Graduate student on 5/21. Please let me know if you have questions.
Thank you

David J. Cavallaro, MS, CBSP
Biological Health and Safety Manager

Environmental Health and Safety
UConn | Division of Public Safety
3102 HORSEBARN HILL RD, U-4097
STORRS, CT 06269-4097
PHONE: 860-486-3180
CELL: Redacted by agreement
FAX: 860-486-1106
ehs.uconn.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Tuesday, June 30, 2020 3:00 PM
To: Coulson, Garry Brian; NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident Report

Dear Dr. Garry Coulson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, June 8, 2020 12:18 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: NIH Incident Report

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a minor spill involving recombinant DNA that occurred in a BSL-3 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599

Obtained via FOIA by Judicial Watch Inc.

Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of North Carolina at Chapel Hill
Date of Report:	6/08/2020
Reporter name and position:	Garry Coulson, Biosafety Officer
Telephone number:	919.962.5722
Email address:	garry.coulson@ehs.unc.edu
Reporter mailing address:	Environment, Health and Safety 1120 Estes drive Campus Box 1650 Chapel Hill, NC 27599
Date of incident:	6/06/2020
Name of Principal Investigator:	Dr. Ralph Baric
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant number: U19AI100625 / U19AI142759 /* Task order 75N93020F00001 for contract HHSN272201700036I *NIH funding institute or center: NIAID* *NIH program officer (name, email address):Qian Liu / Maureen Beanan / Eric Stemmy and Chelsea Lane*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☒Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO Date approved: 3/5/2020
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☒BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Recombinant infectious clone of SARS-CoV-2 in which orf7 is replaced by the reporter gene NanoLuc luciferase.

Obtained via FOIA by Judicial Watch Inc.

Description of the incident:

At approximately 9:00 am on Saturday, June 06, 2020 the Researcher was performing viral neutralizing assays when the incident occurred. The Researcher was working within a biological safety cabinet (BSC) inside a BSL-3 laboratory. For personal protective equipment (PPE), the Researcher was wearing the required protection for the BSL-3 laboratory, which included scrubs, lab shoes, shoe covers, Tyvek suit, hood, purified air powered respirator (PAPR), apron and 2 pairs of gloves. No other researchers were in the laboratory at the time of the incident.

When the Researcher was loading the multi-channel pipette with tips, the tip box slid on the working surface of the BSC and hit a 96-well neutralization assay plate, possibly due to excess residual 75% ethanol (EtOH) used to surface decon the BSC and tip box when bringing it into the BSC. The neutralization assay plate contained various dilutions of neutralizing mouse serum and the recombinant SARS-CoV-2 NanoLuc virus. The collision created a small spill (< 1ml) inside the BSC and the Researcher also noticed about 5 – 10 drops on his waterproof apron. It is unknown whether the drops came from control wells without virus or experimental wells with virus.

Immediately after the spill, the Researcher sprayed down his gloves and apron with 75% ethanol. Following the procedures for small spills in the BSC, the Researcher used paper towels in the BSC completely saturated with 75% ethanol to cover the spill area and waited for 10 min for aerosols in the BSC to clear. Additionally, while no droplets were observed to have spilled out of the BSC onto the floor, the Researcher also sprayed down the area immediately proximal to the BSC, including the chair and the floor, with 75% EtOH. During the 10-minute wait, the Researcher sprayed down his gloves again and changed into a new pair of outer gloves. Used gloves were disposed of in the biohazard trash. After the wait, the Researcher placed all contaminated materials, including the 96- well plate, the paper towels and the pipette tip box into a decon tray containing disinfectant inside the BSC. The Researcher removed all other materials, including pipette and three other 96-well plates outside of the hood following a surface decon with 75% ethanol. The Researcher then deconned and exited out of the lab as per laboratory SOP and returned to his lab space and informed the PI and EHS via email at 10:17am on 6/6/2020. The Department of Environment, Health, and Safety (EHS) reviewed the email notification Sunday 6/07/2020 at 11:58 am and immediately followed up with the Researcher for a detailed description of the incident and communicated the incident to the Medical Director of the University Employee Occupational Health Clinic (UEOHC).

Given that the spill outside of primary containment was classified by the Researcher as small, and that the Researcher verified that there was no breach in PPE or respiratory protection, the assessed risk for actual personnel exposure by the Researcher was considered low. Consequently, the procedures for a Potential Exposure, as outlined in the BSL-3 Medical

Obtained via FOIA by Judicial Watch Inc.

Surveillance Laboratory Standard Operating Procedures (SOP) were followed. A determination was made that self-quarantine was not medically indicated. The Researcher is required to continuously monitor temperatures and perform symptom monitoring for the next 14 days. Any changes in health, or development of symptoms must be reported to the UEOHC immediately.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC is aware of the incident and will discuss the incident at the next IBC meeting (7/1/2020).
Please describe the root cause of this incident:	The excess EtOH on the stainless steel working surface likely created a slippery interface with the pipette tip box leading to the incident. Additionally, having the 96-well plate cover open during the loading of the pipette tips likely contributed to the incident.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As part of the corrective and preventative actions to be taken, an internal Incident Report will be submitted by the Department of Environment, Health and Safety (EHS) to the Principal Investigator (PI) detailing the incident and including recommendations for the lab to follow to mitigate future reoccurrence of the incident.

The affected Researcher was trained in performing neutralizing assays, was performing all duties according to established laboratory procedures, and was wearing the appropriate PPE for the procedure. As part of the recommendations, the PI will be instructed to discuss this incident with his lab, specifically focusing on procedures for addressing spills inside the BSC and spills outside the BSC. The PI will also discuss the importance of immediately reporting any incidents or exposures in the BSL-3 lab to the Biosafety Officer (BSO)/Associate Biosafety Officer (ABSO) by telephone or emergency pager.

The PI will be required to investigate ways to avoid reoccurrence of the incident through procedural work practice controls. This may include options such as i) limiting the volume of EtOH used to surface decon objects in the BSC, ii) keeping the lid on all plates while loading pipette tips, iii) physically distancing pipettes and plates in the BSC; or iv) using a hand to hold and stabilize the pipette tip box while loading tips onto the pipette with the other hand.

The expected date of completion for recommendations is 6/15/2020.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, June 8, 2020 12:18 PM
To: NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.
Subject: NIH Incident Report
Attachments: NIH Incident Report_06082020_FINAL.pdf

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a minor spill involving recombinant DNA that occurred in a BSL-3 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

Confidentiality Notice:
This email and any transmitted documents contain private, privileged and confidential information belonging to the sender. The information therein is solely for the use of the addressee. If your receipt of this transmission has occurred as the result of an error, please immediately notify us so we can arrange for the return of the documents. In such circumstances, you are advised that you may not disclose copy, distribute, or take any other action in reliance on the information transmitted.

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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Tuesday, June 30, 2020 3:00 PM
To: Coulson, Garry Brian; NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident Report

Dear Dr. Garry Coulson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, June 8, 2020 12:18 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: NIH Incident Report

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a minor spill involving recombinant DNA that occurred in a BSL-3 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

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Phone | 919 962-5722
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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of North Carolina at Chapel Hill
Date of Report:	6/08/2020
Reporter name and position:	Garry Coulson, Biosafety Officer
Telephone number:	919.962.5722
Email address:	garry.coulson@ehs.unc.edu
Reporter mailing address:	Environment, Health and Safety 1120 Estes drive Campus Box 1650 Chapel Hill, NC 27599
Date of incident:	6/06/2020
Name of Principal Investigator:	Dr. Ralph Baric
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant number: U19AI100625 / U19AI142759 /* Task order 75N93020F00001 for contract HHSN272201700036I *NIH funding institute or center: NIAID* *NIH program officer (name, email address):Qian Liu / Maureen Beanan / Eric Stemmy and Chelsea Lane*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☒Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO Date approved: 3/5/2020
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☒BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Recombinant infectious clone of SARS-CoV-2 in which orf7 is replaced by the reporter gene NanoLuc luciferase.

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Description of the incident:

At approximately 9:00 am on Saturday, June 06, 2020 the Researcher was performing viral neutralizing assays when the incident occurred. The Researcher was working within a biological safety cabinet (BSC) inside a BSL-3 laboratory. For personal protective equipment (PPE), the Researcher was wearing the required protection for the BSL-3 laboratory, which included scrubs, lab shoes, shoe covers, Tyvek suit, hood, purified air powered respirator (PAPR), apron and 2 pairs of gloves. No other researchers were in the laboratory at the time of the incident.

When the Researcher was loading the multi-channel pipette with tips, the tip box slid on the working surface of the BSC and hit a 96-well neutralization assay plate, possibly due to excess residual 75% ethanol (EtOH) used to surface decon the BSC and tip box when bringing it into the BSC. The neutralization assay plate contained various dilutions of neutralizing mouse serum and the recombinant SARS-CoV-2 NanoLuc virus. The collision created a small spill (< 1ml) inside the BSC and the Researcher also noticed about 5 – 10 drops on his waterproof apron. It is unknown whether the drops came from control wells without virus or experimental wells with virus.

Immediately after the spill, the Researcher sprayed down his gloves and apron with 75% ethanol. Following the procedures for small spills in the BSC, the Researcher used paper towels in the BSC completely saturated with 75% ethanol to cover the spill area and waited for 10 min for aerosols in the BSC to clear. Additionally, while no droplets were observed to have spilled out of the BSC onto the floor, the Researcher also sprayed down the area immediately proximal to the BSC, including the chair and the floor, with 75% EtOH. During the 10-minute wait, the Researcher sprayed down his gloves again and changed into a new pair of outer gloves. Used gloves were disposed of in the biohazard trash. After the wait, the Researcher placed all contaminated materials, including the 96- well plate, the paper towels and the pipette tip box into a decon tray containing disinfectant inside the BSC. The Researcher removed all other materials, including pipette and three other 96-well plates outside of the hood following a surface decon with 75% ethanol. The Researcher then deconned and exited out of the lab as per laboratory SOP and returned to his lab space and informed the PI and EHS via email at 10:17am on 6/6/2020. The Department of Environment, Health, and Safety (EHS) reviewed the email notification Sunday 6/07/2020 at 11:58 am and immediately followed up with the Researcher for a detailed description of the incident and communicated the incident to the Medical Director of the University Employee Occupational Health Clinic (UEOHC).

Given that the spill outside of primary containment was classified by the Researcher as small, and that the Researcher verified that there was no breach in PPE or respiratory protection, the assessed risk for actual personnel exposure by the Researcher was considered low. Consequently, the procedures for a Potential Exposure, as outlined in the BSL-3 Medical

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Surveillance Laboratory Standard Operating Procedures (SOP) were followed. A determination was made that self-quarantine was not medically indicated. The Researcher is required to continuously monitor temperatures and perform symptom monitoring for the next 14 days. Any changes in health, or development of symptoms must be reported to the UEOHC immediately.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC is aware of the incident and will discuss the incident at the next IBC meeting (7/1/2020).
Please describe the root cause of this incident:	The excess EtOH on the stainless steel working surface likely created a slippery interface with the pipette tip box leading to the incident. Additionally, having the 96-well plate cover open during the loading of the pipette tips likely contributed to the incident.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As part of the corrective and preventative actions to be taken, an internal Incident Report will be submitted by the Department of Environment, Health and Safety (EHS) to the Principal Investigator (PI) detailing the incident and including recommendations for the lab to follow to mitigate future reoccurrence of the incident.

The affected Researcher was trained in performing neutralizing assays, was performing all duties according to established laboratory procedures, and was wearing the appropriate PPE for the procedure. As part of the recommendations, the PI will be instructed to discuss this incident with his lab, specifically focusing on procedures for addressing spills inside the BSC and spills outside the BSC. The PI will also discuss the importance of immediately reporting any incidents or exposures in the BSL-3 lab to the Biosafety Officer (BSO)/Associate Biosafety Officer (ABSO) by telephone or emergency pager.

The PI will be required to investigate ways to avoid reoccurrence of the incident through procedural work practice controls. This may include options such as i) limiting the volume of EtOH used to surface decon objects in the BSC, ii) keeping the lid on all plates while loading pipette tips, iii) physically distancing pipettes and plates in the BSC; or iv) using a hand to hold and stabilize the pipette tip box while loading tips onto the pipette with the other hand.

The expected date of completion for recommendations is 6/15/2020.

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Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, June 8, 2020 12:18 PM
To: NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.
Subject: NIH Incident Report
Attachments: NIH Incident Report_06082020_FINAL.pdf

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a minor spill involving recombinant DNA that occurred in a BSL-3 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, July 29, 2020 2:42 PM
To: Judge,Sharon; NIH guidelines
Cc: Gulig,Paul A; RES-Operations; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report

Dear Dr. Sharon Judge,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Judge,Sharon <sjudge@ehs.ufl.edu>
Sent: Thursday, July 9, 2020 2:49 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Gulig,Paul A <gulig@UFL.EDU>; RES-Operations <operations@research.ufl.edu>
Subject: Incident Report

Dear Dr. Harris,

Attached is an incident report detailing failure of a PI to obtain IBC approval prior to starting work. Please let us know if you have questions or require any additional information.

Thank you,
Sharon

Sharon Judge, PhD, RBP
Biosafety Officer
University of Florida
Division of Environmental Health & Safety
Building 179, 916 Newell Drive
PO Box 112190
Gainesville, FL 32611-2190

Obtained via FOIA by Judicial Watch Inc.

Tel: 352-392-1591
Fax: 352-392-3647
Email: sjudge@ehs.ufl.edu

Obtained via FOIA by Judicial Watch Inc.

UF | UNIVERSITY of FLORIDA

Business Affairs
Division of Environmental Health & Safety
Biological Safety Office

Building 179
PO Box 112190
Gainesville, FL 32611-2190
352-392-1591
352-392-3647 Fax
www.ehs.ufl.edu
bso@ehs.ufl.edu

July 8, 2020

Kathryn Harris, PhD, RBP
Senior Outreach and Education Specialist
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
Phone: 301-496-9838
Fax: 301-496-9839
Email: harriskath@od.nih.gov

Dear Dr. Harris,

We are writing to report an incident at the University of Florida in which a PI failed to obtain IBC approval prior to initiating research that falls under section III-D of the NIH Guidelines. On June 11th, the IBC chair read a news article published on the UF Health website which described research by a group of UF faculty to develop a vaccine for SARS-CoV-2 using a recombinant adeno-associated viral vector. The IBC chair notified the Biosafety Officer as he could not recall that the IBC had reviewed and approved the project. The Biosafety Officer investigated the situation and noted that there were two project registrations currently in progress to cover the work described in the news article. One PI had submitted a project to cover cloning a synthetic gene coding for the SARS-CoV-2 spike protein into an AAV transfer plasmid to be used to package AAV. Purified rAAV would then be provided to the second PI who submitted a project to cover use of the viral vector in animal experiments. Although both project submissions were in-progress, the IBC had not yet approved either of them.

After consultation with the Biosafety Officer, the IBC chair reached out to the PIs on June 12th to determine how much work had already been performed. We determined that the gene encoding the spike protein had been cloned into the plasmid but the virus itself had not been produced. Cloning a gene from a RG2 or RG3 pathogen into a nonpathogenic prokaryote or lower eukaryote falls under Section III-D-2-a of the NIH Guidelines and therefore requires IBC approval prior to initiation. The IBC chair let both PIs know that cloning the SARS-CoV-2 spike protein into a plasmid without IBC approval was in violation of the NIH Guidelines and was reportable to NIH. Both projects were subsequently approved by the IBC on June 24th and UF Research was notified of the incident on June 25th.

UF Research employs a Research Regulatory Analyst who is housed in Environmental Health and Safety and participates in IBC meetings in addition to reviewing IACUC protocols for various safety issues, including use of biohazards and recombinant DNA in animals. IACUC protocols are not approved until all use of biohazards/rDNA in animals is properly registered with the IBC/Biosafety Office so the animal experiments with AAV would not have been able to proceed. *In vitro* work is more difficult to monitor but we had sent an email out to UF PIs in late March reminding them of the requirements for registering research related to COVID-19.

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Furthermore, the IBC webpage describes what types of experiments require IBC review and approval prior to initiation (http://ibc.research.ufl.edu/ibc-procedures/). Considering the current incident, we have requested that UF Research also remind faculty that all work involving recombinant DNA must be registered through the Biosafety Office and reviewed and approved by the IBC if required prior to beginning their experiments.

If you have any questions or would like to discuss this incident further, please don't hesitate to contact us.

Sincerely,

Redacted by agreement

Paul A. Gulig, Ph.D.
University Term Professor
Department of Molecular Genetics and Microbiology
Chair, UF Institutional Biosafety Committee
University of Florida College of Medicine
Box 100266
Gainesville, FL 32610-0266
TEL 352-294-5544
FAX 352-846-3466
gulig@ufl.edu

Redacted by agreement

Sharon Judge, PhD, RBP
Biosafety Officer
University of Florida
Division of Environmental Health & Safety
Building 179, 916 Newell Drive
PO Box 112190
Gainesville, FL 32611
T: 352-392-1591
F: 352-392-3647
E: sjudge@ehs.ufl.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Judge,Sharon <sjudge@ehs.ufl.edu>
Sent: Thursday, July 9, 2020 2:49 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Gulig,Paul A; RES-Operations
Subject: Incident Report
Attachments: Reportable NIH Incident 6-11-20.pdf

Dear Dr. Harris,

Attached is an incident report detailing failure of a PI to obtain IBC approval prior to starting work. Please let us know if you have questions or require any additional information.

Thank you,
Sharon

Sharon Judge, PhD, RBP
Biosafety Officer
University of Florida
Division of Environmental Health & Safety
Building 179, 916 Newell Drive
PO Box 112190
Gainesville, FL 32611-2190
Tel: 352-392-1591
Fax: 352-392-3647
Email: sjudge@ehs.ufl.edu

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

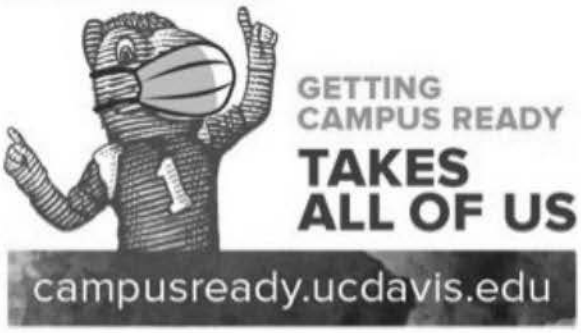
From: Adrienne Elizabeth Zweifel <azweifel@UCDAVIS.EDU>
Sent: Friday, July 24, 2020 4:04 PM
To: NIH guidelines
Cc: Philip Barruel; Jeffrey A Roberts; Gregory Hodge
Subject: Incident of Non-Compliance Report
Attachments: UC Davis_OSP Incident Report (July 2020).docx

To Whom It May Concern,

I am writing you to submit a report of non-compliance involving the unapproved use of a viral vector that occurred at the University of California-Davis campus. Please review the report and contact me if you have any questions.

Thank you,
Adrienne

Adrienne E. Zweifel, PhD, REHS
Pronouns: She/Her/Hers
Associate Biosafety Officer
University of California- Davis
Ph: 530-979-7016
azweifel@ucdavis.edu



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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

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Does this incident involve research subject to the *NIH Guidelines*?	xYES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of California, Davis
Date of Report:	7-13-2020
Reporter name and position:	Adrienne E. Zweifel Associate Biosafety Officer
Telephone number:	530-979-7016
Email address:	azweifel@ucdavis.edu
Reporter mailing address:	276 Hoagland Hall University of California Davis CA 95616
Date of incident:	7/7/2020
Name of Principal Investigator:	Jeffrey Roberts
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☒NO If yes, date of approval: 7/13/2020
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	IIID4
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Use of chimpanzee adenoviral (ChAdV) is a replication deficient viral vector derived from a chimpanzee adenovirus 68 vector (ChAdV68). The adenovirus has the E1 and E3 regions deleted and in the place of E1 is a cassette containing model antigens to enable assessment of antigen-specific immune response. These deletions and insertion prevent the virus from replicating after injection into the animal. Replication competency is tested post vector production.

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	The ChAdV contains an antigen cassette with six known MAMU-A*01 SIV epitopes, the full-length SIV GAG protein, and the SARS-CoV-2 SPIKE protein.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. Include the following information as applicable.

A description of:

- **The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)**

Non-human primate vivarium UC Davis

- **Who was involved in the incident/violation, including others present at the incident location?**

Principal Investigator, Primate Services Support staff

- **Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event**

Recombinant material was added to the BUA and approved by the IBC.

- **The training received by the individual(s) involved and the date(s) the training was conducted**

Dr. Roberts completed NIH Guidelines training on 11/19/2019 and it is valid for 5 years. UC Davis policy states that the NIH Guidelines training is only required for the PI listed on the BUA, not the lab members or the Primate Center Support Staff.

- **The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation**

It is UC Davis policy that the PI of the lab receives approval for work involving any recombinant material before those materials are obtained by the lab. This is done through the process of BUA review and approval by the Institutional Biosafety Committee (IBC).

The Biosafety Office also reviews and approves any Institutional Animal Care and Use protocols involving recombinant material that get submitted in an effort to catch any instances where the lab has not received the appropriate approvals. Animal protocols are flagged for Biosafety Office review during the veterinary review stage of the process. The

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Biosafety Office submits comments on all protocols flagged for its review (materials, procedures, locations, personnel). IACUC will not approve protocols until the BUA is appropriately amended.

The deviation is described below.

- **Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation**

None

- **The personal protective equipment in use at the time of the incident/violation**

All approved PPE for non-human primate ABSL2 work was worn correctly. ABSL2 PPE includes Tyvek sleeves, frock, or coverall, Face shield, face mask, CNPRC uniform, gloves, CNPRC dedicated foot wear.

- **The occupational health requirements for laboratory personnel involved in the research**

All Occupational Health oversight documents had been completed and are up to date for the staff on the project.

- **Any medical surveillance provided or recommended after the incident**

None – this was not an exposure incident

- **Any injury or illness associated with the incident**

None

- **Equipment failures**

None

DESCRIPTION OF INCIDENT: (use additional space as necessary)

The Principal Investigator submitted the Animal Care and Use protocol application for the project. During this time, the lab had a significant change in personnel. The lab administrative responsibilities had shifted from an experience lab manager to primate services staff not familiar with the BU process and the recombinant material for the project was not added to the BUA.

The Animal Care and Use Committee (IACUC) Office also failed to flag this protocol for

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Biosafety review. The submittal of an amendment that got properly flagged brought this issue to the Biosafety Office's attention. As soon as the deficiency was identified, the amendment was submitted and approved by the IBC.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	1) Staffing changes in the project support staff 2) Checks not completed at animal use protocol review

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The internal project review for the non-human primate vivarium and PI for these types of projects has now be shifted to the research operations manager and they have been provided with additional training on when a BUA is required.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, June 22, 2020 1:20 PM
To: Matt Anderson; NIH guidelines
Cc: Mark Riley; Brenda Osthus; Amit Mitra; Dan Hoyt; Institutional Biosafety Committee; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report of Non-Compliance Incident at UNL

Dear Dr. Matthew Anderson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Matt Anderson <manderson11@unl.edu>
Sent: Friday, June 12, 2020 7:35 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Mark Riley <mriley3@unl.edu>; Brenda Osthus <bosthus1@unl.edu>; Amit Mitra <amitra1@unl.edu>; Dan Hoyt <dhoyt2@unl.edu>; Institutional Biosafety Committee <ibc@unl.edu>
Subject: Report of Non-Compliance Incident at UNL

Office of Science Policy,

Please find attached to this email a report of non-compliance with the NIH Guidelines related to work being conducted without approval by the IBC.

Please contact me if further information is required or with questions/comments.

Sincerely,

Matt

Obtained via FOIA by Judicial Watch Inc.

As of Monday, March 23, UNL has instituted remote work for all employees capable of doing so. I will still be reachable via email and the phone number below. I will also be available via Skype for Business using my work email so you can contact me via that means as well.

IN OUR GRIT, OUR GLORY.

Matthew A. Anderson, PhD, RBP(ABSA), CBSP(ABSA)
Biosafety Officer/ARO
University of Nebraska–Lincoln
Environmental Health & Safety
3630 East Campus Loop
Lincoln, NE 68583-0824
manderson11@unl.edu
Tel. 402.472.9554
Fax. 402.472.9650

"Wisdom is not a product of schooling but of the lifelong attempt to acquire it." — Albert Einstein

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Nebraska – Lincoln
Date of Report:	5-20-2020
Reporter name and position:	Matthew Anderson, Biosafety Officer
Telephone number:	402-472-9554
Email address:	manderson11@unl.edu
Reporter mailing address:	3630 East Campus Loop Lincoln, NE 68583-0824
Date of incident:	The BSO became aware of the incident on 5-20-2020. The incident occurred in February 2020.
Name of Principal Investigator:	Scott Johnson
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐YES ☒NO Gene expression in *Pichia pastoris* was approved by the IBC in March 2019. The specific gene expressed was not approved at that time.
What was the approved biosafety level of the research?	☒BL1 ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-E
Has a report of this incident been made to other agencies? If so, please indicate Not reported to any other agencies	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	A proprietary human-derived fusion gene from private company Proprietary Info was cloned into Pichia pastoris for protein expression. The protein is thought to have potential as a disease therapeutic in lupus and other autoimmune diseases.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

The PI is the production manager of the on-campus Bio-Process Development Facility which contracts services to clone and express recombinant proteins for subsequent purification and use by 3rd parties. They are experts in large-scale expression of protein and process development. On May 20th, it was discovered that work had been completed involving expression of a human-derived fusion gene Proprietary Info into *P. pastoris* in February of 2020. The PI did not have this gene listed in the IBC for expression in Pichia prior to starting the work.

The cloning involved protein expression in a volume less than 10L as a pilot study. The work was conducted by lab staff under the direction of the PI. Work with this recombinant material has since paused and the PI has been instructed to not resume work until IBC approval is granted.

A protocol amendment was submitted to the IBC covering work with this gene and was reviewed and approved at the June 8th, 2020 meeting.

Has the IBC reviewed this incident?	☒YES ☐NO Reviewed at the June 8th, 2020 IBC meeting
Please describe the root cause of this incident:	PI had initially thought the gene was included in a previously approved protocol, but he remembered incorrectly.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The BSO discussed at length with the PI the need to submit new projects to the IBC for approval prior to starting the work. The experiments that are covered by the NIH guidelines was also discussed as well as the PIs responsibility to submit updates in a timely manner. The BSO suggested that the PI contact the BSO when new work is in the discussion/negotiation stage so amendments can be submitted and compliance can be assured in the future.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
-
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Matt Anderson <manderson11@unl.edu>
Sent: Friday, June 12, 2020 7:35 PM
To: NIH guidelines
Cc: Mark Riley; Brenda Osthus; Amit Mitra; Dan Hoyt; Institutional Biosafety Committee
Subject: Report of Non-Compliance Incident at UNL
Attachments: Johnson incident report 5-20.docx

Office of Science Policy,

Please find attached to this email a report of non-compliance with the NIH Guidelines related to work being conducted without approval by the IBC.

Please contact me if further information is required or with questions/comments.

Sincerely,

Matt

As of Monday, March 23, UNL has instituted remote work for all employees capable of doing so. I will still be reachable via email and the phone number below. I will also be available via Skype for Business using my work email so you can contact me via that means as well.

IN OUR GRIT, OUR GLORY.

Matthew A. Anderson, PhD, RBP(ABSA), CBSP(ABSA)
Biosafety Officer/ARO
University of Nebraska–Lincoln
Environmental Health & Safety
3630 East Campus Loop
Lincoln, NE 68583-0824
manderson11@unl.edu
Tel. 402.472.9554
Fax. 402.472.9650

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 27, 2020 4:19 PM
To: Kara Drolet; Sarah Byers; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Status of Incident Reports

Dear Dr. Kara Manning Drolet,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kara Drolet <manningk@ohsu.edu>
Sent: Thursday, March 5, 2020 12:29 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; Sarah Byers <byerssa@ohsu.edu>
Subject: RE: Status of Incident Reports

Dear Dr. Harris,
Please find the final report for the third incident referenced below. Let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

From: Kara Drolet
Sent: Monday, March 2, 2020 2:19 PM
To: 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>; Sarah Byers <byerssa@ohsu.edu>
Subject: RE: Status of Incident Reports

Dear Dr. Harris,
Please find attached the final reports for the first two incidents in the list below. For the 3rd incident, we are still gathering some additional information and will provide the final report as soon as we can.
Thank you and please let us know if you have any questions.
Regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Monday, March 2, 2020 12:10 PM
To: Sarah Byers <byerssa@ohsu.edu>
Cc: Kara Drolet <manningk@ohsu.edu>
Subject: Status of Incident Reports

Hi Sara:

Just wanted to follow up on some reports to make sure I didn't miss any incoming final submissions.

I have:

1/17 Vaccinia needlestick
1/13 Leishmania cut from cryovial
1/6 SHIV scalpel cut

Apologies if I missed something.

Regards,

Kathryn

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kara Drolet <manningk@ohsu.edu>
Sent: Thursday, March 5, 2020 12:29 PM
To: Harris, Kathryn (NIH/OD) [C]; Sarah Byers
Subject: RE: Status of Incident Reports
Attachments: OHSU Final Report for 01032020 SHIV scalpel cut.pdf

Dear Dr. Harris,
Please find the final report for the third incident referenced below. Let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

From: Kara Drolet
Sent: Monday, March 2, 2020 2:19 PM
To: 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>; Sarah Byers <byerssa@ohsu.edu>
Subject: RE: Status of Incident Reports

Dear Dr. Harris,
Please find attached the final reports for the first two incidents in the list below. For the 3rd incident, we are still gathering some additional information and will provide the final report as soon as we can.
Thank you and please let us know if you have any questions.
Regards,
Kara

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Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
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:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Monday, March 2, 2020 12:10 PM
To: Sarah Byers <byerssa@ohsu.edu>
Cc: Kara Drolet <manningk@ohsu.edu>
Subject: Status of Incident Reports

Hi Sara:

Just wanted to follow up on some reports to make sure I didn't miss any incoming final submissions.

I have:

1/17 Vaccinia needlestick
1/13 Leishmania cut from cryovial
1/6 SHIV scalpel cut

Apologies if I missed something.

Regards,

Kathryn

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Sarah Byers <byerssa@ohsu.edu>
Sent: Monday, January 6, 2020 8:09 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Kara Drolet
Subject: OHSU initial report of potential exposure 1/3/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 1/3/2020 at Oregon Health & Science University. A staff member cut their finger on a scalpel while processing tissue from a non-human primate that had been infected with SHIV.

A complete report of the incident and follow up will be provided at a later date.

Sarah

Sarah A. Byers, PhD
IBC Program Manager
Research Integrity Office (ORIO)
Oregon Health & Science University
503-494-9763
byerssa@ohsu.edu

Obtained via FOIA by Judicial Watch Inc.

March 5, 2020

Kathryn Harris, Ph.D., RBP
Senior Outreach and Education Specialist
NIH OSP

Institutional Biosafety Committee
Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
ibc@ohsu.edu

Kara M. Drolet, Ph.D.
Associate Vice President
Research Integrity
tel 503 494-6727
manningk@ohsu.edu

Ashlee Moses, Ph.D.
IBC Chair
tel 503 418-2712
mosesa@ohsu.edu

Harjinder Sardar, Ph.D.
OHSU Biosafety Officer
tel 503-346-5028
sardar@ohsu.edu

Sarah Byers, Ph.D.
IBC Program Manager
tel 503 494-9763
byerssa@ohsu.edu

Dear Dr. Harris,

This letter serves as the detailed summary of follow up for a reportable incident that occurred at Oregon Health & Science University (OHSU) that was initially reported to NIH on 1/6/2020.

Date of Incident	1/3/2020
OHSU IBC registration number	IBC-11-15
OHSU project title	Novel approaches to overcome retrovirus diversity for vaccine development
Nature of the material	SHIV SF162P3, which is the SIVmac239 backbone with the HIV-1 Env SF162 grafted on
Risk Group	III
Containment level	BSL-2+
Nature of the incident	Potential Personnel Exposure
PPE in use	Lab coat and double gloves

Description of incident:

The researcher was processing lymph node tissue from a nonhuman primate infected with SHIV and accidently cut their left index finger with the scalpel being used to cut the lymph node. The researcher had received training and had been evaluated for proficiency in following SOPs for processing tissues from non-human primates in the biosafety cabinet.

Actions taken:

The researcher flushed the site with soap and water for 15 minutes and reported to Occupational Health. The physician prescribed Valtrex, Truvada and Isentress as post exposure prophylaxis. The individual's blood was drawn for a baseline. The individual will be monitored and follow up blood draws will be conducted.

The Biosafety Officer visited the laboratory to review the laboratory's SOPs related to processing non-human primate tissues. The Biosafety Officer recommended that the lab purchase a cut resistant glove for the hand that is

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holding the tool used to pin down the tissue sample. The researcher involved in the incident will also be retrained on hand placement and sharps safety will be reviewed at the next lab meeting.

The IBC has determined that this incident has now been resolved with the submission of this report to OSP, pending completion of the above actions. If the individual develops a positive blood test or symptoms related to this exposure the OHSU IBC will notify NIH-OSP.

Sincerely,

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

cc: Debra Brickey, PhD, Research Safety Manager; Dana Director, PhD, OHSU Institutional Official

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 10:48 AM
To: Thome, Nicole L. (Nikki); NIH guidelines
Cc: Biosafety; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Attention: Incident Reports

Dear Nikki Thome,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Thome, Nicole L. (Nikki) <Thome.Nicole@mayo.edu>
Sent: Thursday, January 9, 2020 6:30 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Biosafety <Biosafety@mayo.edu>
Subject: Attention: Incident Reports
Importance: High

Good afternoon,

Attached you will find an Incident Report for the Mayo Clinic – Rochester. If you require additional information, please do not hesitate to contact biosafety@mayo.edu.

Thank you,

Nikki L. Thome
Mayo Clinic
Biosafety Officer
Research Administrative Services
Phone: 507-293-3901 ~ Pager: Redacted by agreement
Fax: 507-538-0051
Email: thome.nicole@mayo.edu

Mayo Clinic

Obtained via FOIA by Judicial Watch Inc.

200 First Street SW
Rochester, MN 55905
mayoclinic.org
facebook.com/MayoClinic
youtube.com/MayoClinic
twitter.com/MayoClinic

John E. Jasker | IBC Specialist | Research Administrative Services | 507-266-5861 | jasker.john@mayo.edu |
Mayo Clinic | 200 First Street SW | Rochester, MN 55905 | mayoclinic.org | facebook.com/MayoClinic | youtube.com/MayoClinic | twitter.com/MayoClinic |

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Harris, Kathryn (NIH/OD) [C]

From: Thome, Nicole L. (Nikki) <Thome.Nicole@mayo.edu>
Sent: Thursday, January 9, 2020 6:30 PM
To: NIH guidelines
Cc: Biosafety
Subject: Attention: Incident Reports
Attachments: Incident Reporting - Mayo Clinic to NIH OSP (1-9-2020).pdf

Importance: High

Good afternoon,

Attached you will find an Incident Report for the Mayo Clinic – Rochester. If you require additional information, please do not hesitate to contact biosafety@mayo.edu.

Thank you,

Nikki L. Thome
Mayo Clinic
Biosafety Officer
Research Administrative Services
Phone: 507-293-3901 ~ Pager: Redacted by agreement
Fax: 507-538-0051
Email: thome.nicole@mayo.edu

Mayo Clinic
200 First Street SW
Rochester, MN 55905
mayoclinic.org
facebook.com/MayoClinic
youtube.com/MayoClinic
twitter.com/MayoClinic

John E. Jasker | IBC Specialist | Research Administrative Services | 507-266-5861 | jasker.john@mayo.edu |
Mayo Clinic | 200 First Street SW | Rochester, MN 55905 | mayoclinic.org | facebook.com/MayoClinic | youtube.com/MayoClinic | twitter.com/MayoClinic |

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

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This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Mayo Clinic - Rochester
Date of Report:	1/9/2020
Reporter name and position:	Nikki L. Thome Biosafety Officer
Telephone number:	507-293-3901
Email address:	thome.nicole@mayo.edu
Reporter mailing address:	200 First Street SW Rochester MN 55095
Date of incident:	1/7/2020
Name of Principal Investigator:	Marion Curtis, Ph.D.
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: Bios00000498.01 Initial Approval of Biosafety Application on: 8/20/219 Application to review new transduced cell lines to occur on 1/21/2020
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☒BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section II-A. Risk Assessment Section III-D-1-b (rDNA in RG3 agent) Section III-D-3-b (Use of RG3 agents in TC) Appendix B-III-D. Risk Group 3 (RG3) - Viruses and Prions
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	ID8 cell line transduced with replication incompetent lentiviral vectors (pLX304) expressing CT45A

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On January 7th, a member of the Curtis Laboratory reported that they had used an ID8 cell line that had been transduced with a replication incompetent lentiviral vector (pLX304) expressing the CT45A5 gene without obtaining prior approval from the IBC. The laboratory did have IBC approval to use other cell lines transduced with lentiviral vectors, but did not amend their most current protocol to include the new cell line and vector combination. For the other approved cell lines, animals were allowed to be moved to a downgraded containment facility since those cells had been externally tested for RCL and proved to be free of replicating virus. Animals exposed to this cell line and vector combination were housed under standard animal housing conditions instead of in an ABSL2+ containment cubicle even though they had not been independently tested for RCL.

The PI noted that he had thought that their past IBC approvals had covered the viral work and that this new project was a pilot project that they were working through for a grant deadline. Since their other animals were able to be downgraded, they followed the same housing procedure for animals containing this new cell line. Moreover, at their previous institution, they PI handled these cells and animals at BSL1/ABSL1 and this previous experience colored her assessment of risk and procedures at her new institution. Through an investigation, it was determined that the unapproved work had begun at the end of October 2019. The PI has halted ongoing work with the virus until the IBC has the ability to review the new experiment. The IBC will review the new experiment at the upcoming IBC meeting on January 21st, 2020 after which this work could resume with the virus/cell line combination provided they do obtain IBC approval.

The laboratory has the proper facilities and procedures to handle work with the virus and it was confirmed that they were handling the virus as recommended by the IBC (in an approved BSL2/2+ tissue culture room, wearing laboratory coat and gloves, handling the virus inside of a BSC until the virus/samples were properly chemically inactivated). Animal housing was not accurate for this type of experimentation since they did not have documentation of testing for RCL. The PI is going to work to obtain this testing. In the interim, animals will be housed at ABSL2+. The laboratory will be retrained regarding animal housing procedures on January 13th, 2020.

Obtained via FOIA by Judicial Watch Inc.

After an evaluation of the incident and due to the biological agent of concern, it was determined that staff was not at risk due to the downgraded housing practices. No illness has been associated with the event.

The laboratory was audited by the Biosafety Office annually, most recently on in June of 2019. No outstanding issues were found during the audit. The laboratory will be re-audited during the week of January 13th by the IBC Specialist.

Workers have taken the appropriate Bloodborne Pathogen training and the PI has taken and passed the Investigator Responsibility training associated with working under the NIH Guidelines.

Given the nature of the report, there were no medical surveillance provided or recommended after the incident and no equipment failures.

Has the IBC reviewed this incident?	☐YES ☒NO Incident and application will be jointly reviewed at the upcoming IBC meeting on January 21st, 2020.
Please describe the root cause of this incident:	The PI/laboratory did not confirm that they had obtained prior approval for working with lentivirus prior to experimental onset.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

1. The laboratory will stop using the unapproved cell line/lentivirus combination until they are appropriately registered and approved by the IBC (date of completion est. January 21st, 2020)
2. The Biosafety Office will audit the laboratory during the week of January 13th, 2020.
3. The Biosafety Office will retrain the laboratory regarding
    a. The need for prior registration of projects falling under the *NIH Guidelines*
    b. How to access applications to determine which organisms have approval for use prior to the onset of an experiment
    c. General safety retraining regarding the use of lentivirus and other viruses covered under the *NIH Guidelines*.
4. The Biosafety Officer will communicate the need for registration of organisms/material falling under IBC purview prior to the onset of experimentation

Obtained via FOIA by Judicial Watch Inc.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 10:41 AM
To: O'Shea, Brian J; NIH guidelines
Cc: Spurbeck, Rachel R; ^BCO Institutional Biosafety Committee; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Battelle Notification of Spill of Recombinant Material

Dear Dr. Brian O'Shea,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: O'Shea, Brian J <oshea@battelle.org>
Sent: Friday, January 24, 2020 3:38 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Spurbeck, Rachel R <spurbeck@battelle.org>; ^BCO Institutional Biosafety Committee <IBC@battelle.org>
Subject: RE: Battelle Notification of Spill of Recombinant Material

Hi Kathryn,

Please find the attached incident report for the spill of recombinant Influenza Candidate Vaccine Virus (CVV) at Battelle labs on 1/8/2020.

If you have any questions, please feel free to reach out to Dr Rachel Spurbeck and I at any time.

Sincerely,

Brian J. O'Shea PhD, CBSP, SM(NRCM)
Biological Safety Program Manager
Alternate Responsible Official
Institutional Contact for Dual Use Research
Safety Health and Emergency Response
Office: 614.424.4831 | Mobile: Redacted by agreement
oshea@battelle.org

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Battelle
1425 Plain-City Georgesville Road
West Jefferson, Ohio 43162
http://www.battelle.org

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Hi Brian:

I can consider your email the initial notification so feel free to take your time on the full report.

Thanks,

Kathryn

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We appreciate your help.

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Cc: Spurbeck, Rachel R <spurbeck@battelle.org>; ^BCO Institutional Biosafety Committee <IBC@battelle.org>
Subject: RE: Battelle Notification of Spill of Recombinant Material

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Dear Dr. O'Shea:

Thank you for your email. Under the *NIH Guidelines*, spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. From the description provided it appears the incident is reportable. Although you are not required to use the NIH incident reporting template. It may be helpful to review it to ensure you include the information we typically require in a report.

The template is available at:

https://osp.od.nih.gov/wp-content/uploads/IBC_Self_Assessment_Tool_fillable_form.docx

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The Battelle Institutional Biosafety Committee is inquiring interpretation on reporting requirements for an incident that happened on Monday, January 6th, 2020.

On Monday, a spill occurred in the BSL-3 biocontainment facility involving recombinant influenza virus. On the day in question, research involving recombinant influenza virus waste from the cultivation of Candidate Vaccine Virus (CVV) production in embryonated chicken eggs was found to be leaking from a waste container outside of the biosafety cabinet. Staff involved responded appropriately in accordance with Battelle's established emergency procedures and the issue was resolved quickly without any contamination to staff or PPE the staff were wearing.

The incident was immediately brought to the attention of Battelle's Biological Safety Officer, Biological Safety Committee, and IBC Chair. Yesterday, Battelle's IBC committee met to discuss the incident and decided we should reach out to the OSP to determine if this incident needs to be reported through the incident report process.

Due to the quick actions of those involved, as well as appropriate and intact PPE used for this study, the potential for exposure to staff was deemed to be negligible. Staff involved are not showing signs and symptoms of infection and they continue to be monitored for signs and symptoms by on-site medical staff. Due to these facts, there was no overt exposure to the recombinant organism, but the potential for exposure is still negligible, even though it is highly unlikely. Since Appendix G-II-C-2-q of the NIH Guidelines states that spills or accidents which result in overt or potential

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exposures are immediately reported to the NIH OSP, we are contacting you to ensure that we are following the correct procedures.

Please advise us if you would like a full incident report to be sent to OSP, or if this inquiry is sufficient.

Sincerely,

Brian J. O'Shea PhD, CBSP, SM(NRCM)
Battelle IBC Chair
Office: 614.424.4831 | Mobile: Redacted by agreement
oshea@battelle.org

Rachel R. Spurbeck, PhD
Battelle IBC Co-Chair
Office: 614.424.7838
spurbeck@battelle.org

Battelle
505 King Ave
Columbus, OH 43201
http://www.battelle.org

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Subject: RE: Battelle Notification of Spill of Recombinant Material
Attachments: Incident-Reporting-Flu Spill Jan 08-2020.docx

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Please find the attached incident report for the spill of recombinant Influenza Candidate Vaccine Virus (CVV) at Battelle labs on 1/8/2020.

If you have any questions, please feel free to reach out to Dr Rachel Spurbeck and I at any time.

Sincerely,

Brian J. O'Shea PhD, CBSP, SM(NRCM)
Biological Safety Program Manager
Alternate Responsible Official
Institutional Contact for Dual Use Research
Safety Health and Emergency Response
Office: 614.424.4831 | Mobile: Redacted by agreement
oshea@battelle.org

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Subject: RE: Battelle Notification of Spill of Recombinant Material

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The incident was immediately brought to the attention of Battelle's Biological Safety Officer, Biological Safety Committee, and IBC Chair. Yesterday, Battelle's IBC committee met to discuss the incident and decided we should reach out to the OSP to determine if this incident needs to be reported through the incident report process.

Due to the quick actions of those involved, as well as appropriate and intact PPE used for this study, the potential for exposure to staff was deemed to be negligible. Staff involved are not showing signs and symptoms of infection and they continue to be monitored for signs and symptoms by on-site medical staff. Due to these facts, there was no overt exposure to the recombinant organism, but the potential for exposure is still negligible, even though it is highly unlikely. Since Appendix G-II-C-2-q of the NIH Guidelines states that spills or accidents which result in overt or potential exposures are immediately reported to the NIH OSP, we are contacting you to ensure that we are following the correct procedures.

Please advise us if you would like a full incident report to be sent to OSP, or if this inquiry is sufficient.

Sincerely,

Brian J. O'Shea PhD, CBSP, SM(NRCM)
Battelle IBC Chair
Office: 614.424.4831 | Mobile: Redacted by agreement
oshea@battelle.org

Rachel R. Spurbeck, PhD
Battelle IBC Co-Chair
Office: 614.424.7838
spurbeck@battelle.org

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National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	X YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Battelle Memorial Institute
Date of Report:	1/24/2020
Reporter name and position:	Rachel Spurbeck, PhD; Principal Research Scientist, Co-Chair-IBC Brian O'Shea, PhD, Biological Safety Program Manager, Chair-IBC
Telephone number:	614-424-7838 614-348-3398
Email address:	spurbeck@battelle.org oshea@battelle.org
Reporter mailing address:	505 King Ave Columbus, OH 43201
Date of incident:	1/6/2020
Name of Principal Investigator:	Jieru Wang, PhD
Is this an NIH-funded project?	☐YES X NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure X Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	X YES ☐NO If yes, date of approval: 09/12/2019
What was the approved biosafety level of the research?	☐ BL1 ☐ BL2 ☐BL2+ (describe specific enhancement in report) ☐ BL3 X BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Sections: III-D-1 III-D-2 III-D-3 III-D-7
Has a report of this incident been made to other agencies? If so, please indicate	X CDC X Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	An influenza reverse genetic vector, pCIPol1PstIT is used with each of the six A/PR/8/1934 internal genes inserted and an expression vector pUC57 is used with Surface Antigen gene, HA, and NA genes from A/Gansu/23277/2019 (H7N9) inserted. The polybasic cleavage site of HA has been mutated through deletion and substitution to disrupt this site reducing pathogenicity.

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failure

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

The incident occurred on Monday, January 6, 2020, at approximately 3:50 PM in our enhanced BSL-3 laboratories.

The Enhanced BSL-3 biofacility contains all enhancements required for safe work practices with influenza virus as required by BMBL and NIH Guidelines. Major enhancements include effluent decontamination systems, required shower facility, pass through autoclaves with integrated bioseals. Other enhancements to the BSL-3 facility can be detailed upon request.

Two technician staff members were working in room JM1-166 processing an attenuated strain of influenza A harvested from eggs. This strain of influenza is a candidate vaccine virus constructed on a PR8 backbone and contains a modified HA gene from A/Gansu/23277/2019 (H7N9) and the wild type NA gene from A/Gansu/23277/2019 (H7N9). Specifically, the inserted HA gene had mutations to remove the polybasic cleavage site that is essential for the virus to be highly pathogenic (confirmed through sequencing).

The SOP that described the activities conducted at the time of the incident is *SOP-LP-366, R-4D, Production of Influenza Virus Stock in Compliance with Good Laboratory Practice Regulations.* SOP sections in use at the time of the incident were the following: *Section 2.2.4, Titration of virus with HA assay* and *Section 2.2.5, Harvesting allantoic fluid from infected SPF eggs.* The training course ID for activities covered is *846-EMBRYO*. Both staff members completed this specific training on May 3, 2019.

When harvesting virus from eggs for this project, the allantoic fluid is collected and the remainder of the egg, including the broken eggshells (regarded as a sharps hazard), is considered waste. This waste is placed in a sharps container which is then double-bagged and removed from the Class II BSC (BSCII) to await disposal. Leading up to the incident on January 6, the harvest of egg virus had been completed and the collected virus was transferred to a sterile container. The double-bagged sharps container was moved to a place near the exit in preparation to remove it from the dedicated laboratory room for disposal. During this movement, Technician A noticed a drip coming from the bag. Upon further inspection, a puddle of egg yolk-appearing liquid was observed on the floor. Technician B exited the BSCII, removed all PPE except for respiratory protection (including shoes left in the laboratory near the door), and exited the room. Technician A followed, also removing all PPE except for respiratory protection and leaving shoes near the door.

At the time of this incident both technicians wore the proper PPE which included: facility dedicated scrubs and shoes, safety glasses, back closing impervious gown, nitrile gloves, shoe covers, hair bonnet, and a PAPR with HEPA filter and face piece. In addition, while working in the BSCII, Technician B wore Tyvek sleeves and a second pair of nitrile gloves. Upon exiting the affected laboratory, the staff initiated the Battelle Emergency Notification System which put them in contact with the BBRC Emergency Response Team. We believe the risk of exposure to be negligible as staff were wearing the appropriate PPE, including a PAPR with HEPA filters, and followed the correct procedures for exiting the BSCII and laboratory room. A review of the building automation system data showed that there was no loss of laboratory containment and negative airflow for the laboratory was maintained prior to the incident, during the incident, and during laboratory remediation. Additionally, while the harvested virus is handled as regulated BSAT material, due to the presence of HA and NA genes from HPAI, current data supports this virus as an exempt

Obtained via FOIA by Judicial Watch Inc.

organism. The results from a recent trypsin-dependent plaque assay have shown a 4-log attenuation in infectivity of this candidate vaccine virus in the absence of TPCK-trypsin when compared to the virus in the presence of trypsin.

After both technicians had a conference call in a safe location with the Battelle Emergency Response Team, both technicians were instructed to shower out of the BSL-3 laboratory and report to Battelle Health Services for evaluation (both staff are asymptomatic as of this report). Staff will continue to monitor for fever according to established influenza practices. Both staff members are vaccinated for seasonal influenza. A spill conference was conducted, and activities completed to re-enter the area to perform spill cleanup using bleach and to secure the materials left inside the BSCII. In addition, further decontamination of the laboratory with vaporous hydrogen peroxide was conducted. This incident is undergoing further investigation and current methods are being evaluated to mitigate the likelihood of similar incidents in the future. Any changes in health status of the technicians will be appropriately communicated.

The incident was immediately brought to the attention of Battelle's Biological Safety Officer, IBC, IBC Chair, and the CDC. The IBC committee met on 01/08/2020 to discuss the incident and reached out to the OSP on 01/09/2020 to ensure compliance to the NIH Guidelines.

Training for staff member #1 (female Research Scientist)

Course #	Course Date	Short Description
300-DEVIATE	6/11/2019	DEVIATION REPORT CONTENT AND REFRESHER FOR DOCUMENTATION REQS.
300-GENETRAN	4/24/2019	GENE TRANSFECTION USING LIPOFECTAMINE 3000
300-GOVERNME	10/28/2019	GOVERNMENT PROPERTY OVERVIEW TRAINING
300-INTRODUC	7/3/2019	INTRODUCTION TO QUBIT 4 FLUOROMETER
300-PREPARE	7/9/2019	PREPARATION OF LB AGAR PLATE
300-SMART4	4/15/2019	SMART TRAINING INCLUDES MODULES 1-4
300-TRACKSTS	12/18/2019	TRACKING OF SAMPLES IN THE SAMPLE TRACKING SYS (STS)
300-VIRALRNA	6/13/2019	VIRAL RNA ISOLATION, RT-PCR, DNA GEL ELECTROPHORESIS
700-BSATWS	10/30/2019	PROCEDURES FOR ACCESS AND MANIPULATING BSAT WORKING SAMPLES
700-INSIDER	4/22/2019	INSIDER THREAT AWARENESS TRAINING
700-SASST	4/25/2019	SELECT AGENT SAFETY AND SECURITY TRAINING
800-HUMANECR	4/15/2019	ACKNOWLEDGEMENT OF HUMANE CARE OF ANIMALS STATEMENT
800-PRMTRAIN	4/23/2019	HERPES B PREVENTION TRAINING
800-ZOONOSIS	4/23/2019	ZOONOSIS A TO Z TRAINING FOR TECHNICAL STAFF
846-AUTOTRN	4/22/2019	AUTOCLAVE TRAINING
846-BIOCABIN	4/24/2019	INTRODUCTION TO WORKING IN A CLASS II BIOSAFETY CABINET
846-BIOFACTS	4/17/2019	FACT SHEETS FOR ACTIVELY USED BIO-AGENTS
846-BIOSAFM3	4/22/2019	FSP INITIAL TRAINING

Obtained via FOIA by Judicial Watch Inc.

846-BIOSAFM5	4/25/2019	BIOCONTAINMENT PRINCIPLES & APPS (BSL-3/ANIMAL BIOSAFETY)
846-BL2SPILL	4/24/2019	BSL-2 SPILL RESPONSE
846-BL3SPILL	4/26/2019	BSL-3 SPILL RESPONSE
846-BL3TOUR	4/25/2019	BSL-3 FACILITY ORIENTATION TOUR
846-CELLCULT	5/9/2019	OVERVIEW OF ASEPTIC MAINTENANCE TECHNIQUES FOR CELL CULTURE LINES
846-EMBRYO	5/3/2019	INFLUENZA INOCULATION OF CHICKEN EMBRYO EGGS
846-FACORIEN	4/23/2019	INTRODUCTION TO CA HAZARDS/FACILITY ORIENTATION
846-FACTOUR	4/23/2019	FACILITY INTERSTITIAL SPACES TOUR
846-FSSPREVW	6/11/2019	FSSP ANNUAL REVIEW
846-GENLABSF	4/22/2019	LAB SAFETY ORIENTATION/ALLERGEN TRAINING
846-GLP101QA	4/30/2019	NEW STAFF GLP AND DOCUMENTATION TRAINING
846-GLP101RE	12/18/2019	GLP ANNUAL REFRESHER
846-GLP101RE	7/22/2019	GLP ANNUAL REFRESHER
846-HPAIPOL	7/2/2019	BBRC PERSONNEL QUARANTINE POLICY FOR HPAI
846-HPAISAFE	7/2/2019	HIGHLY PATHOGENIC AVIAN INFLUENZA SAFETY TRAINING
846-HSSAFEOR	4/15/2019	BBRC SAFETY ORIENTATION
846-IDCDC	5/16/2019	IDCDC - RG60 PRE-STUDY MEETING
846-ISO101RE	7/22/2019	ISO ANNUAL REFRESHER
846-ISO101TR	5/1/2019	REVIEW OF ISO 9000 SERIES STANDARDS AND ISO 9001 IN DETAIL
846-JM1FACOR	4/22/2019	JM-1 FACILITY ORIENTATION
846-JM3SPILL	4/23/2019	JM3 SPILL AWARENESS TRAINING
846-MEDICAL	4/23/2019	BOOT CAMP MEDICAL OVERVIEW
846-PAPRTEST	4/23/2019	USE OF PA20 Bullard PAPR and/or 3M PAPR PROTECTION
846-PROPAGAT	6/27/2019	PROPAGATION OF PLASMIDS IN BACTERIA
846-RG60GLP	5/13/2019	RG60 GLP PRE-STUDY MEETING
846-SECADMIN	4/15/2019	SECURITY TRAINING - ADMIN AREAS
846-VERO	5/11/2019	ELECTROPORATION OF VERO CELLS
900-CERTIFY	7/10/2019	CERTIFIED ESCORT TRAINING

Training for staff member #2 (female Research Associate)

Course #	Course Date	Short Description
300-CUSTBSAT	10/30/2019	CUSTODIAN TRAINING (BSAT)
300-CVVPROG	9/3/2019	BBRC CVV PROGRAM TEAM: QC/TECH REVIEW OVERVIEW (SEPT 2019 VERS)
300-DEVIATE	6/11/2019	DEVIATION REPORT CONTENT AND REFRESHER FOR DOCUMENTATION REQS.
300-GENETRAN	4/24/2019	GENE TRANSFECTION USING LIPOFECTAMINE 3000
300-GOVERNME	10/28/2019	GOVERNMENT PROPERTY OVERVIEW TRAINING

Obtained via FOIA by Judicial Watch Inc.

300-INTRODUC	7/3/2019	INTRODUCTION TO QUBIT 4 FLUOROMETER
300-PREPARE	7/9/2019	PREPARATION OF LB AGAR PLATE
300-SMART4	4/18/2019	SMART TRAINING INCLUDES MODULES 1-4
300-SOPLP365	8/23/2019	SOP LP-365 R3D
300-SOPLP366	8/23/2019	SOP LP-366, R-3D
300-VIRALRNA	6/13/2019	VIRAL RNA ISOLATION, RT-PCR, DNA GEL ELECTROPHORESIS
700-BSATWS	10/30/2019	PROCEDURES FOR ACCESS AND MANIPULATING BSAT WORKING SAMPLES
700-INSIDER	4/22/2019	INSIDER THREAT AWARENESS TRAINING
700-SASST	4/25/2019	SELECT AGENT SAFETY AND SECURITY TRAINING
800-HUMANECR	4/18/2019	ACKNOWLEDGEMENT OF HUMANE CARE OF ANIMALS STATEMENT
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846-EMERGBIO	8/2/2019	EMERGENCY TRAINING DRILLS - BIO
846-FACORIEN	4/23/2019	INTRODUCTION TO CA HAZARDS/FACILITY ORIENTATION
846-FACTOUR	4/23/2019	FACILITY INTERSTITIAL SPACES TOUR
846-FSSPREVW	6/14/2019	FSSP ANNUAL REVIEW
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846-IDCDC	5/16/2019	IDCDC - RG60 PRE-STUDY MEETING
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846-PROPAGAT	6/27/2019	PROPAGATION OF PLASMIDS IN BACTERIA
846-RADIOTR	10/8/2019	RADIO TRAINING
846-RG60GLP	5/13/2019	RG60 GLP PRE-STUDY MEETING
846-SECADMIN	4/18/2019	SECURITY TRAINING - ADMIN AREAS
900-CERTIFY	7/10/2019	CERTIFIED ESCORT TRAINING

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	Sharps container was tipped on side inside of the double biohazard bags. Since egg yolk is liquid, this enabled it to seep out of the container and bags onto the floor.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The incident is currently being investigated, and we will update the NIH and CDC if any mitigations are identified to prevent this incident in the future.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: O'Shea, Brian J <oshea@battelle.org>
Sent: Thursday, January 9, 2020 12:11 PM
To: NIH guidelines
Cc: Spurbeck, Rachel R; ^BCO Institutional Biosafety Committee
Subject: Battelle Notification of Spill of Recombinant Material

To Whom it May Concern:

The Battelle Institutional Biosafety Committee is inquiring interpretation on reporting requirements for an incident that happened on Monday, January 6th, 2020.

On Monday, a spill occurred in the BSL-3 biocontainment facility involving recombinant influenza virus. On the day in question, research involving recombinant influenza virus waste from the cultivation of Candidate Vaccine Virus (CVV) production in embryonated chicken eggs was found to be leaking from a waste container outside of the biosafety cabinet. Staff involved responded appropriately in accordance with Battelle's established emergency procedures and the issue was resolved quickly without any contamination to staff or PPE the staff were wearing.

The incident was immediately brought to the attention of Battelle's Biological Safety Officer, Biological Safety Committee, and IBC Chair. Yesterday, Battelle's IBC committee met to discuss the incident and decided we should reach out to the OSP to determine if this incident needs to be reported through the incident report process.

Due to the quick actions of those involved, as well as appropriate and intact PPE used for this study, the potential for exposure to staff was deemed to be negligible. Staff involved are not showing signs and symptoms of infection and they continue to be monitored for signs and symptoms by on-site medical staff. Due to these facts, there was no overt exposure to the recombinant organism, but the potential for exposure is still negligible, even though it is highly unlikely. Since Appendix G-II-C-2-q of the NIH Guidelines states that spills or accidents which result in overt or potential exposures are immediately reported to the NIH OSP, we are contacting you to ensure that we are following the correct procedures.

Please advise us if you would like a full incident report to be sent to OSP, or if this inquiry is sufficient.

Sincerely,

Brian J. O'Shea PhD, CBSP, SM(NRCM)
Battelle IBC Chair
Office: 614.424.4831 | Mobile: Redacted by agreement
oshea@battelle.org

Rachel R. Spurbeck, PhD
Battelle IBC Co-Chair
Office: 614.424.7838
spurbeck@battelle.org

Battelle
505 King Ave
Columbus, OH 43201
http://www.battelle.org

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Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 10:50 AM
To: Jensen, Sandra; NIH guidelines
Cc: Nattinger, Ann; Keaton, Jason; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report for Research subject to the NIH Guidelines - Medical College of Wisconsin

Dear Sandra Jensen,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Jensen, Sandra <sjensen@mcw.edu>
Sent: Wednesday, January 29, 2020 9:27 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Nattinger, Ann <anatting@mcw.edu>; Keaton, Jason <jkeaton@mcw.edu>
Subject: Incident Report for Research subject to the NIH Guidelines - Medical College of Wisconsin

Hello,

Attached please find an incident report from the Medical College of Wisconsin.

Respectfully,

Sandy

Sandra L. Jensen, M.S., RLATG, CPIA
IACUC & Research Safety Committee Manager, Office of Research
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226
Phone: (414) 955-8223
Fax: (414) 955-6565
Email: sjensen@mcw.edu

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Jensen, Sandra <sjensen@mcw.edu>
Sent: Wednesday, January 29, 2020 9:27 AM
To: NIH guidelines
Cc: Nattinger, Ann; Keaton, Jason
Subject: Incident Report for Research subject to the NIH Guidelines - Medical College of Wisconsin
Attachments: Medical College of Wisconsin Incident Report - 010820.pdf; PRO 35776 Descartes-11 SOP 1-6-2020 clean signed_Redacted.pdf

Hello,

Attached please find an incident report from the Medical College of Wisconsin.

Respectfully,

Sandy

Sandra L. Jensen, M.S., RLATG, CPIA
IACUC & Research Safety Committee Manager, Office of Research
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226
Phone: (414) 955-8223
Fax: (414) 955-6565
Email: sjensen@mcw.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

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Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Medical College of Wisconsin
Date of Report:	1/24/2020 (initial NIH notification email: 1/9/20)
Reporter name and position:	Ann B Nattinger, MD, MPH Senior Associate Dean for Research
Telephone number:	414-955-8495
Email address:	anatting@mcw.edu
Reporter mailing address:	Medical College of Wisconsin 8701 Watertown Plank Road Milwaukee, WI 53226
Date of incident:	1/8/2020
Name of Principal Investigator:	Binod Dhakal, MD
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 9/17/2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-C-1
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☒Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	CAR T-cells

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of

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the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

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Overview: There were two individuals involved in this incident: a Clinical Nurse, and a Clinical Nurse Specialist. The Clinical Nurse was administering a second (and final) syringe containing 57.5ml of CAR T-cells to a human research participant via a 60ml syringe through a PICC line. More pressure than usual seemed to be needed to empty the syringe. At this time, the plunger seal failed, and a drop of the CAR T-cells fell onto the intact skin on the forearm of the Clinical Nurse, a drop fell on their uniform sleeve, and several drops fell on the floor. The Clinical Nurse Specialist immediately cut away the contaminated uniform sleeve, and the exposed Clinical Nurse washed their forearm for 10min. The CAR T-cells were still able to be delivered to the human research participant. The Clinical Nurse Specialist reported the incident to the Biological Safety Officer. The response to the exposure, and the decontamination of drops of the agent which fell on the floor, were in accordance to the IBC approved SOP. The PI notified the industry study sponsor (who provided all materials used) to inform them of the equipment failure.

Incident location: the incident occurred in a hospital exam room.

Involved Individuals: A Clinical Nurse (exposed) and a Clinical Nurse Specialist.

Immediate Actions Taken: The Clinical Nurse Specialist cut off the exposed sleeve and placed it in a biohazard container, the exposed nurse then washed their forearm for 10 minutes (consistent with the IBC approved SOP), the drops on the floor were absorbed with a towel (which was disposed of as biohazardous waste), and the contaminated surface was disinfected with an IBC and EPA approved quaternary ammonia disinfectant.

Training received by the individuals involved:

a. Clinical Nurse Administering the Agent:
    - OSHA BBP Training
        - Date: 11/11/19
        - Exp. Date: 11/11/20
    - rDNA Training for HGT Clinical Trials Training
        - Date: 1/5/20
        - Expiration Date: 1/5/23
b. Clinical Nurse Specialist:
    - OSHA BBP Training
        - Date: 12/31/19
        - Exp. Date: 12/31/20
    - rDNA Training for HGT Clinical Trials Training
        - Date: 11/1/18
        - Exp. Date: 11/1/21

Related SOP's: Please see the related SOP attached to the email containing this document.

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Deviations from SOP at time of exposure: There were no deviations from the IBC approved SOP.

Personal Protective Equipment used at time of incident: Disposable nitrile gloves and scrubs.

Occupational Health Requirements for personnel involved in the incident: There were no occupational health requirements as a result of this exposure to the intact skin on the forearm of the nurse.

Medical advice/treatment/surveillance provided or recommended after the incident: None was deemed necessary because only intact skin on the Clinical Nurse came into contact with the agent.

Any injury or illness associated with the incident: There was no injury or illness as a result of this incident.

Medical surveillance results: Medical surveillance was not necessary

Equipment failures: The cause of this exposure was from syringe plunger seal failure.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	The only identifiable root cause was a failure of the syringe plunger seal.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

We may never know exactly why the syringe plunger seal failed. The type of equipment used during this procedure has been extensively used for similar procedures without any incident. However, the following changes in administration procedure described in the following two paragraphs have been implemented. The goal is to reduce the likelihood of a reoccurrence of syringe plunger seal failure.

The PI contacted the study sponsor to try to identify a way to prevent future incidents. It was determined that a possible cause of the failure could have been due to delivering 57.5ml of study agent via a 60ml syringe. In the future, the use of four 60ml syringes will be used to deliver the agent; instead of two 60ml syringes containing 57.5ml, there will be four 60ml

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syringes containing ~28.8ml. This will reduce the likelihood of a reoccurrence if the failure was associated with utilizing the near-full capacity of the syringe.

A peripheral IV will be added in addition to the PICC line. If there are any perceived issues during administration, the Clinical Nurse will switch to this second line. This will reduce the likelihood of a reoccurrence if the failure was associated with the connection between the syringe and the PICC line used for administration.

Lastly, the clinical nursing staff have added the use of a disposable gown to administration procedures.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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SOP Title: Biosafety SOP **Protocol:** Phase I safety study of Descartes-11 in patients with relapsed/refractory multiple myeloma	
Effective Date: 08/10/2019	**Revision Date:** 01/06/2020
Author(s): [redacted]	**Approved By:** [redacted]

1. GENERAL INFORMATION REGARDING: Descartes-11

1.1 Product Name: Descartes-11

1.2 Product Description: Descartes-11 is an autologous CD8+ T-cell product modified to express a humanized anti-BCMA CAR.

1.3 Packaging of product: Use closed, break-proof containers when transporting infusion bags within the facility. The products should not be removed from the -70°C to -90°C freezer until thawing for infusion. Descartes-11 should only be thawed on the day of infusion and immediately after thaw, it should be diluted with the Thawing Solution as detailed below. If the bag or vials should be transferred from the -70° C to -90°C freezer to drug preparation area (usually a pharmacy or GMP cell therapy laboratory) then they should be kept on dry ice (or any validated method that will keep the temperature below -70oC) to avoid thawing during transfer.

2. RISK INFORMATION

2.1 Routes of Exposure: Possible routes of inadvertent exposure to Descartes-11 product includes contact to skin or eyes and/or accidental needle stick.

2.2 Pre-exposure Requirements: There are no pre-exposure vaccinations or tests recommended specifically for staff involved with handling Descartes-11.

2.3 Possible Effects of Exposure: Descartes-11 product infusion: tachycardia, hypotension and hypoxia

2.4 Staff Restrictions: Staff supporting this protocol are protected by adhering to the hospital's exposure control plan.

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3. STORAGE AND HANDLING OF DESCARTES-11

ACTIVITY	ROOM NAME(S)/NUMBER(S)
Study Agent Receipt	Froedtert hospital cell processing
Study Agent Storage	Froedtert hospital cell processing room 316
Study Agent Preparation	8th floor CFAC or Cancer Center Day Hospital, delivered thawed, will be thawed in the CPL.
Study Agent Administration to Subjects	8th floor CFAC, administration rooms 1-32 Cancer Center Day Hospital rooms B10-B14
Bio Hazardous Waste Storage (Full Containers)	8th floor CFAC soiled utility room, rooms H8234 & H8323 and Cancer Center Biohazard Storage Room C3175

3.1 Personal Protective Equipment (PPE): The following PPE must be used when handling Descartes-11 and any contaminated biohazardous material:

3.1.1 Preparation: At the room, wear gloves

3.1.2 Administration: wear gloves. Hands will be washed with soap and water immediately after removing gloves.

3.1.3 Spill Clean-up: Environmental Services will be contacted and responsible for any spill larger than a quarter (25 cent piece) that occurs. For any spill smaller than a quarter (25 cent piece) use a purple top wipe to clean the spill and allow for 2 minutes of wet contact.

3.2 Receipt: Transport to the clinical site occurs in a liquid nitrogen (LN2)-filled DEWAR shipper that is delivered to the stem cell banking area (CPL). The Descartes-11 product remains frozen until infusion into the subject.

3.3 Storage: The product is frozen and stored in vapor phase liquid nitrogen (LN_2) and will be stored frozen in the cell processing facility room 316.

3.4 Preparation: The product will be thawed using a heat block (heated to 45°C ± 3°C) by a member of the CPL, mixed with Plasma-Lyte A using the ViaLok MV Vented Vial Access Device, transferred to the Thawing Solution bag and incubated at room temperature for 10 minutes, then delivered to the subject's bedside in CFAC 8th floor rooms 1-32 or Cancer Center Day Hospital.

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3.5 Study Agent Transportation

3.5.1 Internal Transport: The Descartes-11 product will be transported from the FH CPL (room number 316) to the patient's room on CFAC 8th floor or Cancer Center Day Hospital by FH CPL Technicians with a sealable biohazardous bag containing absorbent pads and packaged in leak proof, puncture proof, latched, plastic hard-sided cooler. The study agent will be hand delivered from the lab by FH CPL staff to the patient's bedside CFAC or Cancer Center Day Hospital staff member.)

3.6 Administration: Descartes-11 will be administered to subject in the CFAC 8th floor rooms 1-32 or Cancer Center Day Hospital by nursing staff. A biohazard sign is hung outside the patient's room during administration. A central or peripheral IV will be used for the administration of the Descartes-11. A biohazardous bin is present in the room for disposal of all associated study agent equipment (i.e. IV leur locking tubing and product administration bag) and PPE.

4. DECONTAMINATION

4.1 Administration Room: All surfaces will be cleaned with quaternary ammonia ('purple top wipe") and allowed to sit for 2 minutes.

4.2 Soiled Utility Rooms: Located in CFAC 8th floor, rooms H8234 & H8323 is where all solid waste is stored until removal by Stericycle. In the Cancer Center Day Hospital, waste is placed in room C3175 and stored until removal by Stericycle.

4.3 Cell Processing Lab: Located in room 316, Froedtert Hospital; Cell process lab, decontamination is performed using 10% bleach for 30 minutes exposure time.

5. BIOHAZARD SIGNS

5.1 Required Information: The FH standard including the following: universal biohazard symbol, biosafety level, same and contact information for the PI, and PPE required for room entry will be used.

5.2 Posting: When the study agent is in storage, a biohazard sign must be posted on the freezer. Prior to study agent preparation and administration, a biohazard sign will be posted at the entry of the patient room in the CFAC or Cancer Center Day Hospital. After administration of the ax-cell product, the biohazard sign will be taken down.

6. BIOHAZARD WASTE DISPOSAL

6.1 All material having potentially come in to contact with Descartes-11 will be handled as biohazardous waste.

6.2 Disposal of Used and Thawed Product Bags: Disposed of thawed products in biohazard bag in room and taken to soiled utility room H8234, H8323 or C3175.

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6.3 Disposal of Remaining Study Agent on Site after the Completion of Dosing of the Final Subject Enrolled in the Study:

- Cell processing lab: any unused agent will be autoclaved
- CFAC: any unused agent will be disposed of in a biohazard bag and transported to the soiled utility room H8234 & H8323
- Cancer Center Day Hospital: any unused agent will be disposed of in a biohazard bag and transported to the Biohazard Storage Room C3175.

6.4 Waste Bins: Biohazard bins will be located in each CFAC or Cancer Center Day Hospital room and will be disposed of immediately after the procedure is completed. Clinical nursing staff are responsible for taking the biohazard bin to one of the soiled utility rooms, H8234, H8323, or C3175.

6.5 Waste Storage: CFAC, larger soiled utility room either H8234 or H8323. Cancer Center Day Hospital room C3175.

7. ACCIDENTAL SPILLS or EXPOSURE

7.1 Spill: In the event there is an accidental spill of Descartes-11 at Froedtert Hospital

7.1.1 Stop, notify others, isolate the area, and allow aerosols to settle for 10 minutes.
7.1.2 Place an absorbent pad over the spill
7.1.3 Environmental staff members are contacted to clean up spills. The staff is routinely educated to hospital and department guidelines specific to exposure control and spill management.
7.1.4 Put on appropriate PPE if not already worn: Gown, eyewear, mask with shield, shoe covers and gloves. Remove any broken glass or sharps with a forceps or other applicable tool, and place into a sharps container.
7.1.5 Remove any broken glass or sharps with a forceps or other applicable tool, and place into a sharps container
7.1.6 Complete a terminal clean to decontaminate the area of the spill:
- EVS

7.1.7 Dispose of the contaminated paper towel into a biohazard waste container.
7.1.8 Clean up any remaining disinfectant with another paper towel.
7.1.9 Discard all material, including PPE, into the designated biohazard waste containers in the soiled utility room H8234, H8323 or C3175.
7.2.13 Immediately after completing the clean-up notify the Principal Investigator, the institution's internal occupational health, the pertinent clinical leaders and Froedtert Hospital Office of Clinical Research. The Principal Investigator is required to notify the Sponsor, the IBC and NIH OBA if personnel were "overtly exposed."

7.3 Exposure: In the event that there is an overt accidental exposure to Descartes-11

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7.3.1 Remove and dispose of contaminated PPE or clothing into a designated biohazard waste container.

7.3.2 For Skin Contamination: Wash the affected area immediately with soap and water for 10 minutes.

7.3.3 For Needle Stick Injury: Wash the affected area immediately and thoroughly with soap and water for 10 minutes, and cover with a sterile gauze dressing, which must be discarded into a biohazard waste container when removed.

7.3.4 For Eye Contamination: rinse the affected eye immediately for 15 minutes using an ANSI-compliant eyewash, making sure that the water flow across the affected eye is from the nose to the outer corner of the eye. If only one eye is affected, avoid contaminating the other eye (the affected eye must be below the other eye). Maintain the eyelids open and ask the exposed person to look up, down, and sideways, thus more fully exposing the eyeball to the wash.

7.3.5 Immediately after completing first aid measures notify the institution's Occupational Health Department. Call Public Safety at 955-8299 to report the spill and to request spill cleanup assistance. Call EHS if assistance is needed to clean spill at 955-8007. All exposure incidents shall be handled in compliance with the institution's Bloodborne Pathogen Exposure Control Plan. If exposure occurred contact Occupational Health at 805-6699. If after hours, go to the Froedtert Hospital emergency room.

7.3.6 The Principal Investigator is to be notified, and is required to notify the Sponsor, the IBC and NIH OBA if personnel were "overtly exposed".

8. TRAINING REQUIREMENTS

8.1 General Training: All FH and CHW staff at risk of occupational bloodborne pathogen (BBP exposure participate in OSHA/BBP training and HGT rDNA training. This includes the Principal Investigator. Training is conducted on an annual basis for all staff members via online annual bloodborne pathogen (BBP) safety awareness days or through the Froedtert Learning Center or Children's University.

8.2 Hazardous Material Handling/Shipping: The director of the cell processing lab will ensure all staff are trained on proper handling and transport procedures.

8.3 Protocol Training: Personnel who prepare or administer Descartes-11 must be trained in study agent handling. FH require the PI or designee to provide the specific protocol training to FH staff who support the research project. These personnel will also be trained by specific annual review of this SOP. 8th floor CFAC nurse manager will oversee and document 8th floor CFAC staff training. Outpatient Nurse Manager will oversee and document Day Hospital staff training.

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9. PI RESPONSIBILITIES

As the Principal Investor, [redacted] is familiar with his responsibilities under Section IV-B-7 of the NIH Guidelines.

Redacted by agreement

Principal Investigator Signature **Date** 1/6/20

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Keaton, Jason <jkeaton@mcw.edu>
Sent: Thursday, January 9, 2020 5:44 PM
To: Harris, Kathryn (NIH/OD) [C]
Subject: RE: Reporting Requirement for CAR-T cells

Hi Kathryn,

Thank you for your quick response.

I have two more individuals to speak with as a part of my investigation and then I will submit a report to OSP for your review.

Best regards,

Jason

Jason M Keaton, MS, RBP, CBSP, CSP
Director of Environmental Health & Safety
Medical College of Wisconsin
8701 Watertown Plank Road, Milwaukee, WI 53226
P: (414) 955-8060 | **C**: Redacted by agreement

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Thursday, January 9, 2020 1:43 PM
To: Keaton, Jason <jkeaton@mcw.edu>
Subject: RE: Reporting Requirement for CAR-T cells

ATTENTION: This email originated from a sender outside of MCW. Use caution when clicking on links or opening attachments.

Hi Jason:

Yes if the exposure is to recombinant materials.. it would be reportable.

Kathryn

From: Keaton, Jason <jkeaton@mcw.edu>
Sent: Thursday, January 9, 2020 2:36 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Subject: Reporting Requirement for CAR-T cells

Dear Dr. Harris,

I am following up after our phone conversation.

The exposure I spoke with you about was to a CAR-T cell investigational drug product that a clinical nurse had a splash on her arm (seemingly at this time) due to a failure to a syringe plunger gasket.

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I looked closer at the Guidelines after our call and noticed that the reporting requirement indicates exposures to recombinant organisms.

The exact wordage in the NIH Guidelines Appendix G-II-B-2-k states:

- Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Institutional Biosafety Committee and NIH OSP. Reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov). Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Can you please confirm that CAR-T cells have the same reporting requirements as "organisms" as described in the NIH Guidelines?

Thank you in advance for your answer, and I hope you are feeling better soon!

Best regards,

Jason

Jason M Keaton, MS, RBP, CBSP, CSP
Director of Environmental Health & Safety
P: (414) 955-8060 | **C**: Redacted by agreement

See an Unsafe Condition or Behavior?
Report a Close-Call and Prevent an Injury!

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

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Thank you in advance for your answer, and I hope you are feeling better soon!

Best regards,

Jason

Jason M Keaton, MS, RBP, CBSP, CSP
Director of Environmental Health & Safety
P: (414) 955-8060 | **C**: Redacted by agreement

See an Unsafe Condition or Behavior?
Report a Close-Call and Prevent an Injury!

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 11:01 AM
To: Marketon, Melanie; NIH guidelines
Cc: cthorpe@tuftsmedicalcenter.org; Parkison, Valerie; Gipson-Cosier, Heather; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: needlestick involving transduced human cells

Dear Dr. Melanie Taylor,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Tuesday, January 14, 2020 4:33 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: cthorpe@tuftsmedicalcenter.org; Parkison, Valerie <Valerie.Parkison@tufts.edu>; Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>
Subject: RE: needlestick involving transduced human cells

Dear Kathryn,

Please find the attached incident report documents for the needlestick incident described below.

Please let me know if there are any questions.

Best,
Melanie

From: Marketon, Melanie
Sent: Monday, January 13, 2020 8:14 AM

Obtained via FOIA by Judicial Watch Inc.

To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: RE: needlestick involving transduced human cells

Dear Kathryn,

Thanks for the quick response. We will prepare an official report to submit. As a preliminary notification, the individual was stuck with a needle that was being used to aspirate culture medium. The cell line is human induced neural stem cell line (hiNSC) that was previously published (https://www.ncbi.nlm.nih.gov/pubmed/27569063). There should be no lentivirus vector in the culture medium, since it was a self-inactivating vector and the cell line was made several years ago. The BBP status of the parental cell line appears to be unknown. The details of the incident will be reported to the IBC at our monthly meeting on Jan. 30.

Best,
Melanie

From: NIH guidelines <NIHguidelines@od.nih.gov>
Sent: Saturday, January 11, 2020 3:50 AM
To: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Subject: RE: needlestick involving transduced human cells

Dear Melanie:

Yes this would be reportable.

Regards,

Kathryn

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Friday, January 10, 2020 9:34 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: needlestick involving transduced human cells

Hello,

I wanted to inquire about the reporting requirements for a needlestick that has occurred. The incident happened while working with a cell line that was created (several years ago) using a self-inactivating lentivirus. There are no viral particles involved now, but since the cell line carries the LTRs from HIV the cell line would not meet the Appendix C-I exemption and instead would fall under section III-E. Is this an exposure incident that needs to be reported to OSP?

Thanks
Melanie

Melanie M. Marketon, PhD
Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621

Obtained via FOIA by Judicial Watch Inc.

Boston, MA 02111
Boston office (617) 636-0969
cell Redacted by agreement

Office of the Vice Provost for Research
BIOSAFETY OFFICE
BIO SMART SAFE

http://viceprovost.tufts.edu/biosafety/

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

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Sent: Tuesday, January 14, 2020 4:33 PM
To: NIH guidelines
Cc: cthorpe@tuftsmedicalcenter.org; Parkison, Valerie; Gipson-Cosier, Heather
Subject: RE: needlestick involving transduced human cells
Attachments: 1204219 NIH Incident Report_Final.docx; Preda_Biosafety Incident Report_Final.docx

Dear Kathryn,

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Please let me know if there are any questions.

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Kathryn

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Melanie M. Marketon, PhD
Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621
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Office of the Vice Provost for Research
BIOSAFETY OFFICE
BI SMART SAFE

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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Tufts University
Date of Report:	1/14/2020
Reporter name and position:	Melanie Marketon, Biosafety Manager
Telephone number:	617-636-0969
Email address:	Melanie.marketon@tufts.edu
Reporter mailing address:	75 Kneeland St. Room 621 Boston, MA 02111
Date of incident:	12/4/2019
Name of Principal Investigator:	Rucsanda Preda
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 10/26/2017
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-E
Has a report of this incident been made to other agencies? If so, please indicate	No other agencies have been notified. ☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	A recombinant human inducible neural stem cell line generated in 2013, using a self-inactivating lentiviral vector to deliver the reprogramming factors (https://www.ncbi.nlm.nih.gov/pubmed/27569063)

Please provide a narrative of the incident including a timeline of events. The incident should be

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described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

See attached incident report.

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Has the IBC reviewed this incident?	☐YES ☒NO It will be reviewed at the next monthly IBC meeting
Please describe the root cause of this incident:	Re-capping of spent needle prior to disposal in a sharps container. (see attached report)

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

See attached incident report.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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Incident Report

Brief Description of Incident:

A postdoc, new to the lab, used a Luer-lock syringe and sterile needle to remove culture media from human inducible neural stem cells (hiNSC-DLK#5) grown on silk scaffold in culture. The postdoc pricked the pointer finger of their right hand when attempting to re-cap the needle prior to discard into a sharps container.

Notification Process & Description of Events:

Date of Incident: Wednesday December 4th 2019, late afternoon.

The post-doc notified their lab manager of the needlestick incident on Friday December 6th around 9 AM. The lab manager immediately telephoned Dr. Marketon, the Biosafety Office Manager, who spoke with the post-doc and lab manager, and advised them to telephone Mt. Auburn Occupational Health for a medical consult. Dr. Marketon emailed Dr. Augood, the BSO for the Medford campus, and Risk Management, and Dr. Augood met with the lab manager and postdoc later that morning.

The postdoc attempted to re-cap a 23G BD needle that was used to remove culture media from small clusters of recombinant hiNSC-DLK#5 cells on a silk scaffold, when their hand slipped, and pierced the glove of their right index finger. The postdoc removed the glove, forced bled the injury and washed the injured area with soap and water. A band-aid was not applied as minimal bleeding was observed, so the postdoc considered the injury to be superficial. The postdoc then exited the lab and did not return to lab work until the following day; they did not seek a medical consult or report the incident until 12/6/19.

The postdoc is new to the lab and is not currently listed on an IBC registration, but has completed Biosafety Level 2 training and in-person BBP training (EHS) in September 2019.

Safety precautions in place during the experiment:

- The postdoc had completed all appropriate safety trainings including BBP training,
- Appropriate PPE including disposable gloves were worn when handling the biologics and syringe and needle,
- The post-doc was working within a certified Biosafety cabinet

Root Cause of Incident:

Re-capping of spent needle prior to disposal in a sharps container.

Summary of incident response:

The postdoc ceased work and force bled the injured site immediately prior to washing the site with soap and water. No medical consult was sought. On 12/06/19 Mt. Auburn Occupational Health was telephoned and told by the post-doc that the cell line was negative for BBPs. The injury was not visible

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on 12/6, and no redness, swelling or discomfort of the area was noted by the postdoc. Later, outside needlestick-specific medical expertise was sought given the fact that investigation of the cell line revealed that the parental cells had unknown BBP status (see below).

Risk Assessment and Potential for Infection:

The needlestick incident occurred in a BSL-2 lab. The needle had been used to aspirate media from a recombinant human clonal inducible neural stem cell line generated in the lab in 2013, now termed hiNSC-DLK#5 (https://www.ncbi.nlm.nih.gov/pubmed/27569063). Clonal cell line hiNSC-DLK#5 was generated from human newborn foreskin fibroblasts. The fibroblasts were reprogrammed using the factors OCT4, KLF4, SOX2, and cMYC (proto-oncogene) in a polycistronic lentivirus vector (OKSIM - Addgene #24603). This clonal cell line was described as cell line hiNSC#5 in Cairns et al 2016 (https://www.ncbi.nlm.nih.gov/pubmed/27569063). The polycistronic vector, OKSIM, was engineered by Ross et al., (2009) and contains a self-inactivating truncated 5'-viral LTR (https://www.liebertpub.com/doi/10.1089/scd.2009.0459).

During the investigation into the nature of the cell culture (how it was made and whether any infectious agents were known to be present), it was determined that the bloodborne pathogen (BBP) status of the source cells is unknown. When this lab originally received the parental newborn foreskin fibroblast cells, they were told verbally that the cells were BBP-free; however, they were not given documentation. During our investigation, the source lab was contacted and they do not have documentation either. Without documentation, the Biosafety Office considers the status of these cells as unknown.

There is a low risk of exposure to pathogenic biologics or infection resulting from this incident, as:

1. The percutaneous injury was sustained from the tip of a needle contaminated with spent culture media from transduced human cells, with a low risk for BBP as sourced from a newborn infant
2. The percutaneous injury to the finger was reported to be superficial
3. Hand washing with soap and water was carried out immediately after the injury
4. Clonal cell line hiNSC-DLK#5 is reported to have a low likelihood of forming teratomas due to low expression of OCT4 (gatekeeper of stem cell pluripotency) (https://www.sciencedirect.com/science/article/pii/S2213671116301412?via%3Dihub)
5. Cellular supernatant from lentivirus-transduced hiNSC-DLK#5 cultures was not able to transduce secondary cultures of neonatal foreskin fibroblasts when tested, consistent with the generation of replication deficient oncogenic lentivirus.

Lessons learned & follow-up observations:

- Importance of assessing training competency prior to work in the lab.
- Add postdoc to IBC registration 2017-MR53 and ensure that they read and understand content.
- Never re-cap needles per Tufts Biosafety Manual and biosafety training.
- If use of a needle is necessary to manipulate human source material, always substitute a blunt needle for a sharp needle and use Universal Precautions.

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- Report all potential biological exposures immediately to lab supervisor and Biosafety Manager.
- Always seek medical consult/attention immediately after a potential exposure to human source material.
- Ensure that personnel are aware of and/or have access to documentation regarding the BBP status of the cell lines they handle. In this instance, the post-doc was under the impression that the BBP status of the hiNCS-DLK#5 had tested negative. Upon investigation, the BBP status was determined to be unknown.
- Ensure that all personnel working with recombinant materials are listed on an IBC registration.

Recommendation:

- The post-doc should review the WHO Good Microbiological Practices training video on working safely with sharps https://www.youtube.com/watch?v=yqX8hhzX7xU&feature=youtu.be. *Training note: only red biowaste sharps containers should be used at Tufts, not yellow sharps containers shown in WHO video.*
- Best practice would be to include all human cell lines, whether they are recombinant or not, on an IBC registration. Doing so would facilitate documentation of the BBP status of the cell lines for future reference.

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Tuesday, January 14, 2020 11:21 AM
To: NIH guidelines
Subject: report of needlestick

Hello,

I am making an initial notification of a needlestick injury that happened yesterday involving recombinant, human leukemia cells. A worker was attempting to inject the cells into a mouse when the mouse moved, causing the worker to be stuck with the loaded needle. We are investigating the incident now and will follow up with a complete report.

Best,
Melanie

Melanie M. Marketon, PhD
Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621
Boston, MA 02111
Boston office (617) 636-0969
cell Redacted by agreement

Office of the Vice Provost for Research
BIOSAFETY OFFICE
BIOSAFE SMART

http://viceprovost.tufts.edu/biosafety/

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Monday, January 13, 2020 8:14 AM
To: NIH guidelines
Subject: RE: needlestick involving transduced human cells

Dear Kathryn,

Thanks for the quick response. We will prepare an official report to submit. As a preliminary notification, the individual was stuck with a needle that was being used to aspirate culture medium. The cell line is human induced neural stem cell line (hiNSC) that was previously published (https://www.ncbi.nlm.nih.gov/pubmed/27569063). There should be no lentivirus vector in the culture medium, since it was a self-inactivating vector and the cell line was made several years ago. The BBP status of the parental cell line appears to be unknown. The details of the incident will be reported to the IBC at our monthly meeting on Jan. 30.

Best,
Melanie

From: NIH guidelines <NIHguidelines@od.nih.gov>
Sent: Saturday, January 11, 2020 3:50 AM
To: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Subject: RE: needlestick involving transduced human cells

Dear Melanie:

Yes this would be reportable.

Regards,

Kathryn

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Friday, January 10, 2020 9:34 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: needlestick involving transduced human cells

Hello,

I wanted to inquire about the reporting requirements for a needlestick that has occurred. The incident happened while working with a cell line that was created (several years ago) using a self-inactivating lentivirus. There are no viral particles involved now, but since the cell line carries the LTRs from HIV the cell line would not meet the Appendix C-I exemption and instead would fall under section III-E. Is this an exposure incident that needs to be reported to OSP?

Thanks
Melanie

Melanie M. Marketon, PhD

Obtained via FOIA by Judicial Watch Inc.

Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621
Boston, MA 02111
Boston office (617) 636-0969
cell Redacted by agreement

Office of the Vice Provost for Research
BIOSAFETY OFFICE
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http://viceprovost.tufts.edu/biosafety/

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Harris, Kathryn (NIH/OD) [C]

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To: NIH guidelines
Subject: needlestick involving transduced human cells

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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 9:13 AM
To: Kara Drolet; Sarah Byers; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Status of Incident Reports

Dear Dr. Kara Manning Drolet,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to these incidents appear appropriate.

No further information about these incidents is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kara Drolet <manningk@ohsu.edu>
Sent: Monday, March 2, 2020 5:19 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; Sarah Byers <byerssa@ohsu.edu>
Subject: RE: Status of Incident Reports

Dear Dr. Harris,
Please find attached the final reports for the first two incidents in the list below. For the 3rd incident, we are still gathering some additional information and will provide the final report as soon as we can.
Thank you and please let us know if you have any questions.
Regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Monday, March 2, 2020 12:10 PM
To: Sarah Byers <byerssa@ohsu.edu>
Cc: Kara Drolet <manningk@ohsu.edu>
Subject: Status of Incident Reports

Hi Sara:

Just wanted to follow up on some reports to make sure I didn't miss any incoming final submissions.

I have:

1/17 Vaccinia needlestick
1/13 Leishmania cut from cryovial
1/6 SHIV scalpel cut

Apologies if I missed something.

Regards,

Kathryn

Obtained via FOIA by Judicial Watch Inc.

March 2, 2020

Kathryn Harris, Ph.D., RBP
Senior Outreach and Education Specialist
NIH OSP

Institutional Biosafety Committee
Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
ibc@ohsu.edu

Kara M. Drolet, Ph.D.
Associate Vice President
Research Integrity
tel 503 494-6727
manningk@ohsu.edu

Ashlee Moses, Ph.D.
IBC Chair
tel 503 418-2712
mosesa@ohsu.edu

Harjinder Sardar, Ph.D.
OHSU Biosafety Officer
tel 503-346-5028
sardar@ohsu.edu

Sarah Byers, Ph.D.
IBC Program Manager
tel 503 494-9763
byerssa@ohsu.edu

Dear Dr. Harris,

This letter serves as the detailed summary of follow up for a reportable incident that occurred at Oregon Health & Science University (OHSU) that was initially reported to NIH on 01/13/2020.

Date of incident	1/10/2020
OHSU IBC registration number	IBC-03-07
OHSU project title	Experimental studies employing Leishmania and African Trypanosomes
Nature of the material	Frozen transgenic *Leishmania mexicana*
Risk Group	II
Containment level	BSL-2
Nature of the incident	Potential Personnel Exposure
PPE in use	Laboratory coat, goggles, and latex gloves

Description of incident:

A cryotube, stored in liquid nitrogen and containing a stabilate of a transgenic strain of *Leishmania mexicana* parasites, exploded when a researcher removed a box containing multiple tubes from liquid nitrogen to remove some other tubes. The cap from the exploding tube struck the right hand of the laboratory worker, tore through the glove, and caused an abrasion.

Actions taken:

The researcher washed their hand with soap and water for 15 minutes, decontaminated it with 70% ethanol, and then reported to Occupational Health. The healthcare provider assessed this as a low risk exposure and the researcher will be monitored over the next few months for symptoms of leishmaniasis.

The researchers have outlined revisions to their work practices for handling cryotubes, including use of forceps to pick up the tubes, and transporting the tubes in a closable plastic box for transport to the biosafety cabinet. The researchers will also start using a facemask instead of goggles and wear thicker gloves. Going forward a different cryotube with an improved seal will be used.

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The IBC has determined that this incident has now been resolved with the submission of this report to OSP, pending completion of the above actions. If the individual develops symptoms related to this exposure, the OHSU IBC will notify NIH-OSP.

Sincerely,

Redacted by agreement

Kara Drolet
2020.03.02
14:02:16 -08'00'

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

cc: Debra Brickey, PhD, Research Safety Manager Dana Director, PhD, OHSU Institutional Official

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kara Drolet <manningk@ohsu.edu>
Sent: Monday, March 2, 2020 5:19 PM
To: Harris, Kathryn (NIH/OD) [C]; Sarah Byers
Subject: RE: Status of Incident Reports
Attachments: OHSU Final Report for 011620202 VV needle stick.pdf; OHSU Final Report for 01102020 Leishmania incident.pdf

Dear Dr. Harris,
Please find attached the final reports for the first two incidents in the list below. For the 3rd incident, we are still gathering some additional information and will provide the final report as soon as we can.
Thank you and please let us know if you have any questions.
Regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Monday, March 2, 2020 12:10 PM
To: Sarah Byers <byerssa@ohsu.edu>
Cc: Kara Drolet <manningk@ohsu.edu>
Subject: Status of Incident Reports

Hi Sara:

Just wanted to follow up on some reports to make sure I didn't miss any incoming final submissions.

I have:

1/17 Vaccinia needlestick
1/13 Leishmania cut from cryovial
1/6 SHIV scalpel cut

Apologies if I missed something.

Regards,

Kathryn

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Sarah Byers <byerssa@ohsu.edu>
Sent: Monday, January 13, 2020 6:34 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Kara Drolet
Subject: OHSU initial report of potential exposure 1/10/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 1/10/2020 at Oregon Health & Science University. The cap of a cryotube containing recombinant *Leishmania mexicana* exploded off the tube, broke through a researcher's glove and their finger.

A complete report of the incident and follow up will be provided at a later date.

Sarah

Sarah A. Byers, PhD
IBC Program Manager
Research Integrity Office (ORIO)
Oregon Health & Science University
503-494-9763
byerssa@ohsu.edu

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 11:03 AM
To: Marketon, Melanie; NIH guidelines
Cc: cthorpe@tuftsmedicalcenter.org; Parkison, Valerie; Taylor, Mali; Gipson-Cosier, Heather
Subject: RE: report of needlestick

Dear Dr. Melanie Marketon,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Wednesday, January 29, 2020 2:40 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: cthorpe@tuftsmedicalcenter.org; Parkison, Valerie <Valerie.Parkison@tufts.edu>; Taylor, Mali <Mali.Taylor@tufts.edu>; Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>
Subject: RE: report of needlestick

Hello,

Please find the attached incident report documents for the needlestick incident described below.

Please let me know if there are any questions.

Best,
Melanie

From: Marketon, Melanie
Sent: Tuesday, January 14, 2020 11:21 AM
To: NIHGuidelines@od.nih.gov
Subject: report of needlestick

Obtained via FOIA by Judicial Watch Inc.

Hello,

I am making an initial notification of a needlestick injury that happened yesterday involving recombinant, human leukemia cells. A worker was attempting to inject the cells into a mouse when the mouse moved, causing the worker to be stuck with the loaded needle. We are investigating the incident now and will follow up with a complete report.

Best,
Melanie

Melanie M. Marketon, PhD
Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621
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Harris, Kathryn (NIH/OD) [C]

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Wednesday, January 29, 2020 2:40 PM
To: NIH guidelines
Cc: cthorpe@tuftsmedicalcenter.org; Parkison, Valerie; Taylor, Mali; Gipson-Cosier, Heather
Subject: RE: report of needlestick
Attachments: Briggs_NIH Incident Report_011320_FINAL.docx; Briggs_Biosafety Incident Report_011320.docx

Hello,

Please find the attached incident report documents for the needlestick incident described below.

Please let me know if there are any questions.

Best,
Melanie

From: Marketon, Melanie
Sent: Tuesday, January 14, 2020 11:21 AM
To: NIHGuidelines@od.nih.gov
Subject: report of needlestick

Hello,

I am making an initial notification of a needlestick injury that happened yesterday involving recombinant, human leukemia cells. A worker was attempting to inject the cells into a mouse when the mouse moved, causing the worker to be stuck with the loaded needle. We are investigating the incident now and will follow up with a complete report.

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Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

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Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Tufts University
Date of Report:	1/29/2020
Reporter name and position:	Melanie Marketon, Biosafety Manager
Telephone number:	617-636-0969
Email address:	Melanie.marketon@tufts.edu
Reporter mailing address:	75 Kneeland St. Room 621 Boston, MA 02111
Date of incident:	01/13/2020
Name of Principal Investigator:	Michael Briggs
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 06/18/18 (Amendment #2 approved 03/29/19)
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-4
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Human leukemia cell line (AML-2) purchased as recombinant cells, expressing a luminescent reporter. The cells had been transduced using a lentiviral vector (third gen, self-inactivating).

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of

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the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

See attached report.

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Has the IBC reviewed this incident?	☒YES ☐NO Reviewed at the January IBC meeting
Please describe the root cause of this incident:	Distraction, due to mouse suddenly flinching

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

See attached report

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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Incident Report

Brief Description of Incident:

An individual (In vivo lead scientist for Aletabio, a biotech company) working as an affiliate with Woodland Pharmaceuticals was injecting a mouse, that was held in a restraint tube, with a recombinant, human cell line expressing a fluorescent reporter. The tail of the mouse made a sudden flinch and the individual suffered a needlestick to their right index finger, post injection.

Notification Process & Description of Events:

Date of Incident: Monday January 13th 2020, ~1:50pm approx.

The individual notified Woodland Pharmaceutical's V.P. of Operations, Nikole Siegmund, of a needlestick incident on Monday January 13th around 1:50 PM. The V.P. immediately telephoned Dr. Tonkiss, the Biosafety Officer. He advised that the individual should seek prompt medical attention at U. Mass Medical. An accident/incident form was e-mailed to Nikole and she was requested to fill it out once the individual returned from U Mass Med. and was instructed to e-mail the completed form to Tufts Risk Management. Dr. Tonkiss met with the V.P. the following morning. The patient was not available in person.

The In vivo lead scientist was working alone in a biosafety cabinet in an animal suite in Building 21 (room 205A). He had restrained a mouse in a restraint tube and performed an intravenous injection of AML2 (human leukemia) cells using a single-use, BD insulin syringe equipped with a 28-gauge Microfine BD needle. These AML2 cells had been purchased as a recombinant cell line having been modified to express a fluorescent marker (note that a 3rd generation self-inactivating lentiviral system had been used to transduce the cells). After injection the tail of the mouse made a sudden flinch and the In vivo lead scientist stuck their right index finger. There was no depression of the plunger.

Safety precautions in place during the experiment:

- Appropriate PPE including disposable gloves, lab coat, face mask, safety glasses, bouffant cap and booties were worn when handling the cell line, syringe and needle
- The In vivo lead scientist was working within a certified Biosafety cabinet
- Investigation revealed that the In vivo lead scientist was specified on an IACUC registration but was **not specified on an IBC registration**
- The In vivo lead scientist had **not completed BSL2 or BBP training**,

Root Cause of Incident:

Animal handling – distraction

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Summary of incident response:

The In vivo lead scientist removed the glove, sprayed the needlestick location with 70% ethanol, forced bled the injury and then washed the injured area with soap and water. He then informed the V. P. of Operations for Woodland Pharmaceuticals and sought immediate medical attention at U. Mass Medical. U. Mass. Medical staff performed a blood draw within a few hours of the needlestick and will perform monthly blood draws for the next 6 months as a precaution.

Risk Assessment and Potential for Infection:

The needlestick incident occurred in an ABSL-2 facility, using a cell line that had been tested to be free of all known blood-borne pathogens

There is a low risk of exposure to pathogenic biologics or infection resulting from this incident:

1. The percutaneous injury was sustained from the tip of a needle contaminated with cells that had been tested to be free of known BBP.
2. The AML2 cell line causes tumor formation in immunocompromised mice but the risk of tumor formation in humans with a competent immune system is low.
3. The lentiviral vector used to transduce the cells was a third-generation self-inactivating virus. The viral vector used for transduction was purchased as a pre-made stock (GeneCopoeia's Lentifect™ Purified Lentiviral Particles) to deliver the luciferase gene.

Lessons learned & follow-up observations:

- Nobody is allowed to work with recombinant materials without first: completing training and being specified on an IBC registration.
- Nobody is allowed to work with human cell lines without first: completing BBP and BSL2 training.

Recommendation:

- Ensure that all personnel working with recombinant materials are listed on an IBC registration
- Ensure that all personnel working with human cell lines have received BSL2 and BBP training
- Ensure that update forms are given proper care and attention so that all project personnel are listed
- Woodland Pharmaceuticals should immediately review their own personnel records and that of all affiliates and ensure that the above conditions are met*

* Note: Immediately after meeting with the BSO on January 14th, the V.P. of Operations for Woodland Pharmaceuticals instructed all Woodland staff and affiliates to complete the current BSL2/BBP training and set a deadline of 1/31/2020 for that to be accomplished. In addition, project personnel were identified that needed to be added to IBC registrations. The V.P. of Operations contacted the IBC Office to have them added, pending completion of training.

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Harris, Kathryn (NIH/OD) [C]

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Tuesday, January 14, 2020 11:21 AM
To: NIH guidelines
Subject: report of needlestick

Hello,

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Best,
Melanie

Melanie M. Marketon, PhD
Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621
Boston, MA 02111
Boston office (617) 636-0969
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http://viceprovost.tufts.edu/biosafety/

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Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 11:10 AM
To: Cook, Susan; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report

Dear Dr. Susan Cook,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and concur that the research was exempt. Thank you for the notification.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Cook, Susan <shcook@wustl.edu>
Sent: Thursday, January 16, 2020 11:35 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Incident report

Attached, please find a report for a potential personnel exposure to a replication-defective AAV vector. Please let me know if you have any questions or need any additional information.

-Susan

Susan Cook, PhD, CBSP
Director, Office of Biological Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: shcook@wustl.edu; Web: ehs.wustl.edu
(pronouns: she/her/hers)

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Cook, Susan <shcook@wustl.edu>
Sent: Thursday, January 16, 2020 11:35 AM
To: NIH guidelines
Subject: Incident report
Attachments: Incident Report WUSTL 200116.pdf

Attached, please find a report for a potential personnel exposure to a replication-defective AAV vector. Please let me know if you have any questions or need any additional information.

-Susan

Susan Cook, PhD, CBSP
Director, Office of Biological Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: shcook@wustl.edu; Web: ehs.wustl.edu
(pronouns: she/her/hers)

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☑YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Washington University in St Louis
Date of Report:	1/16/2020
Reporter name and position:	Susan Cook Director, Office of Biological Safety
Telephone number:	314-747-0309
Email address:	shcook@wustl.edu
Reporter mailing address:	660 S. Euclid Ave CB 8229 St. Louis, MO 63130
Date of incident:	1/14/2020
Name of Principal Investigator:	Dr Jin-Moo Lee
Is this an NIH-funded project?	☑YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* R37NS110699 *NIH funding institute or center:* NINDS *NIH program officer (name, email address):* CHEN, DAOFEN daofen.chen@nih.gov

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☑ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☑ YES ☐ NO If yes, date of approval: October 6th, 2019
What was the approved biosafety level of the research?	☐ BL1 ☑ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-4
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Floxed AAV8-mCherry. Non replicating

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted.
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

At 4.30pm on January 14, 2020, A staff member was finishing up a rodent brain injection of a non-replicating virus (Floxed AAV8-mCherry) when she grazed her left index finger on a glass pipet needle resulting in a superficial skin puncture. There was no blood flow as a result of the wound.

The incident occurred in a biosafety cabinet and the employee was wearing the required PPE for the task. The employee was wearing a surgeon's head cap, face mask, lab coat and double gloves.

The employee's supervisor was present, and the employee washed her hands vigorously with soap and water for 5 minutes as recommended and OHS were informed at this time.

The employee received training in this procedure by her supervisor and other lab members over the past three months. There was no deviation from the approved IACUC procedure. The employee continued her work and reports no ill effects from the incident.

The employee's training records and OHS health and safety questionnaire are up to date and on file. An incident report was reported through the employee self-service system at 9am on 1/15/2020. OHS advised the individual to monitor for signs of infection.

There is no evidence of equipment failure and the incident appears to be the result of a moment of inattention. We are in the process of reviewing the work area to evaluate improvements to staff safety when handling glass pipet needles.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	Personnel inattention

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The PI is reviewing the work space and procedures to identify opportunities for improvement.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 10:58 AM
To: Laurence Cagnon; NIH guidelines
Cc: Jim Gohres; Rachel Longville; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH reportable incident at Scripps Research

Dear Dr. Laurence Cagnon,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Laurence Cagnon <lcagnon@scripps.edu>
Sent: Friday, January 17, 2020 8:30 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Jim Gohres <jgohres@scripps.edu>; Rachel Longville <rachellv@scripps.edu>
Subject: NIH reportable incident at Scripps Research

Dear Office of Science Policy,

Please see the attached documents reporting a BSL-1 spill at Scripps Research, La Jolla campus.

let me know if you need anything else.

Best regards.

Laurence Cagnon, PhD
BSO, BSL-3 manager, ARO
Scripps Research
EH&S
10550 N. Torrey Pines Road
La Jolla, CA, 92037
mail TPC 27

Obtained via FOIA by Judicial Watch Inc.

tel: 858 784 9216
fax: 858 784 8490
e-mail: lcagnon@scripps.edu

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Laurence Cagnon <lcagnon@scripps.edu>
Sent: Friday, January 17, 2020 8:30 PM
To: NIH guidelines
Cc: Jim Gohres; Rachel Longville
Subject: NIH reportable incident at Scripps Research
Attachments: Incident-Reporting-Scripps_12-19-19 incident.docx; Shen09261808.pdf

Dear Office of Science Policy,

Please see the attached documents reporting a BSL-1 spill at Scripps Research, La Jolla campus.

let me know if you need anything else.

Best regards.

Laurence Cagnon, PhD
BSO, BSL-3 manager, ARO
Scripps Research
EH&S
10550 N. Torrey Pines Road
La Jolla, CA, 92037
mail TPC 27

tel: 858 784 9216
fax: 858 784 8490
e-mail: lcagnon@scripps.edu

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
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Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒ YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Scripps Research
Date of Report:	01/16/2020
Reporter name and position:	Laurence Cagnon, PhD, BSO
Telephone number:	1-858-784-9216
Email address:	lcagnon@scripps.edu
Reporter mailing address:	Scripps Research EH&S, mail TPC 27 10550 North Torrey Pines Road, La Jolla, CA, 92037
Date of incident:	12/19/2019
Name of Principal Investigator:	Weijun Shen
Is this an NIH-funded project?	☐YES ☒ NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☒ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒ YES ☐NO If yes, date of approval: **09/26/2018**
What was the approved biosafety level of the research?	☒ BL1 ☐ BL2 ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-2-a
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Coding sequences of a receptor involved in diabetes and a ligand for a receptor for liver disease in a pET expression plasmid (bacterial expression) in BL21 bacteria. In a 5ml culture for miniprep.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- **The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)**

The incident occurred in the non-public staircase (restricted access) connecting the 2nd and 1st floor laboratories on 12/19/2019, at approximately 2:30 pm.

- **Who was involved in the incident/violation, including others present at the incident location?**

Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

A female postdoctoral associate.

No one witnessed the incident.

- **Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event**

The postdoctoral researcher texted a coworker for help as she twisted her ankle and felt like she could not put weight on it to get up by herself. With the coworker's help, they cleaned an ~2ml bacteria spill.

- **The training received by the individual(s) involved and the date(s) the training was conducted**
- The postdoctoral researcher received the following trainings:
  - blood borne pathogen annual training in 2019 (the employee joined in January 2019).

- **The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation**

PPE was worn as described in the IBC registration documents.
The IBC was not aware that 5ml bacterial cultures were transported between floors, so no transport procedure was described in the IBC registration.

- **Any deviation from the IBC approved containment level or other IBC approval**

Obtained via FOIA by Judicial Watch Inc.

conditions at the time of the incident/violation

There was no deviation from the approved protocol.

- **The personal protective equipment in use at the time of the incident/violation**

Lab coat and gloves.
Safety glasses were not necessary as no splash was expected.

- **The occupational health requirements for laboratory personnel involved in the research**

None for this research project

- **Any medical surveillance provided or recommended after the incident**

The postdoctoral researcher decided to wear an ankle brace to help support her ankle and opted not to seek medical attention. Her ankle was swollen for approximately 10 days.

- **Any injury or illness associated with the incident**

A swollen ankle

- **Equipment failures**

N/A

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A postdoctoral researcher was walking 5ml cultures of bacteria from the incubator shaker located on the 2nd floor to her laboratory located on the 1st floor. She was carrying 10 tubes (15ml capped tubes) with 5ml of bacterial cultures in a rack holder. She was holding the rack in front of her and missed one step while going down the stairs. She fell on the landing, twisting her ankle. She texted a coworker for help as she could not get up by herself. One of the caps became loose during the fall, leading to a small spill on the landing (about 2ml, as she had about 3ml left in the tube when she did her miniprep). The coworker helped her back to her lab. They came back with a 10% bleach solution and paper towels to clean up the spill. No one else used the stairs while the spill was present. After cleaning up the spill, the postdoctoral researcher went back to her lab, and proceeded with her minipreps.

Has the IBC reviewed this incident?	☐ YES ☒NO The IBC was notified of the incident, but no details were available for review at the time of the IBC meeting. This incident will be reviewed and discussed at the next IBC meeting.
Please describe the root cause of this incident:	Poor transport technique

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

EH&S met with the postdoctoral researcher and reviewed her procedures and locations of the incident. It was requested she carry the capped tubes inside a sealed container with a handle. This will allow her to carry the tubes without obstructing her vision and will prevent a spill of biological material in case of fall or collision. A neighboring lab is using such containers to transport their biological samples, and these containers were shown to the postdoctoral researcher.
The postdoctoral researcher's lab will purchase the carrying containers similar to the ones described above. These containers will be used by the researcher and all personnel to safely transport biological samples between laboratories. We expect this to be in place by the end of January 2020. We will verify the lab has purchased and is using the transport containers at the end of January.

We will also review proper transport of biological samples with the entire campus.

Obtained via FOIA by Judicial Watch Inc.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, February 21, 2020 10:16 AM
To: Rausch, Tamara (Tammy); NIH guidelines
Cc: Waggoner, Stephen; Gulick, James; Corsmo, Jeremy; Dowdy, Tabitha; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Formal Report for 1/17/2020 Incident at CCHMC

Dear Tamara Rausch,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Friday, February 7, 2020 3:08 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Waggoner, Stephen <Stephen.Waggoner@cchmc.org>; Gulick, James <James.Gulick@cchmc.org>; Corsmo, Jeremy <Jeremy.Corsmo@cchmc.org>; Dowdy, Tabitha <Tabitha.Dowdy@cchmc.org>
Subject: Formal Report for 1/17/2020 Incident at CCHMC

Good afternoon,

Attached is the formal report for an incident that was reported to you by e-mail on 1/17/2020.

Please feel free to contact me with any questions.

Sincerely,
Tammy

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229

Obtained via FOIA by Judicial Watch Inc.

Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement

Cincinnati Children's
changing the outcome together

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Does this incident involve research subject to the *NIH Guidelines*?	✓YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Cincinnati Children's
Date of Report:	2/7/2020
Reporter name and position:	Tamara B. Rausch, Biosafety Officer
Telephone number:	513.636.4843
Email address:	Tamara.rausch@cchmc.org
Reporter mailing address:	240 Albert Sabin Way MLC 7040 Cincinnati, OH 45229
Date of incident:	01/17/2020
Name of Principal Investigator:	William Swaney Marc Rothenberg
Is this an NIH-funded project?	✓NO (Swaney) ✓NO (Rothenberg) If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ✓ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ ✓ YES ☐ NO Date of approval: 7/11/2017 (Swaney) Date of approval: 8/8/2017 (Rothenberg)
What was the approved biosafety level of the research?	☐ BL1 ✓ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Swaney: III-D-2, III-D-3, III-D-6 Rothenberg: III-D-2, III-D-3, III-D-4, III-E-1, III-E-3
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA The VVC produces viral vectors for researchers and ensures they have approved IBC protocols.
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The material was a third generation lentiviral vector with a VSV-G envelope. The backbone was pLPX-IRES-Puro. The gene of interest is DSP. The map is attached to the report.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space): The incident occurred in S11.601. This is a BSL 2 room designated for use by the Viral Vector Core (VVC).

- Who was involved in the incident/violation, including others present at the incident location? A VVC Research Assistant (RA) was in the room observing a GxP Technician.

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event: The RA immediately removed her shoes, socks and scrub pants. She proceeded to wipe her legs and feet with 70% ethanol followed by washing the area with soap and water. She had no open cuts or scratches. She then called 803-SAFE, the institutional safety hotline, to report the incident.

- The training received by the individual(s) involved and the date(s) the training was conducted:

Biosafety Training	Biohazard Waste
GxP Technician: 4/22/2016	GxP Technician: 8/9/2017
RA: 10/23/2019	RA: 12/18/2020

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation: The approved IBC protocol for the production of viral vectors was followed. In addition, the SOPs for cleaning/disinfecting and Biohazard Waste Disposal were followed. There were no deviations.

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation: There were no deviations from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.

- The personal protective equipment in use at the time of the incident/violation: The RA was wearing scrubs, lab coat and gloves. The VVC Supervisor was wearing scrubs, lab coat, safety goggles and gloves.

Obtained via FOIA by Judicial Watch Inc.

- The occupational health requirements for laboratory personnel involved in the research: Personnel working with human derived materials are required to receive the Hepatitis B vaccine. Record of the vaccines are to be kept on file in the employees' medical record files.

- Any medical surveillance provided or recommended after the incident: No medical surveillance was provided or recommended.

- Any injury or illness associated with the incident: There were no injuries or illnesses associated with the incident.

- Equipment failures: There were no equipment failures.

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

The Viral Vector Core (VVC) was in the last phase of producing a 3rd generation lentiviral vector (backbone pLPX-IRES-Puro). A Research Assistant (RA) in training was observing a GxP Technician, the RA's supervisor, perform the procedure. The Technician was working in a Class II Type A2 biosafety cabinet in an approved BSL 2 lab. He was removing the sample tubes from the ultracentrifuge buckets.

The Technician was trying to remove one of the ultracentrifuge bucket caps by pulling up on it. The Technician stated the cap was difficult to remove due to a vacuum seal created by the ultracentrifugation. When the Technician pulled the cap upward, the sample tube came out and the material spilled into the biosafety cabinet and splashed out onto the lower legs and feet of the RA. Approximately 3 mL spilled into the biosafety cabinet and 2 mL onto the RA's legs and feet. A small amount also splashed onto the floor.

The RA immediately sprayed 70% ethanol on her legs and shoes. She was wearing work scrubs and work shoes. In addition, she was wearing a lab coat and gloves. She then proceeded to the changing room and removed her shoes, socks and scrubs. She washed her legs and feet with soap and water. She had no open cuts or scratches on her legs. After washing her legs and feet, she called 803-SAFE, the institutional safety hotline, to report the incident. She cleaned her shoes with 70% ethanol and soap and water. Her work shoes stay at work. She placed her scrubs in a bag for laundering by Linen Services. The Technician cleaned the floor with 70% ethanol followed by wiping the area with Super Sani Cloths. The RA and Technician notified the VVC Director and the VVC Director contacted the Biosafety Officer. The Biosafety Officer also received notification from the safety hotline.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☐ YES ✓ NO The incident will be reviewed at the February 11, 2020 IBC meeting.
Please describe the root cause of this incident:	Upon investigation, it was determined that the Technician used too much force by pulling up to remove the cap. In addition, the Technician was working too close to the front grille of the cabinet, which is why some of the material splashed out.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

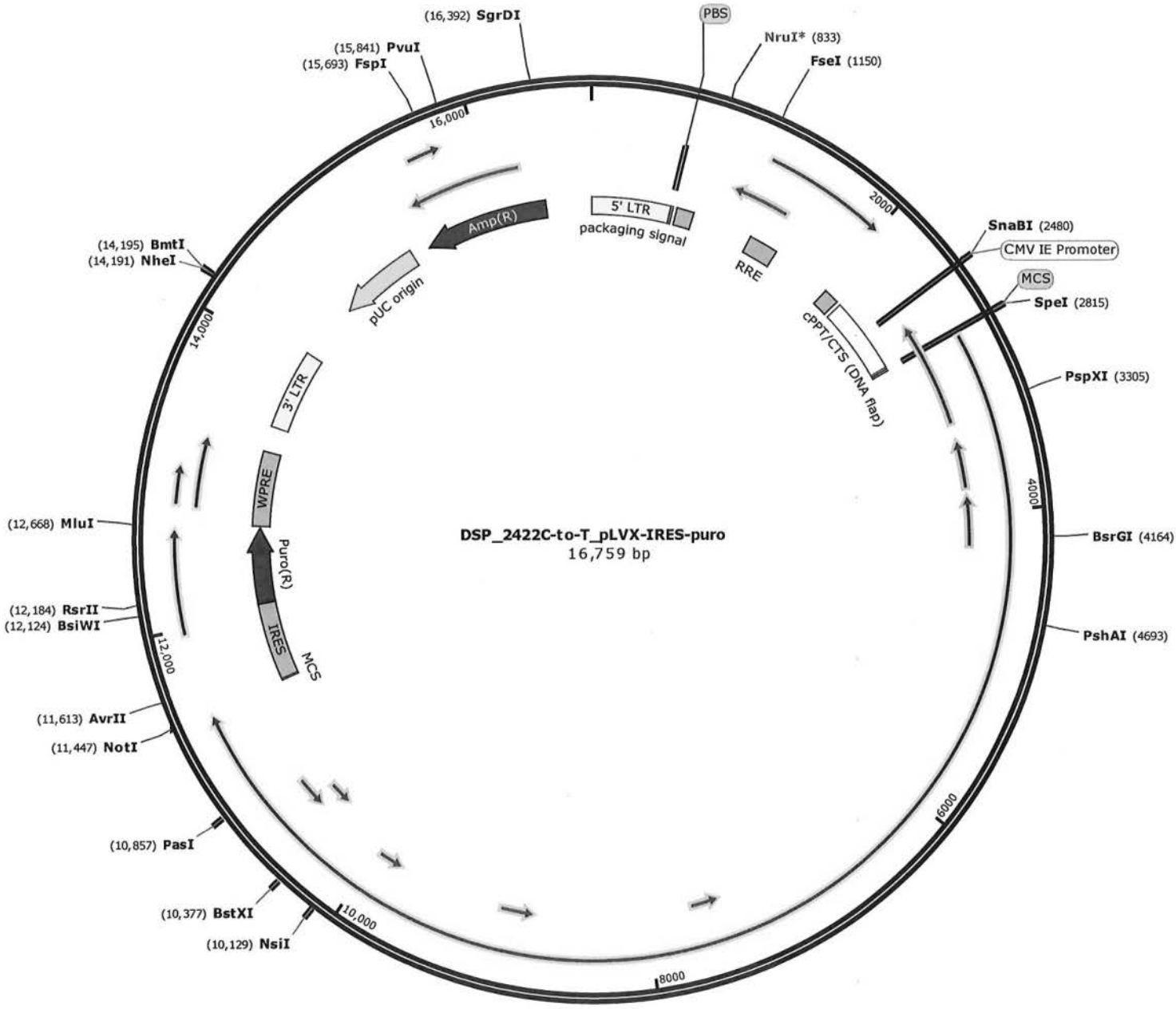
A Senior GxP Specialist who also works in the VVC reviewed how to properly remove the caps with the GxP Technican. He stated that after reviewed the process, he has not had any difficulties removing the caps. He also ensured he will work at least six inches into the cabinet.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Sequence: DSP_2422C-to-T_pLVX-IRES-puro.dna (Circular / 16,759 bp)
Enzymes: Unique 6+ Cutters (20 of 653 total)
Features: 14 total

Unique Cutters **Bold**



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Friday, February 7, 2020 3:08 PM
To: NIH guidelines
Cc: Waggoner, Stephen; Gulick, James; Corsmo, Jeremy; Dowdy, Tabitha
Subject: Formal Report for 1/17/2020 Incident at CCHMC
Attachments: VVC Incident Report 01172020.pdf

Good afternoon,

Attached is the formal report for an incident that was reported to you by e-mail on 1/17/2020.

Please feel free to contact me with any questions.

Sincerely,
Tammy

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229
Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Friday, January 17, 2020 1:56 PM
To: NIH guidelines
Cc: Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Corsmo, Jeremy
Subject: Notification of Incident at CCHMC 1/17/2020

Good afternoon,

I am notifying you as required by the NIH Guidelines of a spill and possible exposure that occurred 1/17/2020 in the Cincinnati Children's Viral Vector Core. A Research Assistant in training was observing her supervisor perform a procedure. She was standing beside him while he was working in the biosafety cabinet. When he was removing a tube from an ultracentrifuge tube, the cap slipped off and lentiviral material splashed in the biosafety cabinet. In addition, a small amount of the material splashed on the RA's lower legs and shoes. The RA immediately removed her shoes and scrubs and washed her legs. There were no open cuts or scratches on her legs.

I will send a full report upon completion of the investigation. Please feel free to contact me with any questions.

Sincerely,
Tammy

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229
Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 9:13 AM
To: Kara Drolet; Sarah Byers; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Status of Incident Reports

Dear Dr. Kara Manning Drolet,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to these incidents appear appropriate.

No further information about these incidents is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kara Drolet <manningk@ohsu.edu>
Sent: Monday, March 2, 2020 5:19 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; Sarah Byers <byerssa@ohsu.edu>
Subject: RE: Status of Incident Reports

Dear Dr. Harris,
Please find attached the final reports for the first two incidents in the list below. For the 3rd incident, we are still gathering some additional information and will provide the final report as soon as we can.
Thank you and please let us know if you have any questions.
Regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Monday, March 2, 2020 12:10 PM
To: Sarah Byers <byerssa@ohsu.edu>
Cc: Kara Drolet <manningk@ohsu.edu>
Subject: Status of Incident Reports

Hi Sara:

Just wanted to follow up on some reports to make sure I didn't miss any incoming final submissions.

I have:

1/17 Vaccinia needlestick
1/13 Leishmania cut from cryovial
1/6 SHIV scalpel cut

Apologies if I missed something.

Regards,

Kathryn

Obtained via FOIA by Judicial Watch Inc.

OHSU

March 2, 2020

Kathryn Harris, Ph.D., RBP
Senior Outreach and Education Specialist
NIH OSP

Institutional Biosafety Committee
Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
Ibc@ohsu.edu

Kara M. Drolet, Ph.D.
Associate Vice President
Research Integrity
tel 503 494-6727
manningk@ohsu.edu

Ashlee Moses, Ph.D.
IBC Chair
tel 503 418-2712
mosesa@ohsu.edu

Harjinder Sardar, Ph.D.
OHSU Biosafety Officer
tel 503-346-5028
sardar@ohsu.edu

Sarah Byers, Ph.D.
IBC Program Manager
tel 503 494-9763
byerssa@ohsu.edu

Dear Dr. Harris,

This letter serves as the detailed summary of follow up for a reportable incident that occurred at Oregon Health & Science University (OHSU) that was initially reported to NIH on 1/17/2020.

Date of Incident	1/16/2020
OHSU IBC registration number	IBC-15-33
OHSU project title	Viral Vectors for Generation of CD8 T cell Responses
Nature of the material	WR strain of Vaccinia Virus with LCMV GP33 inserted into the TK gene
Risk Group	II
Containment level	ABSL-2
Nature of the incident	Potential Personnel Exposure
PPE in use	Two pairs of gloves, bonnet, face mask, gown and two pairs of protective booties
Vaccination	Vaccination is recommended but not required for this project. Individual had been offered the vaccination but declined.

Description of incident:

A researcher had applied 10^6 plaque forming units of recombinant vaccinia virus to the ventral side of a mouse ear. As the researcher performed scarification of the ear they accidentally poked themselves in the finger with the needle.

Actions taken:

The researcher applied pressure to the needle stick area, rinsed with water for 5 minutes and then applied bleach to the finger before going to Occupational Health for medical evaluation. The researcher was counseled to keep the exposure site bandaged, to monitor for the formation of a blister and other potential symptoms. 10 days after the incident the researcher had a follow up appointment with an infectious disease doctor to assess the exposure sight for a

Obtained via FOIA by Judicial Watch Inc.

blister. No blister or other symptoms of a potential infection have been observed.

Additional signage will be created for posting in laboratories and in the vivarium to remind researchers of appropriate steps to be taken immediately after an exposure. This information will be reviewed with the researcher involved in the incident.

The IBC has determined that this incident has now been resolved with the submission of this report to OSP, pending completion of the above actions. If the individual develops symptoms related to this exposure, the OHSU IBC will notify NIH-OSP.

Sincerely,

Redacted by agreement

Kara Drolet
2020.03.02
14:05:37 -08'00'

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

cc: Debra Brickey, PhD, Research Safety Manager; Dana Director, PhD, OHSU Institutional Official

Obtained via FOIA by Judicial Watch Inc.

OHSU

March 2, 2020

Kathryn Harris, Ph.D., RBP
Senior Outreach and Education Specialist
NIH OSP

Institutional Biosafety Committee
Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
ibc@ohsu.edu

Kara M. Drolet, Ph.D.
Associate Vice President
Research Integrity
tel 503 494-6727
manningk@ohsu.edu

Ashlee Moses, Ph.D.
IBC Chair
tel 503 418-2712
mosesa@ohsu.edu

Harjinder Sardar, Ph.D.
OHSU Biosafety Officer
tel 503-346-5028
sardar@ohsu.edu

Sarah Byers, Ph.D.
IBC Program Manager
tel 503 494-9763
byerssa@ohsu.edu

Dear Dr. Harris,

This letter serves as the detailed summary of follow up for a reportable incident that occurred at Oregon Health & Science University (OHSU) that was initially reported to NIH on 01/13/2020.

Date of incident	1/10/2020
OHSU IBC registration number	IBC-03-07
OHSU project title	Experimental studies employing Leishmania and African Trypanosomes
Nature of the material	Frozen transgenic *Leishmania mexicana*
Risk Group	II
Containment level	BSL-2
Nature of the incident	Potential Personnel Exposure
PPE in use	Laboratory coat, goggles, and latex gloves

Description of incident:

A cryotube, stored in liquid nitrogen and containing a stabilate of a transgenic strain of *Leishmania mexicana* parasites, exploded when a researcher removed a box containing multiple tubes from liquid nitrogen to remove some other tubes. The cap from the exploding tube struck the right hand of the laboratory worker, tore through the glove, and caused an abrasion.

Actions taken:

The researcher washed their hand with soap and water for 15 minutes, decontaminated it with 70% ethanol, and then reported to Occupational Health. The healthcare provider assessed this as a low risk exposure and the researcher will be monitored over the next few months for symptoms of leishmaniasis.

The researchers have outlined revisions to their work practices for handling cryotubes, including use of forceps to pick up the tubes, and transporting the tubes in a closable plastic box for transport to the biosafety cabinet. The researchers will also start using a facemask instead of goggles and wear thicker gloves. Going forward a different cryotube with an improved seal will be used.

Obtained via FOIA by Judicial Watch Inc.

The IBC has determined that this incident has now been resolved with the submission of this report to OSP, pending completion of the above actions. If the individual develops symptoms related to this exposure, the OHSU IBC will notify NIH-OSP.

Sincerely,

Redacted by agreement

Kara Drolet
2020.03.02
14:02:16 -08'00'

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

cc: Debra Brickey, PhD, Research Safety Manager Dana Director, PhD, OHSU Institutional Official

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kara Drolet <manningk@ohsu.edu>
Sent: Monday, March 2, 2020 5:19 PM
To: Harris, Kathryn (NIH/OD) [C]; Sarah Byers
Subject: RE: Status of Incident Reports
Attachments: OHSU Final Report for 011620202 VV needle stick.pdf; OHSU Final Report for 01102020 Leishmania incident.pdf

Dear Dr. Harris,
Please find attached the final reports for the first two incidents in the list below. For the 3rd incident, we are still gathering some additional information and will provide the final report as soon as we can.
Thank you and please let us know if you have any questions.
Regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Monday, March 2, 2020 12:10 PM
To: Sarah Byers <byerssa@ohsu.edu>
Cc: Kara Drolet <manningk@ohsu.edu>
Subject: Status of Incident Reports

Hi Sara:

Just wanted to follow up on some reports to make sure I didn't miss any incoming final submissions.

I have:

1/17 Vaccinia needlestick
1/13 Leishmania cut from cryovial
1/6 SHIV scalpel cut

Apologies if I missed something.

Regards,

Kathryn

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Sarah Byers <byerssa@ohsu.edu>
Sent: Friday, January 17, 2020 6:41 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Kara Drolet
Subject: OHSU initial report of potential exposure 1/16/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 1/16/2020 at Oregon Health & Science University. A researcher was potentially exposed to recombinant Vaccinia virus through a needle stick.

A complete report of the incident and follow up will be provided at a later date.

Sarah

Sarah A. Byers, PhD
IBC Program Manager
Research Integrity Office (ORIO)
Oregon Health & Science University
503-494-9763
byerssa@ohsu.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, February 21, 2020 9:44 AM
To: Institutional Biosafety Committee; NIH guidelines
Cc: Chow, Samson; Tafoya, Christine; Stoner, Breena; Perkins, Jennifer; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Final Report: 1/22/20 UCLA Mouse Bite Incident- PI: Zack

Dear Christine Bruton,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Institutional Biosafety Committee <ibc@research.ucla.edu>
Sent: Wednesday, February 12, 2020 1:24 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chow, Samson <schow@mednet.ucla.edu>; Tafoya, Christine <ctafoya@ehs.ucla.edu>; Stoner, Breena <bstoner@ehs.ucla.edu>; Perkins, Jennifer <JPerkins@research.ucla.edu>
Subject: Final Report: 1/22/20 UCLA Mouse Bite Incident- PI: Zack

Dear OSP,

Please find the attached final report related to this incident.

Best,

Christine Bruton

IBC Manager

Email: christine.bruton@research.ucla.edu

Obtained via FOIA by Judicial Watch Inc.

Phone: 310.794.0474

Need extra help with the IBC process or safetyNet?

Stop by during weekly in-person office hours on campus.

Wednesdays, 2pm-5pm in CHS 17-132A

From: Institutional Biosafety Committee
Sent: Wednesday, January 22, 2020 3:14 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chow, Samson <schow@mednet.ucla.edu>; Tafoya, Christine <ctafoya@ehs.ucla.edu>; Stoner, Breena <bstoner@ehs.ucla.edu>; Perkins, Jennifer <JPerkins@research.ucla.edu>
Subject: 1/22/20 UCLA Mouse Bite Incident- PI: Zack

Dear OSP,

Our office has been notified of the following incident:

Date of incident:

1/22/2020

Incident Description:

A senior research associate 2 (SRA2) was bitten by an HIV-infected humanized mouse this morning. The HIV is a recombinant strain. The SRA has approximately 14 years of experience working with mice, and 8 years working with HIV-infected humanized mice. This mouse had been transplanted with human cells and tissues, and then infected with a recombinant strain of HIV (called NL-HA), which expresses a selectable "HA" cell surface marker in place of the vpr open reading frame and a short non-expressed 21 nucleotide barcode tag. The mouse had been infected for 4 weeks and was being sacrificed. When the SRA picked up the mouse to scruff it, the mouse managed to turn and bite her through 2 pairs of gloves drawing a small amount of blood. She rinsed the wound and then went to occupational health for treatment.

Containment:

BSL2+

A final report is forthcoming.

Obtained via FOIA by Judicial Watch Inc.

Regards,

Christine Bruton

IBC Manager

Email: christine.bruton@research.ucla.edu

Phone: 310.794.0474

Need extra help with the IBC process or safetyNet?

Stop by during weekly in-person office hours on campus.

Wednesdays, 2pm-5pm in CHS 17-132A

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	**UCLA**
Date of Report:	**2/12/2020**
Reporter name and position:	**Christine Bruton, IBC Manager**
Telephone number:	**310-794-0474**
Email address:	**Christine.bruton@research.ucla.edu**
Reporter mailing address:	**UCLA- IBC Administrative Office 10889 Wilshire Blvd., Suite 600 Los Angeles, CA 90095-1406**
Date of incident:	**1/22/2020**
Name of Principal Investigator:	**JEROME ZACK**
Is this an NIH-funded project?	**☒YES ☐NO** **CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE(CIRM)** — **TRAN1-11265** — **Clinical Translation of Autologous Regenerative Cell Therapy for Blindness** **CALIFORNIA INSTITUTE FOR** — **TRAN1-08533** — **Stem Cell-Based iNKT Cell Therapy for Cancer**

Obtained via FOIA by Judicial Watch Inc.

	REGENERATIVE MEDICINE(CIRM)		
	NIH - NATIONAL INSTITUTES OF HEALTH	**AI124843**	**Development of SMAC mimetics as latency-reversing agents**
	NIH - NATIONAL INSTITUTES OF HEALTH	**AI124743**	**HIV Latency Reversal through Novel, Potent PKC Modulators**
	NIH - NATIONAL INSTITUTES OF HEALTH	**AI124763**	**Novel method for evaluating HIV latency and persistence in vivo**
	NIH - NATIONAL INSTITUTES OF HEALTH	**U19 AI117941**	**Anti-HIV Gene Therapy: Defend and Attack**
	NIH - NATIONAL INSTITUTES OF HEALTH	**UL1TR001881**	**: UCLA Clinical and Translational Science Institute (Intramural Award to Matthew Marsden, Ph.D: Evaluating HIV latency and persistence in vivo using genetically barcoded virus)**
	NIH - NATIONAL INSTITUTES OF HEALTH	**UL1TR000124**	**: UCLA Clinical and Translational Science Institute (Intramural Award to Matthew Marsden, Ph.D: Evaluating HIV latency and persistence in vivo using genetically barcoded virus)**
	NIH - NATIONAL INSTITUTES OF HEALTH	**AI028697**	**The UCLA Center for AIDS Research (CFAR)**
	NIH - NATIONAL INSTITUTES OF HEALTH	**HD080474**	**Early Antiretroviral Therapy and HIV Remission in Perinatal Infection**
	NIH - NATIONAL INSTITUTES OF HEALTH	**P01 AI131294**	**Defining Factors Controlling HIV Rebound**

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure

Obtained via FOIA by Judicial Watch Inc.

	☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO ***If yes, date of approval: 06/13/2018***
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☒BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	***III-D, III-E***
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	***This mouse had been transplanted with human cells and tissues, and then infected with a recombinant strain of HIV***

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A senior research associate 2 (SRA2) was bitten by an HIV-infected humanized mouse this morning. The HIV is a recombinant strain. The SRA has approximately 14 years of experience working with mice, and 8 years working with HIV-infected humanized mice. This mouse had been transplanted with human cells and tissues, and then infected with a recombinant strain of HIV (called NL-HABC), which expresses a selectable "HA" cell surface marker in place of the vpr open reading frame and a short non-expressed 21 nucleotide barcode tag. The mouse had been infected for 4 weeks and was being sacrificed. When the SRA picked up the mouse to scruff it, the mouse managed to turn and bite her through 2 pairs of gloves drawing a small amount of blood. She rinsed the wound and then went to occupational health for treatment

Has the IBC reviewed this incident?	☒YES ☐NO ***Reviewed at 2/6/2019 meeting***
Please describe the root cause of this incident:	***The SRA utilized an outdated technique for handling the mouse.***

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary): ***Measures taken to mitigate this problem included providing the updated recommendations for mouse handling and euthanasia. Updated recommendations include sedating the animal before handling, using forceps and other restraining devices, and exploring other means of euthanasia. The incident and mitigation were discussed in a subsequent lab meeting.***

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Institutional Biosafety Committee <ibc@research.ucla.edu>
Sent: Wednesday, February 12, 2020 1:24 PM
To: NIH guidelines
Cc: Chow, Samson; Tafoya, Christine; Stoner, Breena; Perkins, Jennifer
Subject: Final Report: 1/22/20 UCLA Mouse Bite Incident- PI: Zack
Attachments: UCLA Incident Report_Zack_1_22_2020.docx

Dear OSP,

Please find the attached final report related to this incident.

Best,

Christine Bruton
IBC Manager
Email: christine.bruton@research.ucla.edu
Phone: 310.794.0474
Need extra help with the IBC process or safetyNet?
Stop by during weekly in-person office hours on campus.
Wednesdays, 2pm-5pm in CHS 17-132A

From: Institutional Biosafety Committee
Sent: Wednesday, January 22, 2020 3:14 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chow, Samson <schow@mednet.ucla.edu>; Tafoya, Christine <ctafoya@ehs.ucla.edu>; Stoner, Breena <bstoner@ehs.ucla.edu>; Perkins, Jennifer <JPerkins@research.ucla.edu>
Subject: 1/22/20 UCLA Mouse Bite Incident- PI: Zack

Dear OSP,

Our office has been notified of the following incident:

Date of incident:
1/22/2020

Incident Description:
A senior research associate 2 (SRA2) was bitten by an HIV-infected humanized mouse this morning. The HIV is a recombinant strain. The SRA has approximately 14 years of experience working with mice, and 8 years working with HIV-infected humanized mice. This mouse had been transplanted with human cells and tissues, and then infected with a recombinant strain of HIV (called NL-HA), which expresses a selectable "HA" cell surface marker in place of the vpr open reading frame and a short non-expressed 21 nucleotide barcode tag. The mouse had been infected for 4 weeks and was being sacrificed. When the SRA picked up the mouse to scruff it, the mouse managed to turn and bite her through 2 pairs of gloves drawing a small amount of blood. She rinsed the wound and then went to occupational health for treatment.

Containment:
BSL2+

Obtained via FOIA by Judicial Watch Inc.

A final report is forthcoming.

Regards,

Christine Bruton
IBC Manager
Email: christine.bruton@research.ucla.edu
Phone: 310.794.0474
Need extra help with the IBC process or safetyNet?
Stop by during weekly in-person office hours on campus.
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Hunter, Renee (NIH/OD) [C]

From: Institutional Biosafety Committee <ibc@research.ucla.edu>
Sent: Wednesday, January 22, 2020 6:14 PM
To: NIH guidelines
Cc: Chow, Samson; Tafoya, Christine; Stoner, Breena; Perkins, Jennifer
Subject: 1/22/20 UCLA Mouse Bite Incident- PI: Zack

Dear OSP,

Our office has been notified of the following incident:

Date of incident:
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Containment:
BSL2+

A final report is forthcoming.

Regards,

Christine Bruton
IBC Manager
Email: christine.bruton@research.ucla.edu
Phone: 310.794.0474
Need extra help with the IBC process or safetyNet?
Stop by during weekly in-person office hours on campus.
Wednesdays, 2pm-5pm in CHS 17-132A

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:35 AM
To: Michael I. Betteken; NIH guidelines
Cc: Debra A. Dwyer; Christine A. Bellezza; Joshua E. Turse; Colin Ross Parrish; Esther R. Angert; Marcos Simoes-Costa; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Cornell University exposure incident report

Dear Dr. Michael Betteken,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Michael I. Betteken <mib46@cornell.edu>
Sent: Thursday, February 20, 2020 10:11 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Debra A. Dwyer <dad3@cornell.edu>; Christine A. Bellezza <cab37@cornell.edu>; Joshua E. Turse <joshturse@cornell.edu>; Colin Ross Parrish <crp3@cornell.edu>; Esther R. Angert <era23@cornell.edu>; Marcos Simoes-Costa <simoescosta@cornell.edu>
Subject: Cornell University exposure incident report

Dear Sir/Madam:

Please find attached an incident report from Cornell University. Please let me know if you need further information. This report is related to our initial communication concerning an exposure event from 1/24/2020. The original email is attached for your reference.

Thanks,
Michael

Michael I. Betteken, PhD
IBC - Administrator
Institutional Biosafety Committee
Office of Research Integrity and Assurance

Obtained via FOIA by Judicial Watch Inc.

Suite 320-H, East Hill Office Building
395 Pine Tree Rd
(607) 255-0741
Mib46@cornell.edu



CornellResearch

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Cornell University
Date of Report:	
Reporter name and position:	Michael Betteken, IBC administrator
Telephone number:	607-255-0741
Email address:	Cu_ibc@cornell.edu
Reporter mailing address:	Cornell University East Hill Office Building 395 Pine Tree Road Suite 320-H
Date of incident:	1/23/2020
Name of Principal Investigator:	Marcos Simoes-Costa, PhD
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 7/01/2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ (describe specific enhancement in report) ☐BL3 ☐BL3+ (describe specific enhancement in report) ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-3
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA X Other (please describe): Cornell U. ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	4th generation lentivirus carrying the plasmid FUW-tetO-hOKMS (Addgene #51543).

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

The incident occurred in a tissue culture room approved for BSL2 work on Thursday, January 23, 2020, at 11:30 AM. While performing a routine viral-transfection in the biosafety cabinet, the graduate student accidentally pressed the release button of a 1 ml pipet, which was loaded with 4th generation lentivirus carrying the plasmid FUW-tetO-hOKMS (Addgene number 51543). The solution landed on the surface (inside) of the biosafety cabinet, but some of the liquid splashed through the biosafety cabinet opening, landing on the left leg of the graduate student's pants. The lentivirus was in a DMEM solution with 10% FBS. The graduate student was wearing a lab coat, two sets of gloves and denim pants at the time of the incident. However, the coat did not prevent the lentivirus containing-media from soaking through to the level of the user's pants. No one else was present in the room at the time of the incident. Once the incident occurred, the pants were removed and the area of skin that received the splash was washed thoroughly for 15 minutes, with a change of clothes acquired from another student (who did not come in contact with the room or contaminated clothing). The Graduate student went home to get new clothing, contacted Cornell Health, and was given an appointment at 2:30 p.m. with a Cornell Physician. In the medical appointment, the graduate student was prescribed two medications to be taken for the remainder of the week, Truvada® and Isentress®. The nature of the medication is preventative - to reduce theoretical gene insertion, since no open wounds were located where splash occurred and since HIV risk is negligible with 4th generation lentivirus. The PI contacted the Cornell IBC to report the potential exposure on the day of the incident, and filed a Cornell University Injury/Illness/Exposure Report.

The student was up to date on Bloodborne Pathogens training for Research and Diagnostic Personnel. There were no equipment failures, and the protocol for the affected area of the splash in the biosafety cabinet was handled in accordance to EHS Cornell guidelines, where the area was covered with paper towel and disinfectant.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Accidental spill.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Have PI review the following with all lab personnel:

1. Review reporting procedures for exposures with all lab personnel
2. Review working procedures in Biosafety cabinet and determine best practices to avoid future accidental splashes.

Additionally we received feedback that we could improve our website navigation to better find the instructions page for reporting exposures. We have made a change to put the link to the reporting page at the top of our main page for Recombinant and biohazardous research as a "Call to Action" button. This is a change from previously having the page link at the button requiring the user to scroll all the way down to find.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Michael I. Betteken <mib46@cornell.edu>
Sent: Thursday, February 20, 2020 10:11 AM
To: NIH guidelines
Cc: Debra A. Dwyer; Christine A. Bellezza; Joshua E. Turse; Colin Ross Parrish; Esther R. Angert; Marcos Simoes-Costa
Subject: Cornell University exposure incident report
Attachments: Incident-Reporting-NIH-1.23.2020-v3 Final.docx; Cornell University potential exposure

Dear Sir/Madam:

Please find attached an incident report from Cornell University. Please let me know if you need further information. This report is related to our initial communication concerning an exposure event from 1/24/2020. The original email is attached for your reference.

Thanks,
Michael

Michael I. Betteken, PhD
IBC - Administrator
Institutional Biosafety Committee
Office of Research Integrity and Assurance
Suite 320-H, East Hill Office Building
395 Pine Tree Rd
(607) 255-0741
Mib46@cornell.edu

CornellResearch

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Michael I. Betteken <mib46@cornell.edu>
Sent: Friday, January 24, 2020 1:21 PM
To: NIH guidelines
Cc: Joshua E. Turse; Marcos Simoes-Costa; Christine A. Bellezza; Esther R. Angert; Colin Ross Parrish
Subject: Cornell University potential exposure

Dear NIH OSP,

My name is Michael Betteken and I am an IBC administrator from Cornell University. We are writing to inform you that we had a potential exposure (splash to skin) of a 4th generation lenti-viral vector occur to a laboratory student yesterday afternoon (1/24/2020). The student has elected to seek medical consultation. Our Biosafety officer and IBC have been made aware of the exposure and are currently conducting our incident follow up. We will provide a full report to the NIH within the next 30 days.

Thanks,
Michael

Michael I. Betteken, PhD
Administrator
Institutional Biosafety Committee
Office of Research Integrity and Assurance
Suite 320-H, East Hill Office Building
395 Pine Tree Rd
(607) 255-0741
Mib46@cornell.edu

CornellResearch

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 9:01 AM
To: ANDREA N LADD; NIH guidelines
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report attached

Dear Dr. Andrea Ladd,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Wednesday, February 19, 2020 10:06 AM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: Incident report attached

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the needle stick initially reported on 1/27/20 (below). The Office of Biological Safety has carefully investigated the incident cause, materials, and response.

Please let me know if you have any questions or need additional information.

UW-Madison personnel included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Obtained via FOIA by Judicial Watch Inc.

Andrea N. Ladd, Ph.D.
Biological Safety Officer
Assistant Director, EH&S
University of Wisconsin-Madison
30 East Campus Mall
Madison, WI 53715
(608) 263-9013 office
Redacted by agreement mobile
andrea.ladd@wisc.edu

From: ANDREA N LADD
Sent: Monday, January 27, 2020 2:00 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Chris Strang (christopher.strang@wisc.edu) <christopher.strang@wisc.edu>
Subject: Initial notification of incident

Dear Kathryn or Whom It May Concern,

We were notified today of a needle stick involving recombinant materials in one of our BSL2 laboratories. The employee has been directed to University Health Services for medical follow-up.

At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Biological Safety Officer
Assistant Director, EH&S
University of Wisconsin-Madison
30 East Campus Mall
Madison, WI 53715
(608) 263-9013 office
Redacted by agreement mobile
andrea.ladd@wisc.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Wisconsin-Madison
Date of Report:	01/27/20 (initial email to OSP) 02/19/20 (formal report filed)
Reporter name and position:	Andrea N. Ladd, Biological Safety Officer
Telephone number:	(608) 263-9013
Email address:	andrea.ladd@wisc.edu
Reporter mailing address:	Environment, Health and Safety 30 East Campus Mall Madison, WI 53715
Date of incident:	01/27/20
Name of Principal Investigator:	John-Demian Sauer
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 02/28/19
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☒ABSL2 ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-a
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA Not applicable
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	*Listeria monocytogenes* strain in which the kinase PrkA was deleted, resulting in significant attenuation (approximately 10^5-fold) compared to wild type

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

Location: ABSL2 animal procedure room

Persons involved: UW-Madison employee

Training received by individual: Lab-specific training according to approved biosafety protocol was done and documented. The employee had completed hands-on training for mouse handling and inoculation through the UW-Madison Research Animal Resources Center.

PPE in use at time of event: face shield, disposable gown, hairnet, surgical mask, gloves

Event description: The employee was inoculating mice with a recombinant, attenuated strain of *Listeria monocytogenes* by tail vein injection inside a biosafety cabinet (BSC), in accordance with their approved biosafety protocol. Just as the employee was about to inject the last mouse of twenty being infected, the mouse moved suddenly and the needle stuck the employee's finger instead.

Immediate follow-up and medical follow-up: The employee immediately replaced the mouse in its cage, removed their gloves, and washed the wound site with soap and water for five minutes. The PI was informed and the incident was reported to the Office of Biological Safety (OBS). The employee connected with Occupational Medicine for medical questions and follow-up. The Biological Safety Officer submitted an initial report to OSP.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC Chair was aware of the event upon initial report to OSP. The IBC was fully apprised of the incident at the next IBC meeting on February 5, 2020.
Please describe the root cause of this incident:	Root cause is the natural instinct of an animal to be uncooperative with a procedure it dislikes. A contributing factor may be the relative inexperience of the employee; the employee had been trained on this procedure, but this was the first time the employee was performing tail vein injections for an experiment.

Obtained via FOIA by Judicial Watch Inc.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The institution followed approved emergency and reporting procedures. The Office of Biological Safety met with the employee and PI to review the incident.

The PI reviewed the incident with the employee one-on-one, and with all of the laboratory staff at an all-hands lab meeting. The employee will undergo refresher training for the tail vein injection procedure before performing additional inoculations. Lab members will be encouraged to take microbreaks between animals when inoculating sets to avoid fatigue. Finally, the laboratory is evaluating whether other inoculation methods could be used that have reduced potential of needle stick (e.g., retroorbital injection under anesthesia) without compromising the scientific objectives of the study.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Wednesday, February 19, 2020 10:06 AM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
Subject: Incident report attached
Attachments: Sauer_012720_OSP Reportable.docx

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the needle stick initially reported on 1/27/20 (below). The Office of Biological Safety has carefully investigated the incident cause, materials, and response.

Please let me know if you have any questions or need additional information.

UW-Madison personnel included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Biological Safety Officer
Assistant Director, EH&S
University of Wisconsin-Madison
30 East Campus Mall
Madison, WI 53715
(608) 263-9013 office
Redacted by agreement mobile
andrea.ladd@wisc.edu

From: ANDREA N LADD
Sent: Monday, January 27, 2020 2:00 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Chris Strang (christopher.strang@wisc.edu) <christopher.strang@wisc.edu>
Subject: Initial notification of incident

Dear Kathryn or Whom It May Concern,

We were notified today of a needle stick involving recombinant materials in one of our BSL2 laboratories. The employee has been directed to University Health Services for medical follow-up.

At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Obtained via FOIA by Judicial Watch Inc.

Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Biological Safety Officer
Assistant Director, EH&S
University of Wisconsin-Madison
30 East Campus Mall
Madison, WI 53715
(608) 263-9013 office
Redacted by agreement mobile
andrea.ladd@wisc.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Monday, January 27, 2020 3:00 PM
To: NIH guidelines; Harris, Kathryn (NIH/OD) [C]
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
Subject: Initial notification of incident

Dear Kathryn or Whom It May Concern,

We were notified today of a needle stick involving recombinant materials in one of our BSL2 laboratories. The employee has been directed to University Health Services for medical follow-up.

At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Biological Safety Officer
Assistant Director, EH&S
University of Wisconsin-Madison
30 East Campus Mall
Madison, WI 53715
(608) 263-9013 office
Redacted by agreement mobile
andrea.ladd@wisc.edu

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 11:10 AM
To: Cook, Susan; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Personnel exposure report

Dear Dr. Susan Cook,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and concur that the research was exempt. Thank you for the notification.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Cook, Susan <shcook@wustl.edu>
Sent: Tuesday, January 28, 2020 7:22 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Personnel exposure report

I am attaching a completed report for an occupational exposure to an AAV vector. Please let me know if you need any additional information.

-Susan

Susan Cook, PhD, CBSP
Director, Office of Biological Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: shcook@wustl.edu; Web: ehs.wustl.edu
(pronouns: she/her/hers)

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Cook, Susan <shcook@wustl.edu>
Sent: Tuesday, January 28, 2020 7:22 PM
To: NIH guidelines
Subject: Personnel exposure report
Attachments: WUSTL Incident Report 200128.pdf

I am attaching a completed report for an occupational exposure to an AAV vector. Please let me know if you need any additional information.

-Susan

Susan Cook, PhD, CBSP
Director, Office of Biological Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: shcook@wustl.edu; Web: ehs.wustl.edu
(pronouns: she/her/hers)

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	X YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Washington University School of Medicine
Date of Report:	01/28/2020
Reporter name and position:	Susan Cook, Biological Safety Officer
Telephone number:	314-747-0309
Email address:	shcook@wustl.edu
Reporter mailing address:	660 S. Euclid Box 8229 St. Louis, MO 63110
Date of incident:	01/27/2020
Name of Principal Investigator:	Ali Javaheri
Is this an NIH-funded project?	☐YES XNO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal X Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	X YES ☐NO If yes, date of approval: 10/11/2019
What was the approved biosafety level of the research?	X BL1 ☐ BL2 ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-E-1
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Adeno-associated virus (null virus)

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Staff scientist was preparing needles in a biosafety cabinet for injection of AAV9 null virus. As needles were being prepared, he accidently stuck himself (while attempting to recap needle) with a loaded syringe that pierced his glove and drew blood. Employee immediately washed hands and reported the exposure to Occupational Health and the biosafety officer. The scientist was instructed to monitor the wound for signs of infection.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	X YES ☐NO The IBC chairs were notified on January 27. The incident will be discussed at the next IBC meeting (2/19/2020).
Please describe the root cause of this incident:	Recapping needles.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Individuals are trained to not recap needles, both through EH&S lab safety training and in the lab-specific training. This incident happened to an experienced staff scientist who has been retrained on the importance of not recapping needles as a result of this incident.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 11:12 AM
To: Gregory Park; NIH guidelines
Cc: Chris Cramer; Masato Yamamoto; Frances Lawrenz; Dan Voytas; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Guidelines-related incident report from U of MN

Dear Dr. Gregory Park,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. However, it is recommended that you consider providing refresher training for the investigator on the requirements for IBC review and approval. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Gregory Park <parkx479@umn.edu>
Sent: Thursday, January 30, 2020 11:41 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chris Cramer <cramer@umn.edu>; Masato Yamamoto <yamam016@umn.edu>; Frances Lawrenz <lawrenz@umn.edu>; Dan Voytas <voytas@umn.edu>
Subject: NIH Guidelines-related incident report from U of MN

Dear NIH-OSP,
Please find attached a cover letter with an NIH incident report. Do not hesitate to contact me if you have any further questions.
Regards,
Greg

--
Gregory Park, PhD
parkx479@umn.edu
+1 612-625-9153 (direct line)

Assistant Director
Office of Biotechnology Activities Oversight
https://research.umn.edu/units/obao
Office of the Vice President for Research
D192 Mayo Memorial Building MMC820
420 Delaware ST SE
University of Minnesota

Obtained via FOIA by Judicial Watch Inc.

Minneapolis, MN 55455
USA

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Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Gregory Park <parkx479@umn.edu>
Sent: Thursday, January 30, 2020 11:41 AM
To: NIH guidelines
Cc: Chris Cramer; Masato Yamamoto; Frances Lawrenz; Dan Voytas
Subject: NIH Guidelines-related incident report from U of MN
Attachments: UMN NIH Incident 20200130.pdf

Dear NIH-OSP,
Please find attached a cover letter with an NIH incident report. Do not hesitate to contact me if you have any further questions.
Regards,
Greg

--
Gregory Park, PhD
parkx479@umn.edu
+1 612-625-9153 (direct line)

Assistant Director
Office of Biotechnology Activities Oversight
https://research.umn.edu/units/obao
Office of the Vice President for Research
D192 Mayo Memorial Building MMC820
420 Delaware ST SE
University of Minnesota
Minneapolis, MN 55455
USA

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Obtained via FOIA by Judicial Watch Inc.

UNIVERSITY OF MINNESOTA

Office of the Vice President for Research
Institutional Biosafety Committee

420 Delaware ST SE
D192 Mayo MMC 820
Minneapolis, MN 55455

E-mail: ibc@umn.edu
Main line: 612-626-2161
Fax: 612-626-6061 (shared)

January 29, 2020

Attention: Incident Reports
NIH Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20817
Phone: 301-496-9838
Email: NIHGuidelines@od.nih.gov

Dear NIH OSP Representative,

Please find attached an incident report from the University of Minnesota. The Incident Reporting Template has been completed.

The reported incident involved a failure to seek IBC approval for research activities subject to the NIH Guidelines.

If you have any questions about this information, please contact Gregory Park, Assistant Director of the Institutional Biosafety Committee Administration at 612-625-9153.
Thank you.

Sincerely,

Redacted by agreement

Christopher J. Cramer, Ph.D.
Vice President for Research
Institutional Official

c: Gregory Park
Masato Yamamoto
Frances Lawrenz

Enc: NIH-OSP Final Incident Report

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Minnesota
Date of Report:	01/29/2020
Reporter name and position:	Christopher Cramer, Vice President for Research, Institutional Official
Telephone number:	612-624-5054
Email address:	cramer@umn.edu
Reporter mailing address:	101 Pleasant ST SE 419 Johnston Hall Minneapolis, MN 55455
Date of incident:	01/14/2020
Name of Principal Investigator:	Daniel F. Voytas
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐YES ☒NO If yes, date of approval:
What was the approved biosafety level of the research?	☒BL1 ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-E
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Generation and use of recombinant *Agrobacterium tumefaciens* (GV3101) and transgenic *Nicotiana benthamiana*, *Arabidopsis thaliana*, *Rosa rubiginosa*, *Catharanthus roseus*, *Vitis vinifera*, *Solanum lycopersicum*, *Moricandia arvensis*, *Petunia axillaris*, *Solanum tuberosum*, *Helianthus annuus*, *Capsicum annuum*, and *Capsicum chinense*

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On 1/14/2020, the IBC Assistant Director discovered that research activities subject to the NIH Guidelines had been performed from 10/2017 to 12/2019 without IBC review and approval. An investigation into these activities revealed that a BSL1/BSL1-P laboratory had generated recombinants of *Agrobacterium tumefaciens* (strain GV3101), and subsequently used them for the infection, transduction, and generation of recombinant cells and transgenic plants. The Principal Investigator was notified to cease all unapproved activities and that he must seek IBC approval. An investigation into the work showed that all personnel involved (8 staff/students + PI) had the IBC required training, and that the PPE, procedures, and containment followed are in-line with expected IBC guidance. Waste disposal and decontamination procedures also followed standard IBC requirements. There were no reported injuries, illnesses, or other reported incidents from this investigator or his lab during the time period of the unapproved activities.

An application has been submitted and will be reviewed, as will this incident of non-compliance, at the next IBC meeting (2/17/2020).

Has the IBC reviewed this incident?	☐YES ☒NO
Please describe the root cause of this incident:	Failure to seek IBC approval for research activities subject to the NIH Guidelines.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Upon determination that research activities subject to the NIH Guidelines had taken place, the IBC Assistant Director instructed the PI to halt all on-going research activities that were not approved by the IBC. Because the IBC has not yet reviewed the incident, the IBC has not made recommendations to mitigate any problems identified. The IBC will review this incident on February 17, 2020. The Assistant Director will make recommendations for refresher training of all involved personnel in the requirements of the NIH Guidelines and our related University policies.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 11:13 AM
To: Hill, David J (HEALTH); NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report

Dear David Hill,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. However, it is recommended that you consider providing refresher training for the investigator on the requirements for IBC review and approval. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Hill, David J (HEALTH) <david.hill@health.ny.gov>
Sent: Thursday, January 30, 2020 1:08 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Incident Report

To whom it may concern,

Please see the attached incident report describing a laboratory acquired infection with recombinant Salmonella. FYI, I called and discussed this incident with Kathryn Harris on 1/28/20. If you have any questions or require additional information, please feel free to contact me by email or at the phone number below.

Thank you.

David Hill
Director of Safety
Wadsworth Center, NYS Department of Health
Room B940, Biggs Laboratory
(518) 473-8034 | david.hill@health.ny.gov
www.wadsworth.org

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	✖YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	New York State Department of Health, Wadsworth Center
Date of Report:	January 29, 2020
Reporter name and position:	David Hill Director of Safety/Biosafety Officer
Telephone number:	518 473-8034
Email address:	David.hill@health.ny.gov
Reporter mailing address:	Wadsworth Center P.O. Box 509 Room B940, Biggs Laboratory Albany, NY 12201
Date of incident:	A specific exposure event has not been identified, but a lab-associated infection was initially suggested from genomic sequencing results received on 12/5/2019 and subsequently confirmed by subsequent analysis on 1/16/20.
Name of Principal Investigator:	Nicholas Mantis, Ph.D.
Is this an NIH-funded project?	☐YES ✖NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ✖ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES ✖ NO If yes, date of approval: NOTE: This research was approved by IACUC on December 12, 2017, but not recognized by PI or IACUC committee as research subject to the NIH Guidelines.
What was the approved biosafety level of the research?	☐ BL1 ✖ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-4. Experiments Involving Whole Animals
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA

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Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	*Salmonella* Typhimurium (strain JS107 of genotype *zjg8101::kan* obtained orginally from Dr. James Slauch, University of Illinois and cited in Forbes et al., 2008 (PMC2519396)

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Background and Summary of Diagnostic Testing Results

A male post doctoral fellow working at the New York State Department of Health Wadsworth Center was admitted to the hospital for a gastrointestinal illness on September 24, 2019 and treated with intravenous antibiotics. During his medical evaluation he communicated to the medical staff that he worked in a research laboratory with *Salmonella enterica* serovar. Typhimurium, although he had no known exposure event involving the organism. As a result, the hospital staff selectively cultured his stool specimen in *Salmonella* enrichment medium and the results were positive for *S*. Typhimurium. As Salmonella is a reportable pathogen, the clinical isolate was subsequently sent to the Wadsworth Center Bacteriology Laboratory and DNA sequencing was performed to determine if the patient culture strain matched the laboratory strain(s) the post doc had been handling approximately two weeks prior to the onset of illness. At this point, there was no reason to suspect a work-related illness because his symptoms manifested two days after attending a large social gathering (wedding) – suggesting a possible connection to that event – and there had been no known workplace exposure event. Furthermore, *Salmonella* infection typically occurs 6 - 72 hours after exposure, making the wedding the likely source rather than the laboratory, considering that he had not worked with S. Typhimurium for two weeks prior to the illness.

The culture isolate (IDR1900048582) of *Salmonella* Typhimurium isolated from the post doc, as well as the ATCC *Salmonella* Typhimurium type strain 14028 the post doc reported working with approximately two weeks prior to illness, were sent to the Bacteriology program for short-read sequencing and analysis by their standard *Salmonella* pipeline. Bacteriology reported that the pipeline identified only 4 differences between the two strains of *Salmonella*, i.e., 3 SNPs and a single-base indel. The pipeline, however, does not report out genome differences larger than 100 bp indels, so they subsequently performed a gene annotation analysis for the two genomes and searched the annotations for the term 'aminoglycosides'. The results indicated that the type strain had an *aminoglycoside N(6')-acetyltransferase type 1* gene while the clinical isolate from the lab worker had both an *aminoglycoside N(6')-acetyltransferase type 1* gene as well as an *aminoglycoside 3'-phosphotransferase* gene, also called the kanamycin kinase gene, which confers resistance to kanamycin and is routinely used as a selectable marker gene for cloning in *Salmonella*. This result strongly suggested that the post doc was infected with the recombinant

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strain of *Salmonella* Typhimurium.

It is important to note that the post doc provided the Bacteriology lab with the wild type ATCC *Salmonella* Typhimurium type strain ATCC 14028 since the type strain is the formal reference strain for the lab's S. Typhimurium collection. However, he had actually handled/prepared not the type strain but two derivatives from the lab collection: JS107 (*zjg8101::kan*) and JS93 (*zjg8101::kan oafA126::Tn10d-Tc fkpA-lacZ*). These strains were obtained from the laboratory of Dr. James Slauch in 2006 and reported in a publication in 2008 (PMC2519396). This would explain why the Bacteriology results reported the presence of the kanamycin kinase gene.

To further confirm the results reported by the Bacteriology Lab and extend the original analysis, the FASTA sequencing results from the two strains of *Salmonella* Typhimurium were sent to the Bioinformatics core where they compared the two strains. Their analysis confirmed the results reported by Bacteriology on January 16th, 2020. In addition, the Bioinformatics core used the program 'resFinder' to determine that the only protein difference between the two strains was the presence of the *aminoglycoside 3'-phosphotransferase* gene in the clinical isolate. Furthermore, using BLASTn searching, they discovered that sequences at the 5' edge of the *aminoglycoside 3'-phosphotransferase* gene were homologous to 'Cloning vector pRL446, complete sequence' and at the 3' edge to 'Synthetic construct *Salmonella* virus SopEphi kanamycin cassette insertion derivative'. These results indicated definitively that the post doc was infected by a recombinant strain of *Salmonella* Typhimurium, and given the strains he was known to have been working with, it was likely strain JS107 of genotype *zjg8101::kan*. It should be noted that the *zjg8101::kan* insertion is widely used as a selectable marker when working with recombinant *Salmonella* and is used specifically because it has no known phenotypic effect other than conferring kanamycin resistance.

Summary of Accident Investigation and Corrective Actions

Upon learning about the suspect laboratory acquired illness, the Wadsworth Center Safety Director met with the Lab Director and initiated an investigation on November 6, 2019 where he interviewed both the post doc involved and laboratory supervisor and conducted a review of procedures involving *Salmonella* Typhimurium in the Biosafety Level 2 laboratory. During this meeting the post doc reported that his responsibilities include preparation of *Salmonella* Typhimurium cultures for other staff in the laboratory working on animal studies involving *Salmonella* Typhimurium. Culture preparations are performed on the open laboratory bench adjacent to his computer work station which is designated as a "clean" area. When working with *Salmonella* cultures, the post doc indicated that he is very cautious to avoid spills or generation of aerosols, immediately washes his hands upon removing his gloves, and decontaminates any potentially contaminated work surfaces or equipment with an appropriate disinfectant upon completion of work. However, it was noted that he wears disposable lab gloves when working with infectious cultures on the lab bench but does not wear a laboratory coat unless he is working within the biosafety cabinet (BSC). Additionally, it was noted that he wears disposable gloves while writing notes in his laboratory notebook in between manipulations involving *Salmonella* Typhimurium. These pens are not dedicated to infectious work or disinfected with an appropriate disinfectant after manipulating while wearing disposable gloves and may be reused without gloves at his computer work station directly adjacent to the bench area. Although there is no known exposure event associated with this illness, not routinely wearing lab coats and using the same writing utensils and notebooks outside of designated lab areas have been reported as risk factors

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for exposure in other reports of multistate outbreaks of Salmonella Typhimurium infections linked to various clinical, commercial, and teaching microbiology laboratories.

As noted in above, we learned during the investigation that the *Salmonella* Typhimurium research protocols involved have been reviewed and approved by the Wadsworth Center's Institutional Animal Care and Use Committee (IACUC), but it was not recognized at that time as research subject to the NIH Guidelines and, therefore, was not reviewed by the Institutional Biosafety Committee (IBC).

Has the IBC reviewed this incident?	✖YES ☐NO
Please describe the root cause of this incident:	There is no known root cause associated with this lab-associated illness. However, the employee's reported 1) lack of lab coat usage when manipulating cultures; and 2) common use of writing instruments for both infectious culture work and non-infectious deskwork directly adjacent to laboratory work bench, are both known risk factors for accidental cross-contamination and infection with *Salmonella* Typhimurium.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Corrective actions that were implemented immediately following the accident investigation included:

1. Required use of laboratory coat when manipulating cultures of *Salmonella* Typhimurium at the bench.

2. Use of dedicated pens for infectious work activities that are clearly identified and restricted for infectious work only.

3. Interviews with additional laboratory staff working in same biosafety level 2 laboratory and risk assessment of overall laboratory procedures.

Pending corrective actions include the following:

1. Development of a Laboratory-specific biosafety plan by the Principal Investigator (Due 2/14/20).

2. Training for all laboratory staff on Laboratory-specific biosafety plan (Due 2/28/20).

3. Re-training of Principal Investigator and IACUC members on categories of experiments covered by the NIH Guidelines (Due 2/25/20)

Obtained via FOIA by Judicial Watch Inc.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Hill, David J (HEALTH) <david.hill@health.ny.gov>
Sent: Thursday, January 30, 2020 1:08 PM
To: NIH guidelines
Subject: Incident Report
Attachments: Incident-Report_Salmonella_013020.docx

To whom it may concern,

Please see the attached incident report describing a laboratory acquired infection with recombinant Salmonella. FYI, I called and discussed this incident with Kathryn Harris on 1/28/20. If you have any questions or require additional information, please feel free to contact me by email or at the phone number below.

Thank you.

David Hill
Director of Safety
Wadsworth Center, NYS Department of Health
Room B940, Biggs Laboratory
(518) 473-8034 | david.hill@health.ny.gov
www.wadsworth.org

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, January 31, 2020 11:11 AM
To: Henry, James; NIH guidelines
Cc: Webby, Richard; Potter, Phil; Diaz, Robyn; Marsh, McGehee; Long, Scott; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Possible rDNA Overt Exposure #21889

Dear James Henry,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Henry, James <James.Henry@STJUDE.ORG>
Sent: Thursday, January 30, 2020 3:29 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Webby, Richard <Richard.Webby@STJUDE.ORG>; Potter, Phil <Phil.Potter@STJUDE.ORG>; Diaz, Robyn <Robyn.Diaz@STJUDE.ORG>; Marsh, McGehee <McGehee.Marsh@STJUDE.ORG>; Long, Scott <Scott.Long@STJUDE.ORG>
Subject: Possible rDNA Overt Exposure #21889

To Whom It May Concern:

Please find attached the final incident report regarding a possible rDNA overt exposure involving *ex vivo* transduced murine cells. If you have any questions, please do not hesitate to contact me.

Best regards,
James Henry

James Henry, MBA, RBP
Biological Safety Officer
Alternate Responsible Official Select Agent Program
Environmental Health and Safety
St. Jude Children's Research Hospital
262 Danny Thomas Place, MS# 730

Obtained via FOIA by Judicial Watch Inc.

Memphis, TN 38105
T (901) 595-3250
F (901) 595-3055
james.henry@stjude.org

Email Disclaimer: www.stjude.org/emaildisclaimer
Consultation Disclaimer: www.stjude.org/consultationdisclaimer

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	St. Jude Children's Research Hospital
Date of Report:	January 30, 2020
Reporter name and position:	James Henry, Biological Safety Officer
Telephone number:	(901) 595-3250
Email address:	james.henry@stjude.org
Reporter mailing address:	262 Danny Thomas Place Mail Stop 730 Memphis, TN 38105
Date of incident:	December 31, 2019
Name of Principal Investigator:	Dr. Terrance Geiger
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 6/14/2018
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-3, Section III-D-3-a, and III-E-1
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Primary mouse Arf-/- pre B cells were transduced with MSCV- BCR-ABL-1 to create a murine tumor cell line.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

An ARC technical service technician, while performing routine duties, sustained a needle stick to her left index finger while reaching across another colleague to retrieve gauze. After a thorough investigation, it was determined that the needle involved was possibly contaminated after being used for tail vein injection of primary mouse Arf-/- pre-B cells transduced with MSCV-BCR-ABL-1 gene. Upon realizing what had occurred, she immediately initiated first aid by expressing the blood and scrubbing the area for 15 minutes with soap and water. She entered the information into the electronic event reporting system (EERS), notified her supervisor, and reported to Occupational Health (OH) for further assessment and counseling. The Occupational Health Nurse (OHN) reviewed the information provided in EERS by the technician for accuracy. She then notified the Biological Safety Officer and contacted the Occupational Health Medical Director (OHMD) regarding the exposure. Based on the available information, assessed there to be no clinically meaningful exposure to the research sample. Some of the facts informing the OHMD's decision included 1) There was no active injection of the suspended cells in the syringe during the needle stick. Whatever exposure to the suspended cells would have been to the traces of the sample that may have been on the surface of the small, 25-gauge needle that had also been used to draw up the suspended cells in the syringe; and 2) The needle first pierced the glove the person was wearing and this could have further minimized the chances of any meaningful surface contamination of the needle surface with the suspended cells. After discussing all of this with the technician, the decision was made to do nothing further and the technician was comfortable with the recommendation. Finally, she was instructed to monitor for signs and symptoms of infection at the site of the needle stick over the next few days.

1. The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space). *The location of the event was in Procedural lab E2061.*

2. Who was involved in the incident/violation, including others present at the incident location *An ARC technical service technician, while performing routine duties, sustained a needle stick to her left index finger while reaching across another colleague to retrieve gauze. Also, the incident was witnessed by a postdoc.*

   Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

3. Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event. *Immediate action taken following the incident has been articulated in the brief narrative. The person was seen by the OHN that was in consult with the OHMD who reviewed, evaluated what medical care was immediately warranted based on the agent involved, as well as, additional information that was obtained from the PI.*

4. The training received by the individual(s) involved and the date(s) the training was conducted. *In addition to annual mandatory training, the technician has completed NIH*

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Guidelines training on (1/26/2018), Bloodborne Pathogens and Sharps Policy (12/31/2019), and Technical Services training program (Fall 2016). Also, she has been performing the task for three years.

5. The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation. *The technician did not deviate from the standard practice. The event that occurred was an isolated incident.*

6. Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation. *There were no deviations noted regarding the IBC approved containment level or other IBC approval conditions at the time of the incident other than improper operational workflow.*

7. The personal protective equipment in use at the time of the incident/violation. *The standard PPE that was worn at the time of the event was isolation gown, disposable gloves, dust mask, shoe covers, and eye protection as needed.*

8. The occupational health requirements for laboratory personnel involved in the research. *In the event of an overt exposure, persons are required to immediately render appropriate first aid, notify their supervisor, enter the event into EERS, and report to Occupational Health for further evaluation.*

9. Any medical surveillance provided or recommended after the incident. *This information was articulated in the brief narrative.*

10. Any injury or illness associated with the incident. *The technician has not exhibited any indication of any sequelae.*

11. Equipment failures. *The outcome of this event was not related to equipment failure.*

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Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Workflow issue

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary): *The incident that occurred was an isolated incident. No further action is required.*

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Henry, James <James.Henry@STJUDE.ORG>
Sent: Thursday, January 30, 2020 3:29 PM
To: NIH guidelines
Cc: Webby, Richard; Potter, Phil; Diaz, Robyn; Marsh, McGehee; Long, Scott
Subject: Possible rDNA Overt Exposure #21889
Attachments: rDNA Incident Report Event 21889 31_December_2019.pdf

To Whom It May Concern:

Please find attached the final incident report regarding a possible rDNA overt exposure involving *ex vivo* transduced murine cells. If you have any questions, please do not hesitate to contact me.

Best regards,
James Henry

James Henry, MBA, RBP
Biological Safety Officer
Alternate Responsible Official Select Agent Program
Environmental Health and Safety
St. Jude Children's Research Hospital
262 Danny Thomas Place, MS# 730
Memphis, TN 38105
T (901) 595-3250
F (901) 595-3055
james.henry@stjude.org

Email Disclaimer: www.stjude.org/emaildisclaimer
Consultation Disclaimer: www.stjude.org/consultationdisclaimer

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, February 21, 2020 9:33 AM
To: Stephen Dahl; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Potential exposure to recombinant materials

Dear Dr. Stephen Dahl,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Stephen Dahl <sdahl@jhu.edu>
Sent: Friday, January 31, 2020 11:22 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Potential exposure to recombinant materials

To whom it may concern,

I am writing to report a potential exposure to recombinant DNA as specified in the NIH Guidelines.

The details of the incident are as follows:

On January 9th, 2020 a postdoctoral investigator working in the laboratory of Dr. Paul Worley here at Johns Hopkins was performing microinjections of an adeno-associated viral vector that contained the gene for neuronal pentraxin II (NPTX2) and a fluorescent tag, super-ecliptic pHluorin (SEP), which is a GFP isoform that can be used as a pH sensor due to its ability to fluoresce at higher pH. The concentration of the material was approximately 1x10^9 GC/ml (Genome Copies (GC) per milliliter). The micro injection system uses a glass micropipette to inject material into the brains of mice held in a stereotaxic surgery station. The glass micropipette contained approximately 300 nanoliters (0.3ul) of material at the time of the incident. After injecting a mouse, the investigator accidentally brushed her/his left hand against the pipette resulting in a stick in her/his left ring finger followed by the immediate appearance of blood into the micropipette suggesting a flow of material away from the investigator and into the pipette. This may indicate a minimal exposure to the recombinant viral vector.

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The investigator reported to the Occupational Injury for initial treatment on the day of the injury and continued with the Occupational Injury Clinic to receive follow-up care.

The principal investigator of the laboratory is properly registered with the Biosafety Office and has JH-IBC approval for the use of recombinant materials and AAV-based vectors.

The PPE worn by the investigator at the time of the incident included gloves, lab coat, face mask.

For the record, the JHU IBC requests all viral vector work be performed at BSL2 containment. Although AAV based vectors have been suggested to be acceptable for BSL1 containment practices, the Johns Hopkins Institutional Biosafety Committee has chosen to assign all viral vector usage to BSL2 containment or higher depending on the nature of the insert and overall scientific program. This is because it was felt the wide variety of experiments performed at Johns Hopkins with viral-based vectors makes for potentially confusing situations where one AAV construct in a lab could be handled at BSL1 containment while another in the same lab may require BSL2 containment.

The investigator was re-trained in the proper use of sharps and avoidance of sharps in both experimental setup and manipulation.

Please feel free to contact me if there are any questions or need for clarification.

Steve

Stephen C. Dahl, Ph.D., RBP
Director, Biological Safety
Johns Hopkins University & Medicine

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Stephen Dahl <sdahl@jhu.edu>
Sent: Friday, January 31, 2020 11:22 PM
To: NIH guidelines
Subject: Potential exposure to recombinant materials

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The investigator reported to the Occupational Injury for initial treatment on the day of the injury and continued with the Occupational Injury Clinic to receive follow-up care.

The principal investigator of the laboratory is properly registered with the Biosafety Office and has JH-IBC approval for the use of recombinant materials and AAV-based vectors.

The PPE worn by the investigator at the time of the incident included gloves, lab coat, face mask.

For the record, the JHU IBC requests all viral vector work be performed at BSL2 containment. Although AAV based vectors have been suggested to be acceptable for BSL1 containment practices, the Johns Hopkins Institutional Biosafety Committee has chosen to assign all viral vector usage to BSL2 containment or higher depending on the nature of the insert and overall scientific program. This is because it was felt the wide variety of experiments performed at Johns Hopkins with viral-based vectors makes for potentially confusing situations where one AAV construct in a lab could be handled at BSL1 containment while another in the same lab may require BSL2 containment.

The investigator was re-trained in the proper use of sharps and avoidance of sharps in both experimental setup and manipulation.

Please feel free to contact me if there are any questions or need for clarification.

Steve

Stephen C. Dahl, Ph.D., RBP
Director, Biological Safety
Johns Hopkins University & Medicine

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, May 11, 2020 2:39 PM
To: Kara Drolet; NIH guidelines
Cc: Sarah Byers; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: follow up report from OHSU

Dear Dr. Kara Manning Drolet,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kara Drolet <manningk@ohsu.edu>
Sent: Thursday, April 23, 2020 3:47 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Cc: Sarah Byers <byerssa@ohsu.edu>
Subject: follow up report from OHSU

Hello Dr. Harris,
Please find attached a follow-up report to an issue previously reported to the NIH OSP and let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kara Drolet <manningk@ohsu.edu>
Sent: Thursday, April 23, 2020 3:47 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Sarah Byers
Subject: follow up report from OHSU
Attachments: OHSU Final Report for Section IIIB toxin gene.pdf

Hello Dr. Harris,
Please find attached a follow-up report to an issue previously reported to the NIH OSP and let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

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OHSU

April 23, 2020

Kathryn Harris, Ph.D., RBP
Senior Outreach and Education Specialist
NIH OSP

Institutional Biosafety Committee
Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
ibc@ohsu.edu

Kara M. Drolet, Ph.D.
Associate Vice President
Research Integrity
tel 503 494-6727
manningk@ohsu.edu

Ashlee Moses, Ph.D.
IBC Chair
tel 503 418-2712
mosesa@ohsu.edu

Harjinder Sardar, Ph.D.
OHSU Biosafety Officer
tel 503-346-5028
sardar@ohsu.edu

Sarah Byers, Ph.D.
IBC Program Manager
tel 503 494-9763
byerssa@ohsu.edu

Dear Dr. Harris,

This letter serves as the detailed summary of follow up for a reportable incident that occurred at Oregon Health & Science University (OHSU) that was initially reported to NIH on 2/4/2020.

OHSU IBC registration number	IBC-11-45
OHSU project title	Cloning and production of adeno-associated viral vectors (AAV vectors) by the Molecular Virology Support Core (MVS)
Nature of the material	Helper Free AAV expressing the diphtheria toxin A subunit gene in a Cre dependent fashion
Risk Group	I
Containment level	BSL-2
Nature of the incident	Conduct work prior to IBC approval
PPE in use	Gloves, lab coat, eye protection

Description of incident:

On January 24, 2020, the IBC determined that the campus viral vector core had produced an AAV vector capable of expressing the diphtheria toxin A subunit. This work was conducted without IBC or NIH-OSP approval as required by Section III-B of the NIH Guidelines. The researcher had conducted this work with BSL-2 work practices and containment. While the core had produced the vector, no further work with the vector had been done.

The researcher immediately submitted an amendment to their IBC protocol documenting the production of the helper free AAV vector expressing the diphtheria toxin A subunit gene. The IBC reviewed the revised protocol at its January 27, 2020 IBC meeting and determined the BSL-2 work practices outlined for the work to be appropriate. A request was submitted to NIH-OSP on February 4, 2020 to verify that the IBC recommended containment and work practices were appropriate. NIH-OSP approved this work under Section III-B on

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February 6, 2020 and the OHSU IBC issued approval for this work on February 11, 2020.

Actions taken:

The IBC reviewed the incident and determined that the request form for viral vector production should include additional information for the researchers to identify toxin genes that are subject to Section IIIB of the NIH Guidelines.

The IBC also updated its Toxin Fact Sheet guidance document to identify toxin gene subunits that are known to be subject to Section IIIB and reviewed this revised fact sheet with the investigator.

The IBC has determined that this incident has now been resolved with the submission of this report to OSP.

Sincerely,

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

cc: Debra Brickey, PhD, Research Safety Manager; Dana Director, PhD, OHSU Institutional Official

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 9:05 AM
To: Institutional Biosafety Comm (inbiocom); NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Final Report: Needle Stick

Dear Dr. Marcia Espinola,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Institutional Biosafety Comm (inbiocom) <INBIOCOM@UCMAIL.UC.EDU>
Sent: Friday, February 21, 2020 12:29 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Subject: Final Report: Needle Stick

Dear Dr. Harris,
Please see attached the form with the final report for the 02/04/20 incident.
Please let us know if you need any additional information.
Many thanks,
Marcia

Institutional Biosafety Committee
Marcia Espinola, DVM MS CBSP - **Biosafety Officer**
University of Cincinnati
51 Goodman Drive , University Hall, Suite 540
Mail Location: 0767
Phone (513) 558-6182 or (513) 558-6355
email: inbiocom@ucmail.uc.edu
Biosafety Website

Obtained via FOIA by Judicial Watch Inc.

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Wednesday, February 5, 2020 3:13 PM
To: Institutional Biosafety Comm (inbiocom) <INBIOCOM@UCMAIL.UC.EDU>
Subject: RE: Incident Report: Needle Stick

Thank you for your email. We will await the final report.

Regards,

Dr. Kathryn Harris

From: Institutional Biosafety Comm (inbiocom) <INBIOCOM@UCMAIL.UC.EDU>
Sent: Wednesday, February 5, 2020 2:23 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Dean, Gary (deange) <DEANGE@UCMAIL.UC.EDU>
Subject: Incident Report: Needle Stick

To whom it may concern,

Our office has just received a report about a needle stick incident that happened last night. During our initial investigation, we learned that the accident involved a pantropic gamma-retroviral viral vector expressing an oncogene. The individual involved has been instructed to immediately contact our Occupational Health Department to discuss PEP. We will continue our investigations and will submit our formal report within 30 days from this date.
The incident will be brought tomorrow to the IBC meeting for discussion.

Many thanks,
Marcia

Institutional Biosafety Committee
Marcia Espinola, DVM MS CBSP **- Biosafety Officer**
University of Cincinnati
51 Goodman Drive , University Hall, Suite 540
Mail Location: 0767
Phone (513) 558-6182 or (513) 558-6355
email: inbiocom@ucmail.uc.edu
Biosafety Website

Obtained via FOIA by Judicial Watch Inc.

UNIVERSITY OF Cincinnati

Institutional Biosafety Committee / Biosafety Office

Recombinant or Synthetic Nucleic Acid - Incident Report Form

Does this incident involve research subject to the *NIH Guidelines*?	☒ Yes ☐ No If NO, this form does not apply. Incident does not have to be reported to NIH/OBA.

Institution name	University of Cincinnati
Date of Report	02/21/20
Reporter name and position	Marcia Espinola - Biosafety Officer
Reporter telephone	513-558-6182
Reporter email	espinoma@ucmail.uc.edu
Date of incident	02/04/20
Name of Principal Investigator	Jun-Lin Guan
Is this an NIH funded project?	☒ Yes ☐ No
If yes, please provide:	NIH grant or contract number: 5R01HL073394-15
	NIH funding institute or center NHLBI
	NIH program officer contact information (name, email, etc.) SCHRAMM, CHARLENE A; schrammc@nhlbi.nih.gov
What was the **nature** of the incident?	☒ Personnel exposure ☐ Spill ☐ Loss of transgenic animal ☐ Failure to obtain IBC approval ☐ Failure to follow approved containment conditions ☐ Other – please describe:
Did the Institutional Biosafety Committee (IBC) approve this research?	☒ Yes ☐ No
If yes, please provide:	Approval date: 12/12/19
	Approved biosafety level for the research: BSL2
	Additional approval requirements:IACUC # 13-10-08-02 (N/A to this accident)
What section(s) of the NIH *Guidelines* is the research subject to?	III-D-3-b, appendix B-III-D, appendix G-II-B
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	☐ CDC ☐ USDA ☐ FDA ☐ EPA ☐ OSHA ☐ Research Funding Agency/Sponsor: (name)

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	☐ State/Local Public Health ☐ Federal/State/Local Law Enforcement ☒ Other- please describe: Ohio Bureau of Workers' Compensation
Has the IBC reviewed this incident?	☒ Yes ☐ No If yes, indicate date This incident was reported one day prior to our monthly meeting. Information obtained at the time was shared with the Committee.
Has a root cause for this incident been identified?	☒ Yes ☐ No If yes, please describe:

DESCRIPTION OF INCIDENT:

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. ***Include the following information as applicable.***

- *The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space).*
- *Who was involved in the incident/violation, including others present at the incident location?* ***Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)****.*
- *Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.*
- *The training received by the individual(s) involved and the date(s) the training was conducted.*
- *The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.*
- *Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.*
- *The personal protective equipment in use at the time of the incident/violation.*
- *The occupational health requirements for laboratory personnel involved in the research.*
- *Any medical advice/treatment/surveillance provided or recommended after the incident.*
- *Any injury or illness associated with the incident.*
- *Medical surveillance results (if not available at the time of initial report please indicate when results will be available).*
- *Equipment failures.*

On 02/05/20, the Biosafety Office received a report regarding an accidental exposure involving a needle stick injury.

The accident happened on the night of 02/04 at the PI's laboratory, during the production of the following gamma-retroviral vector: pMSCV-pBABE-IRES-GFP with the mouse IGF2BP3 gene (an oncogene), pseudotyped with the VSV-G envelope. During the accident, the individual was working within a biosafety cabinet wearing gloves and a lab coat. The injured individual completed the UC IBC required Viral Vector training on 05/06/16 and updates the OSHA Blood borne Pathogens training every twelve months.

Please see below the description of the accident provided by the injured individual:

"I had an 8 ml viral medium in a 15 ml tube. I used a 5 ml syringe with a needle to aspirate viral medium for filtering the medium. So I can only filter 5 ml medium at one time. After aspirating medium from the 15 ml tube, I recapped the needle, removed it, and then changed to a 33 mm filter for the syringe to filter viral medium. The needle stick happened when I prepared to filter the remaining viral medium in the tube. During this procedure, I

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detached the filter from the syringe, and re-attached the used needle with a cap, then I needed to remove the cap for aspirating the remaining viral medium in the 15 ml tube. The injury occurred when uncapping the needle attached to the syringe".

Immediately after the accident, the individual washed his injured hand and went to the University Medical Center Emergency Room. In the morning of the following day, the individual consulted with the University Health Services (Employee Health) and initiated Post Exposure Prophylaxis with anti-viral drugs.

During the interview of the Biosafety Officer with the PI and the injured researcher, the PI indicated that the SOP for the viral production does not include how viral supernatant should be collected but was very surprised that his researcher was using needles for that step of the experiment. The Biosafety Officer stressed the importance of refraining from the use of sharps whenever possible and discussed safety procedures while handling needles and other sharps materials.

As an immediate corrective action, beveled needles have been banned for viral vector production experiments. Further, on 02/17, the PI met with his lab staff to review his IBC protocol, and to discuss sharps safety and accident immediate response & reporting procedures.

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Hunter, Renee (NIH/OD) [C]

From: Institutional Biosafety Comm (inbiocom) <INBIOCOM@UCMAIL.UC.EDU>
Sent: Friday, February 21, 2020 12:29 PM
To: NIH guidelines
Cc: Harris, Kathryn (NIH/OD) [C]
Subject: Final Report: Needle Stick
Attachments: Guan - Incident Report Form_filled.pdf

Dear Dr. Harris,
Please see attached the form with the final report for the 02/04/20 incident.
Please let us know if you need any additional information.
Many thanks,
Marcia

Institutional Biosafety Committee
Marcia Espinola, DVM MS CBSP **- Biosafety Officer**
University of Cincinnati
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Phone (513) 558-6182 or (513) 558-6355
email: inbiocom@ucmail.uc.edu
Biosafety Website

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Wednesday, February 5, 2020 3:13 PM
To: Institutional Biosafety Comm (inbiocom) <INBIOCOM@UCMAIL.UC.EDU>
Subject: RE: Incident Report: Needle Stick

Thank you for your email. We will await the final report.

Regards,

Dr. Kathryn Harris

From: Institutional Biosafety Comm (inbiocom) <INBIOCOM@UCMAIL.UC.EDU>
Sent: Wednesday, February 5, 2020 2:23 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Dean, Gary (deange) <DEANGE@UCMAIL.UC.EDU>
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The incident will be brought tomorrow to the IBC meeting for discussion.

Many thanks,

Obtained via FOIA by Judicial Watch Inc.

Marcia

Institutional Biosafety Committee
Marcia Espinola, DVM MS CBSP **- Biosafety Officer**
University of Cincinnati
51 Goodman Drive , University Hall, Suite 540
Mail Location: 0767
Phone (513) 558-6182 or (513) 558-6355
email: inbiocom@ucmail.uc.edu
Biosafety Website

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Harris, Kathryn (NIH/OD) [C]
Sent: Wednesday, February 5, 2020 3:13 PM
To: Institutional Biosafety Comm (inbiocom)
Subject: RE: Incident Report: Needle Stick

Thank you for your email. We will await the final report.

Regards,

Dr. Kathryn Harris

From: Institutional Biosafety Comm (inbiocom) <INBIOCOM@UCMAIL.UC.EDU>
Sent: Wednesday, February 5, 2020 2:23 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Dean, Gary (deange) <DEANGE@UCMAIL.UC.EDU>
Subject: Incident Report: Needle Stick

To whom it may concern,

Our office has just received a report about a needle stick incident that happened last night. During our initial investigation, we learned that the accident involved a pantropic gamma-retroviral viral vector expressing an oncogene. The individual involved has been instructed to immediately contact our Occupational Health Department to discuss PEP. We will continue our investigations and will submit our formal report within 30 days from this date.
The incident will be brought tomorrow to the IBC meeting for discussion.

Many thanks,
Marcia

Institutional Biosafety Committee
Marcia Espinola, DVM MS CBSP - **Biosafety Officer**
University of Cincinnati
51 Goodman Drive , University Hall, Suite 540
Mail Location: 0767
Phone (513) 558-6182 or (513) 558-6355
email: inbiocom@ucmail.uc.edu
Biosafety Website

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Institutional Biosafety Comm (inbiocom) <INBIOCOM@UCMAIL.UC.EDU>
Sent: Wednesday, February 5, 2020 2:23 PM
To: NIH guidelines
Cc: Dean, Gary (deange)
Subject: Incident Report: Needle Stick

To whom it may concern,

Our office has just received a report about a needle stick incident that happened last night. During our initial investigation, we learned that the accident involved a pantropic gamma-retroviral viral vector expressing an oncogene. The individual involved has been instructed to immediately contact our Occupational Health Department to discuss PEP. We will continue our investigations and will submit our formal report within 30 days from this date.
The incident will be brought tomorrow to the IBC meeting for discussion.

Many thanks,
Marcia

Institutional Biosafety Committee
Marcia Espinola, DVM MS CBSP **- Biosafety Officer**
University of Cincinnati
51 Goodman Drive , University Hall, Suite 540
Mail Location: 0767
Phone (513) 558-6182 or (513) 558-6355
email: inbiocom@ucmail.uc.edu
Biosafety Website

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, February 21, 2020 9:34 AM
To: Joseph, Elaine; NIH guidelines
Cc: Calzonetti, Frank; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Subject to NIH Guidelines

Dear Dr. Elaine Joseph,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Joseph, Elaine <Elaine.Joseph@UToledo.Edu>
Sent: Thursday, February 6, 2020 8:49 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Calzonetti, Frank <frank.calzonetti@utoledo.edu>
Subject: Incident Subject to NIH Guidelines

To Whom it May Concern:

Please see the attached Incident Report related to an incident subject to the NIH Guidelines that occurred here at the University of Toledo. If you have any questions, please do not hesitate to contact us.

Thank you,
Elaine

Elaine Joseph, Ph.D.
IACUC/IBC/IRE Project Administrator
Research and Sponsored Programs
2106 CCE / MS 1020
3000 Arlington Ave.
Toledo, Ohio 43614-2598
University of Toledo

Obtained via FOIA by Judicial Watch Inc.

419-383-4251
Elaine.Joseph@utoledo.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Toledo
Date of Report:	February 6, 2020
Reporter name and position:	Frank Calzonetti, Ph.D., Vice President for Research
Telephone number:	419-530-4749
Email address:	frank.calzonetti@utoledo.edu
Reporter mailing address:	University of Toledo 2801 Bancroft St, MS 218 Toledo, OH 43606
Date of incident:	January 7, 2020
Name of Principal Investigator:	Ivana de la Serna
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: (original approval) 6/25/2015
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D1
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Lentivirus

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A post-approval monitoring audit was conducted on January 7, 2020 for the IBC protocol involving the Principal Investigator (PI) and the IBC Project Administrator. At that time, it was discovered that the PI had purchased a lentivirus from a vendor and was using it to transfect human cell lines in the laboratory, without IBC approval. Subsequent discussions with the PI revealed that the work was being conducted according to Biosafety Level 2 conditions within the laboratory.

At the time of the post-approval audit (January 7, 2020), the IBC Project Administrator notified the IBC Chair, Biosafety Officer and Institutional Official of the incident and the IBC Non-compliance. The PI was informed to cease activity and submit an amendment to add the lentivirus work to the IBC protocol.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	The PI inadvertently purchased the lentivirus construct and began work prior to adding this to the IBC via an amendment.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

An email has been drafted and sent to all faculty at the institution reminding them that all recombinant and synthetic nucleic acid molecules require prior approval by the Institutional Biosafety Committee (IBC) before work can commence. Post-approval monitoring audits are ongoing for all protocols and should be completed within the next several months. Finally, the investigator submitted the amendment to add the lentivirus vector to the IBC protocol on January 10, 2020 and it was reviewed and approved on January 16. 2020.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Joseph, Elaine <Elaine.Joseph@UToledo.Edu>
Sent: Thursday, February 6, 2020 8:49 AM
To: NIH guidelines
Cc: Calzonetti, Frank
Subject: Incident Subject to NIH Guidelines
Attachments: Incident Report - February 2020.docx

To Whom it May Concern:

Please see the attached Incident Report related to an incident subject to the NIH Guidelines that occurred here at the University of Toledo. If you have any questions, please do not hesitate to contact us.

Thank you,
Elaine

Elaine Joseph, Ph.D.
IACUC/IBC/IRE Project Administrator
Research and Sponsored Programs
2106 CCE / MS 1020
3000 Arlington Ave.
Toledo, Ohio 43614-2598
University of Toledo
419-383-4251
Elaine.Joseph@utoledo.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:32 AM
To: Rausch, Tamara (Tammy); NIH guidelines
Cc: Corsmo, Jeremy; Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: CCHMC 2/6/2020

Dear Tamara Rausch,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Friday, February 21, 2020 2:10 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Corsmo, Jeremy <Jeremy.Corsmo@cchmc.org>; Waggoner, Stephen <Stephen.Waggoner@cchmc.org>; Gulick, James <James.Gulick@cchmc.org>; Dowdy, Tabitha <Tabitha.Dowdy@cchmc.org>
Subject: CCHMC 2/6/2020

Good afternoon,

Attached is the final report of a needle stick incident that was reported on 2/6/2020. The initial e-mail stated that a researcher was stuck with a used needle after injecting phenobarbital into a DTr transgenic mouse. Upon investigating the incident, pentobarbital was the drug and the mouse was a Slc32a1-2A-FlpO-D knock-in.

Please feel free to contact me with any questions.

Sincerely,
Tammy

Obtained via FOIA by Judicial Watch Inc.

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229
Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Does this incident involve research subject to the *NIH Guidelines*?	✓YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Cincinnati Children's Hospital Medical Center
Date of Report:	2/21/2020
Reporter name and position:	Tamara B. Rausch, Biosafety Officer
Telephone number:	513.636.4843
Email address:	tamara.rausch@cchm .org
Reporter mailing address:	240 Albert Sabin Way MLC7040 Cincinnati, OH 45229
Date of incident:	02/06/2020
Name of Principal Investigator:	Dr. Steve Danzer
Is this an NIH-funded project?	✓YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number: NS065020* *NIH funding institute or center: NINDS* *NIH program officer (name, email address): Miriam Leenders; leenderm@ninds.nih.gov*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill X Other (please describe): Needle stick from a needle that had been used to inject pentobarbital into a knock-in mouse.
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ ✓YES ☐NO If yes, date of approval: 9/12/2017
What was the approved biosafety level of the research?	☐ BL1 ✓BL2 ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-3 III-D-4 III-E-1 III-E-3
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA N/A
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The Slc32a1-2A-FlpO-D knock-in mutation has a T2A sequence and an optimized FLP recombinase (FlpO) gene inserted into the Slc32a1 translational STOP codon - this is designed to have the endogenous promoter/enhancer elements direct FlpO expression to VGAT+ cells. When Slc32a1-2A-FlpO-D mice are bred with mice containing frt-flanked sequences, FlpO-mediated recombination will result in deletion of the frt-flanked sequences in VGAT-expressing cells in the offspring.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
  Vivarium Necropsy Room (R6184-6188)

- Who was involved in the incident/violation, including others present at the incident location?
  Graduate Student - Involved
  Instructor - Present
  Research Assistant - Present
  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
  The graduate student removed her gloves and washed her hands with warm, soapy water for 15 minutes. She then called the institutional safety hotline, 803-SAFE, to report the needle stick.

- The training received by the individual(s) involved and the date(s) the training was conducted. The following trainings were received by the graduate student.

  CCHMC Vivarium Facility Training: 1/07/2020
  CCHMC Biobubble Training: 1/06/2020
  CCHMC Mouse Wet Lab Training (Basic, Intermediate, Advanced Sessions): 1/04/2020
  CCHMC BSL2/ Biosafety Lab Training: 11/19/2019

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation: There were no deviations from the SOPs.

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation: There was no deviation from the IBC approved containment level.

- The personal protective equipment in use at the time of the incident/violation
  The graduate was wearing a disposable gown, surgical mask, and gloves at the time of the incident.

- The occupational health requirements for laboratory personnel involved in the research:
  Personnel working with animals are required to be enrolled in the Medical Surveillance Program for Animal Users. Td booster is recommended every 10 years. Personnel

Obtained via FOIA by Judicial Watch Inc.

working with human derived materials are required to receive the Hepatitis B vaccine series and records are to be kept on file in the employee's medical record.

- Any medical surveillance provided or recommended after the incident: No medical surveillance was recommended after the incident.
- Any injury or illness associated with the incident: The graduate student received a very small puncture wound from the needle stick. No other injury or illness resulted from the stick.
- Equipment failures: There were no equipment failures.

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

The graduate student was euthanizing study animals* with pentobarbital in a standard syringe for perfusion. One mouse had already been injected (IP injection) with 0.7 mL of the pentobarbital. In attempting to inject the second mouse, the mouse struggled aggressively and kicked the syringe, causing an accidental needle stick in the palm just below the thumb of the graduate student's right hand. No pentobarbital was injected into her hand. The graduate student noted she did not feel the prick of the needle. However, she noticed a small drop of blood inside the glove. She immediately removed the gloves realizing there had been an accidental stick, and washed her hands for 15 minutes with warm soapy water. She called the 803-SAFE safety hotline to report the accidental needle stick. No swelling or further bleeding occurred and there were no unusual symptoms present. Follow-ups were conducted via telephone conversation and in person.

*These mice were part of a knock-in line as described previously. The mice had also received intracranial injections of an AAV9 virus for Diphtheria toxin receptors 4 weeks before this event. In addition, the mice had also been injected with Diphtheria toxin for the 9 days before this incident.

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Has the IBC reviewed this incident?	☐ YES ✓ NO The incident will be reviewed at the March 10, 2020 IBC meeting.
Please describe the root cause of this incident:	It was not due to lack of experience as the graduate student has over 4 years of experience including her time at CCHMC and 2 other institutions. The graduate student has only been working with this strain of mice since January 2020. According to the student's PI, this is an aggressive strain. Therefore, it was determined that the graduate student was not comfortable handling these mice. In addition, she did not have a good hold on the mouse when preparing to give the injection of pentobarbital.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The Instructor and Research Assistant will continue to work with the graduate student when working with this particular strain of mice until she feels comfortable handling them on her own.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Friday, February 21, 2020 2:10 PM
To: NIH guidelines
Cc: Corsmo, Jeremy; Waggoner, Stephen; Gulick, James; Dowdy, Tabitha
Subject: CCHMC 2/6/2020
Attachments: CCHMC NIH Incident Report 02062020.pdf

Good afternoon,

Attached is the final report of a needle stick incident that was reported on 2/6/2020. The initial e-mail stated that a researcher was stuck with a used needle after injecting phenobarbital into a DTr transgenic mouse. Upon investigating the incident, pentobarbital was the drug and the mouse was a Slc32a1-2A-FlpO-D knock-in.

Please feel free to contact me with any questions.

Sincerely,
Tammy

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229
Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Thursday, February 6, 2020 4:54 PM
To: NIH guidelines
Cc: Waggoner, Stephen; Gulick, James; Corsmo, Jeremy; Dowdy, Tabitha
Subject: Cincinnati Children's Incident 02/06/2020

Good afternoon,

This is to inform you of an incident that occurred at Cincinnati Children's on the afternoon of February 6, 2020.

A researcher stuck herself with a used needle after injecting phenobarbital into a mouse. The mouse was a DTr transgenic mouse that had been injected four weeks ago with AAV9 and Diphtheria toxin nine days ago.

I will submit a full report upon further investigation.

Please feel free to contact me with any questions.

Sincerely,
Tammy Rausch

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229
Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, April 17, 2020 3:05 PM
To: Woods, James; NIH guidelines
Cc: Sefidvash-Hockley, Sepideh; Kelly FitzGerald; Daniel Kavanagh; Chris Doyle; Karen McCulloch; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Self-Report RE: Incident Subject to the NIH Guidelines for Research Involving rsNA

Dear Dr. James Woods,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Woods, James <JWoods@midwestern.edu>
Sent: Thursday, February 27, 2020 4:10 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Sefidvash-Hockley, Sepideh <ssefid@midwestern.edu>; Kelly FitzGerald <KFitzGerald@wirb.com>; Daniel Kavanagh <dkavanagh@wirb.com>; Chris Doyle <cdoyle@wirb.com>; Karen McCulloch <KMcCulloch@wcgclinical.com>
Subject: Self-Report RE: Incident Subject to the NIH Guidelines for Research Involving rsNA

Hello,

Please see the attached report of an incident subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Best regards,

Jim

James M. Woods, Ph.D.

Director, Office of Research & Sponsored Programs
Professor, Department of Microbiology & Immunology
College of Graduate Studies
Midwestern University

Obtained via FOIA by Judicial Watch Inc.

555 31st Street
Haspel Hambrick Hall, Suite 108
Downers Grove, IL 60515
Phone: (630)515-6173
Fax: (630)515-6430

19555 N. 59th Avenue
Glendale Hall, Suite 201
Glendale, AZ 85308
Phone: (623)572-3444
Fax: (623)572-3498

The information provided in this electronic mail message is confidential information intended only for the use of the individual or entity named above, and may be privileged. If the reader of this message is not the intended recipient or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any use, dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please immediately notify us by telephone at 623-572-3490 and delete the original message.

Obtained via FOIA by Judicial Watch Inc.

MIDWESTERN UNIVERSITY

555 31st Street
Downers Grove, Illinois 60515
630/969-4400

www.midwestern.edu

February 27, 2020

To the NIH Office of Science Policy

RE: Self-Report of Initiated Unapproved Research on Midwestern University's Glendale Campus

Attached is a self-report related to the February 7, 2020 and February 24, 2020 letters sent by Kelly FitzGerald, PhD, the point of contact for Midwestern University's (MWU's) NIH-registered IBC. A self-audit performed on MWU's Glendale campus by our Biosafety Officer resulted in the identification of recombinant or synthetic nucleic acid molecule (rsNA) research subject to *NIH Guidelines* that was initiated without IBC approval. Upon investigating the matter, we have identified 13 PIs with projects that were ongoing in addition to two PIs that initiated and completed projects in the past. All rsNA research on our Glendale campus was halted on January 27, 2020 and will not be allowed to start again until approval for each project is obtained from our NIH-registered IBC.

It is noteworthy that MWU does not engage in human gene therapy research, and that we are not aware of any injuries, illnesses or loss of containment related to this matter. The attached self-report was written to provide general information about the PIs along with more detailed information about the incident and preventive/corrective actions. We deeply regret that this occurred and we believe that the actions taken will ensure that nothing like this will happen again at our institution.

Sincerely,

Redacted by agreement

James M. Woods, Ph.D.

Director, Office of Research & Sponsored Programs
Professor, Department of Microbiology & Immunology
College of Graduate Studies
Midwestern University

555 31st Street
Haspel Hambrick Hall, Suite 108
Downers Grove, IL 60515
Phone: (630)515-6173
Fax: (630)515-6430

19555 N. 59th Avenue
Glendale Hall, Suite 201
Glendale, AZ 85308
Phone: (623)572-3444
Fax: (623)572-3498

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	XYES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Midwestern University Glendale
Date of Report:	02/27/2020
Reporter name and position:	James Woods, PhD; Director, Office of Research and Sponsored Programs (Institutional Official)
Telephone number:	630-515-6173
Email address:	jwoods@midwestern.edu
Reporter mailing address:	Midwestern University 555 31st Street Haspel-Hambrick Hall, Suite 108 Downers Grove, IL 60515
Date of incident:	01/27/2020
Name of Principal Investigator:	15 PIs were involved, 13 had ongoing projects and two had projects that were completed. All rsNA research has been halted until appropriate IBC approval has been obtained.
Is this an NIH-funded project?	X YES NO Two of the 15 PIs had NIH funded projects. If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions X Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES X NO If yes, date of approval:
What was the approved biosafety level of the research?	X BL1 (3 PI's research was BL1; 12 PI's research was BL2) X BL2 ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation.
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The PIs utilize a wide variety of rsNA.

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
    - The location of the incident was in various Midwestern University (MWU) research laboratories, all of which were in our Foothills or Cactus Wren buildings.

- Who was involved in the incident/violation, including others present at the incident location?
    - PIs at MWU initiated research without IBC approval, but the lack of a clear process and dissemination of that process was the responsibility of the Biosafety Committee/Biosafety Officer (BSC/BSO), the IBC and the Institutional Official (IO).

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
    - On January 27, 2020, the same day that studies were confirmed initiated without review, the BSO sent an email titled “URGENT: Stop Research Involving rsNA” to all PIs involved, until MWU and our IBC could ensure that all rsNA research received an appropriate review. In that email, the BSO explained that all research involving rsNA was to be halted immediately in a manner that does not increase risk to MWU researchers, the public, or the environment, until all studies could be reviewed to determine whether they were exempt or non-exempt under *NIH Guidelines*.

- The training received by the individual(s) involved and the date(s) the training was conducted.
    - MWU's Glendale campus adopted CITI Biosafety Training in 2015, which includes modules on human gene transfer and rsNA research under *NIH Guidelines* as part of our initial training.

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation.
    - The research of the 15 PIs involved a variety of SOPs. We are not aware of any deviation from the SOPs.

- Any deviation from the IBC approved containment level or other IBC approval conditions

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at the time of the incident/violation
    - Not applicable.

- The personal protective equipment in use at the time of the incident/violation
    - Not applicable.

- The occupational health requirements for laboratory personnel involved in the research
    - We are not aware of any adverse situations created for lab personnel in any study that was halted. Specifically, we are not aware of any spills, injuries or illnesses related to this incident in any of the labs.

- Any medical surveillance provided or recommended after the incident
    - Not applicable.

- Any injury or illness associated with the incident
    - Not applicable.

- Equipment failures
    - Not applicable.

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

First, please note that Midwestern University does not engage in human gene transfer research and that we have no reason to believe that there have been any injuries, illnesses or loss of containment related to this report.

Midwestern University's (MWU) Biosafety Officer (BSO) performed a self-audit of all research on our Glendale, AZ campus by reviewing lab biosafety record registrations submitted to the Office of Research & Sponsored Programs. The BSO then contacted each PI working with rsNA identified in that audit and requested a summary of their rsNA research. On December 13, 2019, the BSO forwarded those summaries to MWU's NIH-registered IBC requesting a review to determine if they are exempt or non-exempt from *NIH Guidelines*. The IBC presumed these were new projects, but during the course of review, it became concerned that some of them may have already been initiated, because none of the projects had been submitted for IBC review. On 1/23/2020, Daniel Kavanagh, Kelly FitzGerald, Sepideh Hockley, and James Woods met to discuss the research to ascertain whether research requiring IBC review under the *NIH Guidelines* had been initiated without IBC review. Confirmation that some projects requiring IBC review had been initiated without review was sent to the IBC on 01/27/2020.

On January 27, 2020, the same day that studies were confirmed initiated without review, the BSO sent an email titled "URGENT: Stop Research Involving rsNA" to all PIs identified, until MWU and our IBC could ensure that all rsNA research received an appropriate review. In that email, the BSO explained that all research involving rsNA was to be halted immediately in a manner that does not increase risk to MWU researchers, the public, or the environment, until all studies could be reviewed to determine whether they were exempt or non-exempt under *NIH Guidelines*. Researchers were required to acknowledge receipt of the email, indicating that they would halt all rsNA research until our IBC could determine whether the work was exempt or required IBC review and approval. All PIs were cooperative.

Overall, this self-audit identified a number of rsNA studies that ultimately fell into five categories:

1) Approved by our IBC: We identified a PI with an rsNA research project that was approved by our NIH-registered IBC. Since this work was compliant with all regulations, it is not included in the self-report.

2) Not initiated: We identified PIs who intend to use rsNA research in the near future, but no work has been initiated. Each of these is required to seek IBC approval prior to initiation. Since these were not initiated, these PIs are not included in the self-report.

3) Initiated/Exempt: We identified PIs with research projects involving rsNA that were initiated, but after consultation with our NIH-registered IBC, the studies were found to be exempt from the regulations. These are not included in this self-report.

4) Initiated/Non-exempt: We identified 13 PIs with ongoing research projects in this category and we are submitting this self-report to describe the situation to the NIH.

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5) Non-exempt/Completed: MWU identified two PIs with projects that were not-exempt, but initiated, and already completed. We have included information about these two PIs in the self-report.

As requested, the NIH is receiving one self-report describing the incident and the preventive and corrective actions.

Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	We believe there was one main root cause on our Glendale campus that led to this incident, as well as a secondary contributing factor. The root cause was that MWU's biosafety practices and procedures were not disseminated properly to PIs, and we lacked a clear procedure defining when rsNA research required IBC review. A secondary contributing factor was a lack of training and understanding of the extent of rsNA that falls under the regulations requiring IBC review.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

To understand the cause of this issue, our BSO has taken a careful look at our process for evaluation of rsNA research. Additionally, our external IBC made a site-visit to campus and met individually in the labs with 10 faculty members along with the BSO and IO. After that site-visit, the IO and BSO scheduled an additional meeting with one of MWU's newest faculty members and had that PI walk us through our biosafety procedures as they relate to rsNA research so that we might better understand our procedures from the perspective of a PI. This meeting was particularly insightful, as the PI clearly showed us why they thought they complied with all steps required without seeking IBC approval. We believe it is noteworthy that throughout all of these evaluation processes, we failed to identify any of our faculty to be intentionally hiding information or trying to circumvent the review process. Rather, we found confusion about MWU's procedure as it relates to the review of rsNA research, as well as a lack of understanding of what research requires rsNA review by an NIH-registered IBC. In the vast majority of rsNA studies that were initiated, the faculty members were not aware that research protocols needed to be reviewed by the IBC and that their SOP submissions to MWU's Biosafety Committee did not obtain IBC review or approval.

The "take home" message for the IO and BSO was that our procedures were confusing. While the procedures were sufficient for one faculty member to apply and receive IBC approval in advance and for another to hold off rsNA research until receiving IBC approval, most PIs who had submitted protocols to MWU's Biosafety Committee thought that they

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were compliant. MWU's Biosafety Committee handles general lab safety (e.g. provides approvals of biosafety-related SOPs, approval of BSL2 agents and hazardous chemicals, performs annual lab inspections, develops laboratory safety manuals, chemical hygiene plans, safe laboratory practices, compliance with updated Safety Data Sheets, etc.) but is not MWU's NIH-registered IBC.

In short, we recognized a major gap, in that MWU lacked a clear procedure that requires PIs to bring all research involving rsNA forward for review. On February 25, 2020, MWU's Biosafety Committee reviewed and approved a new Standard Operating Procedure (SOP #46) titled "Experiments involving recombinant or synthetic nucleic acid molecules." Attached to the SOP as an appendix is a Disclosure Checklist that guides researchers through the NIH Guidelines and Exemptions and allows them to disclose the scope of their rsNA research making it easier to determine if the study is exempt or non-exempt. The purpose of the new SOP is to clearly define the process for review and approval of research involving rsNA. It states upfront that all work with rsNA molecules at MWU must be submitted to our internal Biosafety Committee and notes that our internal Biosafety Committee acts as a liaison with our partner NIH-registered IBC. We believe that this new SOP #46, as well as heightened awareness of SOP #46 (described below), is a major step forward in preventing a situation such as reported here from happening again on our campus.

To promote awareness of SOP #46, the Vice President for Research and Strategic Initiatives sent an email to all faculty PIs in Glendale with research labs on February 26, 2020, letting them know that this SOP has been approved. Moreover, the email itself also noted as a reminder that no research involving rsNA can be initiated without the approval of our NIH-registered IBC, when determined to be non-exempt. As an additional reminder, a similar note has been prominently placed on the front page of MWU's internal biosafety webpage, where faculty are directed to obtain information related to biosafety at MWU.

By clearly defining MWU's Biosafety Committee role as liaison between PIs and our partner IBC, we believe we have established a mechanism to monitor institutional compliance. We believe that halting all rsNA research certainly caught everyone's attention and raised awareness as well, since all PIs in Glendale who wish to use rsNA are currently in the process of obtaining IBC approval and have not been able to perform rsNA research since January 27, 2020. All researchers have been made aware that IBC approval is needed before rsNA non-exempt research can be initiated.

In addition to the new SOP and awareness campaign of that SOP, we have identified several other checkpoints at which we have improved our practices to ensure that these errors will not be repeated.

a. **Our BSO meets personally with all faculty involved with rsNA research and follows up with an email noting that their research cannot be initiated without prior approval**. An existing practice that we are enhancing is that our BSO currently meets one-on-one with all new PIs prior to allowing research lab ID access. During these meetings, the BSO asks about the use of rsNA, and when appropriate informs the new faculty member verbally that rsNA research requires IBC approval. We believe this is a good practice but we have improved it by now having our BSO follow-up with an email providing the PI SOP #46. The BSO will

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inform the PI that the study abstract related to the rsNA component will be sent to the IBC for determination and review, if needed. At this time, the PI will also be reminded that the rsNA study must not be initiated until he/she has received notification that the IBC has approved the research.

b. **We have added additional information for rsNA research on our BSL-2 SOP**. MWU's BSC has revised its BSL-2 SOP form to include a more complete section of rsNA for PIs to provide a description of their rsNA project, if applicable. We have provided information on *NIH Guidelines* pertaining to rsNA research in this section, and PIs are required to sign a disclosure stating they have read SOP #46 and understand the rsNA component of their project cannot be initiated until they have received notification that the IBC has completed its review.

c. **We review Material Transfer Agreements where rsNA is involved.** A practice that MWU implemented in April of 2019, which helps ensure that we identify potential existing faculty that want to start a new project with rsNAs, is that the BSO is reviewing and approving all Material Transfer Agreements (e.g. plasmids, bacteria, viruses, etc.). We believe that this practice helps ensure that the BSO is aware of and has the opportunity to ask questions about the use of such materials, and it provides another opportunity for the BSO to remind PIs of the requirement for IBC approval, when appropriate. Moving forward, if the use of the materials may require IBC review, the PI will be informed in writing and reminded that they cannot initiate rsNA research with the materials until the IBC has approved.

d. **Our BSO will now review grant application submissions that involve rsNA**. An additional measure we have implemented to ensure rsNA studies are reviewed by an IBC prior to initiation is that the BSO will closely review extramural grant applications and will work with faculty whose study involves rsNA to initiate an IBC review. Faculty are required to disclose rsNA involved research when it is included in a grant application.

e. **We have implemented additional training on rsNA.** We firmly believe that additional training on the topic of rsNA is essential for our faculty, members of our biosafety committee and our IO. On February 19, 2020, during the site visit, Daniel Kavanagh, PhD, Senior Scientific Advisor at WIRB, gave an overview training seminar to the faculty, research staff, BSO and IO on requirements related to rsNA research including examples of experiments involving rsNA that would be exempt and non-exempt from *NIH Guidelines*. There were 28 faculty and staff in attendance, including the BSO, IO and most of the faculty involved with rsNA research; attendance at this seminar was tracked. Dr. Kavanagh will provide MWU a copy of his slides for review by the individuals who were not able to attend, and our BSO will follow-up to ensure that all PIs involved with rsNA research receive this training and that that training is recorded. Our BSO will also ensure that faculty have an opportunity to ask questions in person and we will maintain a “frequently asked questions” sheet to assist faculty who have questions regarding implementation of their research projects.

f. **We now require annual training on rsNA**. In 2015, MWU's Glendale campus adopted CITI Biosafety training which includes modules on human gene transfer

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and rsNA research under *NIH Guidelines*. It is noteworthy that the rsNA training was only required initially, such that at the time of this incident, MWU's Biosafety Committee did not require refresher training on the rsNA component annually. To enhance our training requirements, on February 25, 2020, the MWU Biosafety Committee voted to require annual rsNA training as a part of the annual refresher.

g. **We now provide additional training for our BSO and IO**. Our BSO and IO will participate in a webinar training for IBC members delivered by ABSA International on April 2nd, 2020. Additionally, we will work with ABSA to provide rsNA researcher training for our faculty the next time that an appropriate opportunity becomes available. Our current BSO/Chair of MWU's Biosafety Committee has been serving in this capacity since July 2018 and has been instrumental in identifying compliance gaps within our processes and introducing corrective action. She is a founding member of Arizona Biosafety Alliance, Inc., a regional affiliate of ABSA International, and has served as Treasurer (2012-2015), and President (2016-2017) on the Board of Directors. She has been an active member of ABSA International since 2014 and currently serves on the Publications Committee, International Engagement Committee, and Local Arrangements Committee for the 2020 annual conference. Our current BSO has worked in research administration and the biosafety arena, conducting risk assessments and developing training/compliance programs since 2009.

In summary, MWU deeply regrets that these incidents occurred, as we believe that the root cause was biosafety committee practices and procedures that were not properly disseminated to PIs, and the lack of a clear procedure requiring all rsNA to be reviewed by our IBC. We firmly believe that the combination of our newly approved SOP related to rsNA, the awareness campaign surrounding the new SOP, and the "halt research" notification of rsNA research on campus have made our faculty acutely aware of the need for IBC approval prior to initiating rsNA research. In addition, we believe our enhanced training, including that already performed in this past week, as well as the new annual training refresher requirement and training opportunities that we will make available in the future, are all significant improvements to our program. Finally, we would like to reiterate that while we have come to understand and address some important procedural errors, this incident did not involve any human gene therapy or safety issues resulting in injuries, illnesses or loss of containment to our knowledge. While we believe that we have addressed the issue and now have procedures in place to prevent a repeat incident, we understand that the NIH may have questions or additional recommendations, and we welcome such comments.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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Hunter, Renee (NIH/OD) [C]

From: Woods, James <JWoods@midwestern.edu>
Sent: Thursday, February 27, 2020 4:10 PM
To: NIH guidelines
Cc: Sefidvash-Hockley, Sepideh; Kelly FitzGerald; Daniel Kavanagh; Chris Doyle; Karen McCulloch
Subject: Self-Report RE: Incident Subject to the NIH Guidelines for Research Involving rsNA
Attachments: NIH Self-Report 2-27-20.pdf

Hello,

Please see the attached report of an incident subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Best regards,

Jim

James M. Woods, Ph.D.

Director, Office of Research & Sponsored Programs
Professor, Department of Microbiology & Immunology
College of Graduate Studies
Midwestern University

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Hunter, Renee (NIH/OD) [C]

From: Woods, James <JWoods@midwestern.edu>
Sent: Wednesday, February 26, 2020 11:21 AM
To: NIH guidelines
Subject: Self-Report
Attachments: Signed NIH Letter 02-07-2020.pdf; Signed NIH Letter 02-25-2020.pdf

Hello, my name is James Woods and I'm the Institutional Official for Midwestern University, and I will be submitting a NIH OSP self-report today regarding initiated but unapproved recombinant DNA research on our Glendale campus. NIH OSP received letters on February 7, 2020 and February 24, 2020 from our IBC related to this matter (attached). Our looking into this has revealed a number of research projects that were initiated without IBC approval, where all were related to procedures that were not properly disseminated to PIs by our Biosafety Committee. Our self-report will describe the situation in detail, as well as the preventive and corrective actions that we've taken to prevent something like this from happening again. There are a total of 15 PIs involved, and we are prepared to submit 15 separate self-reports today, all of which have the same incident description and preventive and corrective actions. However, I noticed under the NIH OSP FAQs section that it says "one report for each incident or set of information is generally sufficient." Therefore, I was hoping to speak to someone today, to ensure that we're approaching this properly, regarding whether you would prefer 15 self-reports or one.

Please note that Midwestern University does not engage in human gene therapy research and that we have no reason to believe that there are any injuries, illnesses or loss of containment related to this matter.

I can be reached today at (630)515-6173. Thank you.

Jim

James M. Woods, Ph.D.

Director, Office of Research & Sponsored Programs
Professor, Department of Microbiology & Immunology
College of Graduate Studies
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February 24, 2020

To NIH Office of Science Policy

SUBJECT: Unapproved Research at Midwestern University

This report is a follow-up to my letter of February 7, 2020 (attached). WIRB currently administers the only IBCs registered with NIH on behalf of Midwestern University. One IBC is registered on behalf of the Downer's Grove, IL Campus, and one IBC is registered on behalf of the Glendale, AZ Campus.

As described in the previous letter, WIRB received notice from MWU of probable unapproved research at the Glendale Campus on January 27, 2020. On February 19, 2020 I visited the Glendale campus for a site visit, accompanied by Daniel Kavanagh, PhD, Senior Scientific Advisor at WIRB. The MWU Institutional Official (James Woods) and Biological Safety Officer (Sepideh Hockley) supervised our visit and were present for all faculty interviews. We interviewed approximately 10 MWU faculty members during our visit.

Over the course of the visit we discovered that MWU Glendale has empaneled an alternate biosafety committee, administered by MWU and not registered with the NIH. We discovered that this committee has been reviewing and approving recombinant and synthetic nucleic acid molecule research at MWU for several years without reference to the NIH-registered committee administered by WIRB. Based on our interviews with MWU faculty, we understand that many MWU faculty believed that approval by the alternate biosafety committee was sufficient to ensure compliance with the NIH Guidelines.

We advised Dr. Woods, Ms. Hockley, and all faculty present during our visit that an IBC must be registered with the NIH OSP in order for IBC approval to satisfy the requirements of the NIH Guidelines.

MWU has already instructed all MWU Glendale faculty to halt unapproved nonexempt research with recombinant or synthetic nucleic acid molecules. In recent weeks MWU investigators have submitted many protocols to the WIRB-administered IBC for review and approval, and we expect the IBC to convene a meeting by March 20th to review the unapproved research.

During our visit Mr. Woods affirmed the following:

1) MWU will not resume or initiate any nonexempt research involving recombinant or synthetic nucleic acid molecules until such research receives necessary approvals from an NIH-registered IBC.
2) Mr. Woods prefers to file reports of the unapproved research to OSP separately from this letter and will submit these reports to OSP in a timely manner.
3) Mr. Woods is not aware of any human gene transfer research at MWU.

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4) Mr. Woods is not aware of any injuries, illnesses, or loss of containment associated with recombinant or synthetic nucleic acid molecule research at MWU.
5) MWU intends to register an IBC, to be administered by MWU, with the NIH in the near future. When the new IBC is registered, MWU will request transfer of oversight of some or all recombinant or synthetic nucleic acid molecule research to the locally-administered IBC.

WIRB agrees to cooperate and assist in the safe and orderly transfer of IBC oversight to the MWU-administered IBC.

I am the point of contact for questions of the IBC on this matter. Please direct any questions or notices to me at kfitzgerald@wirb.com or by phone at (360) 252-2578.

Sincerely,

Redacted by agreement

Kelly FitzGerald, PhD
Vice President IRB and IBC Affairs
WCG – WIRB

cc: James Woods PhD, Midwestern University, Glendale
Sepideh Hockley MBA, Midwestern University, Glendale
Kathleen Goeppinger, President and CEO, Midwestern University
Theresa Fossum, Vice President of Research and Strategic Initiatives, Midwestern University

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Hunter, Renee (NIH/OD) [C]

From: Kelly FitzGerald <KFitzGerald@wirb.com>
Sent: Friday, February 7, 2020 6:03 PM
To: NIH guidelines
Cc: Chris Doyle; Karen McCulloch; Daniel Kavanagh; David Forster; 'Woods, James'
Subject: Reporting Incident Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
Attachments: Signed NIH Letter 02-07-2020.pdf

Hello,
Please see the attached preliminary report of an incident subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Best regards,

Kelly FitzGerald, PhD | Vice President IRB and IBC Affairs
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February 7, 2020

To NIH Office of Science Policy

SUBJECT: Report of Probable Unapproved Nonexempt Research

WIRB administers an IBC on behalf of Midwestern University (MWU), Glendale campus. The site does not engage in human gene transfer research.

On January 27, 2020, the MWU BSO, Sepideh Hockley, notified the Chair of the WIRB-administered IBC of probable unapproved nonexempt research involving recombinant or synthetic nucleic acids conducted on the Glendale campus. The IBC is working with the Institutional Official, James Woods PhD, and with Ms. Hockley, to assess and document the full details of this situation.

At this time, we have no reason to believe there have been any injuries, illnesses or loss of containment related to this research. WIRB will work with MWU to ensure proper documentation and inspection of research at MWU Glendale. We will provide a complete report and corrective and preventive action plan to you by February 27, 2020.

I will be the point of contact for questions of the IBC on this matter. Please direct any questions or notices to me at kfitzgerald@wirb.com or by phone at (360) 252-2578.

Sincerely,

Redacted by agreement

Kelly FitzGerald, PhD
Vice President IRB and IBC Affairs
WCG – WIRB

cc: James Woods PhD, Midwestern University, Glendale
Sepideh Hockley MBA, Midwestern University, Glendale

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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:56 AM
To: Zara Llewellyn; NIH guidelines
Cc: Katia Harb; Andre Lieber; Thea L Brabb; Steve Libby; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report - University of Washington

Dear Dr. Zara Llewellyn,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Zara Llewellyn <zaral@uw.edu>
Sent: Friday, February 28, 2020 7:48 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Katia Harb <kharb@uw.edu>; Zara Llewellyn <zaral@uw.edu>; Andre Lieber <lieber00@uw.edu>; Thea L Brabb <thea@uw.edu>; Steve Libby <slibby@uw.edu>
Subject: Incident report - University of Washington

Dear NIH,

Please find attached an incident report involving an employee performing research subjected to the NIH Section III-D guidelines.

Please let me know if you have any questions or need additional information.

Sincerely,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager

Obtained via FOIA by Judicial Watch Inc.

Alternate Responsible Official
Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
Direct: 206.221.2676 | Main: 206.221.7770 | Fax: 206.221.3068
zaral@uw.edu | www.ehs.washington.edu

UNIVERSITY of WASHINGTON

This information is intended for the individual named above. If you are not the intended recipient, any disclosure, copying, distribution, or use of the contents of this information is prohibited. Please notify the sender by reply email and then destroy all copies of the message and any attachments.

The above email may contain patient identifiable or confidential information. Because email is not secure, please be aware of associated risk of email transmission. If you are a patient, communication to a UW Medicine (or applicable) Provider via email implies your agreement to email communication; see http://uwmedicine.washington.edu/Global/Compliance/Pages/Notice-Of-Privacy-Practices.aspx .

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Washington
Date of Report:	February 28,2020 First reported via email to NIH on February 7,2020
Reporter name and position:	Zara Llewellyn, PhD, RBP Assistant Director for Research and Occupational Safety
Telephone number:	206-221-2676
Email address:	zaral@uw.edu
Reporter mailing address:	University of Washington Environmental Health and Safety Department Research and Occupational Safety Section 1705 NE Pacific Street T287 UW Box 357165 Seattle, WA 98195-7165
Date of incident:	February 6, 2020
Name of Principal Investigator:	Andre Lieber, MD, PhD
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* NIH R01HL141781 *NIH funding institute or center:* NHLBI *NIH program officer (name, email address):* Qasba, Pankaj, qasbap@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: February 20, 2019.
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☒OSHA: Reported on Institution's OSHA log.
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The recombinant is a gutless human adenovirus based on serotype 5 and containing chimeric Ad35 fibers. The vector expressed a human factor VIII from an erythroid specific promoter.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On February 6, 2020 a research scientist was handling a male C57BL/6 mouse that had been inoculated on December 13, 2019 with bone marrow lineage-negative cells after lethal irradiation. The lineage negative cells were harvested from a mouse at week 16 after a gutless adenovirus injection. The gutless human adenovirus contains chimeric Ad35 fibers expressing the human factor VIII from an erythroid specific promoter. The expression of FVIII in secondary recipients is not known to have biological effects.

The mouse was located in a BSL-2 animal laboratory vivarium at the University of Washington. The scientist was handling the mouse to perform a clinical exam and to trim the toe nails. The mouse had dermal lesions on the back, shoulders, and head. It was housed with five mice in the cage, of which three mice presented lesions. The mouse's left eye was dried shut from discharge. While scruffing the neck of the mouse lightly, the research scientist went to touch the eye and the mouse bit the scientist on the thumb side of the right index finger near the first knuckle. The scientist was wearing standard personal protective equipment that included facility scrubs, laboratory gown, nitrile gloves (single pair), dedicated facility shoes, and hair bonnet.

The scientist noticed a small amount of blood from the site of the wound. The scientist removed the gloves and washed the hands with soap and water for approximately 15 minutes. The employee followed up with the University Employee Health Clinic the following day on February 7, 2020 for medical counseling and monitoring.

The scientist had completed the following training:

Course	Completion Date	Expiration Date
Animal Technician Sick Animal Recognition & Reporting	6/10/2005	
Lab-Managed Sick Rodent Recognition	6/15/2005	
Mouse Hands-On Laboratory	9/23/2010	
Orbital Bleed, Mouse Anesthetized	12/21/2005	
Orbital Injection, Mouse Anesthetized	12/21/2005	
Animal Use Laws & Regulations	3/13/2018	3/13/2023
*Biosafety for animal handlers	7/30/2015	7/30/2018
Occupational health for animal handlers	7/30/2015	

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*The scientist will be taking the biosafety for animal handler's course as the current training has expired.

Has the IBC reviewed this incident?	☒YES ☐NO The incident was reviewed at the February 19, 2020 IBC meeting.
Please describe the root cause of this incident:	The mouse was not restrained properly and securely enough to perform a clinical exam on the left eye of the mouse.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The research scientist will not be performing an eye exam with the same clinical signs and symptoms on a mouse without properly scruffing and securing the hold on the mouse; or the research scientist will use a device, such as a cotton swab or similar device to prevent the person's finger from being in close proximity to the mouse's eye or mouth.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Zara Llewellyn <zaral@uw.edu>
Sent: Friday, February 28, 2020 7:48 PM
To: NIH guidelines
Cc: Katia Harb; Zara Llewellyn; Andre Lieber; Thea L Brabb; Steve Libby
Subject: Incident report - University of Washington
Attachments: NIH incident report_UW_Lieber_Feb_2020.pdf

Dear NIH,

Please find attached an incident report involving an employee performing research subjected to the NIH Section III-D guidelines.

Please let me know if you have any questions or need additional information.

Sincerely,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager
Alternate Responsible Official
Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
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zaral@uw.edu | www.ehs.washington.edu

UNIVERSITY of WASHINGTON

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Zara Llewellyn <zaral@uw.edu>
Sent: Friday, February 7, 2020 8:14 PM
To: NIH guidelines
Cc: Zara Llewellyn
Subject: Incident Involving Recombinant Nucleic Acid at University of Washington

Dear NIH,

This message is to inform you that a laboratory worker experienced an injury while working with recombinant nucleic acid on February 6, 2020.

We will be investigating the incident and submitting a formal report to the NIH.

Please let me know if you have any questions before then.

Thank you,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager
Alternate Responsible Official
Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
Direct: 206.221.2676 | Main: 206.221.7770 | Fax: 206.221.3068
zaral@uw.edu | www.ehs.washington.edu

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, February 21, 2020 10:11 AM
To: Matt Anderson; NIH guidelines
Cc: Shi-Hua Xiang; Amit Mitra; Dan Hoyt; Clayton Kelling; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report of Non-compliance at UNL

Dear Dr. Matthew Anderson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Matt Anderson <manderson11@unl.edu>
Sent: Wednesday, February 12, 2020 2:48 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Shi-Hua Xiang <sxiang2@unl.edu>; Amit Mitra <amitra1@unl.edu>; Dan Hoyt <dhoyt2@unl.edu>; Clayton Kelling <ckelling1@unl.edu>
Subject: Report of Non-compliance at UNL

Office of Science Policy,

Please find attached to this email a report of non-compliance with the NIH Guidelines related to work being conducted without approval by the IBC.

Please contact me if further information is required or with questions/comments.

Sincerely,

Matt

Obtained via FOIA by Judicial Watch Inc.

IN OUR GRIT, OUR GLORY.

Matthew A. Anderson, PhD, RBP(ABSA), CBSP(ABSA)
Biosafety Officer/ARO
University of Nebraska–Lincoln
Environmental Health & Safety
3630 East Campus Loop
Lincoln, NE 68583-0824
manderson11@unl.edu
Tel: 402.472.9554
Fax: 402.472.9650

"Wisdom is not a product of schooling but of the lifelong attempt to acquire it." — Albert Einstein

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☑YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Nebraska, Lincoln
Date of Report:	February 11, 2020
Reporter name and position:	Matthew Anderson, Biosafety Officer
Telephone number:	402-742-9554
Email address:	manderson11@unl.edu
Reporter mailing address:	3630 East Campus Loop Lincoln, NE 68588-0824
Date of incident:	Incident discovered on 2/5/2020, upon interview with the PI, the work started in March 2018.
Name of Principal Investigator:	Shi-Hua Xiang
Is this an NIH-funded project?	☑YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* 1 R21 AI126299-01A1 *NIH funding institute or center:* DHHS-NIAID *NIH program officer (name, email address):* Michael W. Fato (michael.fato@nih.gov) *Program Official:* Patricia Repik (prepik@nsaid.nih.gov)

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☑ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES ☑ NO If yes, date of approval: IBC will review the research at the scheduled meeting in March 2020.
What was the approved biosafety level of the research?	☐ BL1 ☑ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-E-1
Has a report of this incident been made to other agencies? If so, please indicate No report has been made to other agencies	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	HIV-1 derived genes in a plasmid (pSG3Δenv or pNL4-3-Luc-R-E) were used and co-injected into a HEK-293 cell with a pcDNA3.1 plasmid containing Marburg virus envelope glycoprotein M78. This resulted in production of HIV virions pseudotyped with GP M78 on the surface and no transgene cargo. The virions were used in experiments testing novel peptide inhibitors of viral entry.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

In November 2017, Dr. Xiang was approved by the institutional IBC for work to create a pseudotyped HIV virus containing the Ebola virus glycoprotein using the plasmids indicated above in this document. It was proposed that this pseudovirus would be produced in HEK-293T cells for subsequent viral entry inhibition experiments *in-vitro*.

Following a Pathogen Inventory review in on Feb 5th, 2020, creation of an HIV pseudovirus containing the Marburg GP was discovered and confirmed. The PI was **not** approved for experiments with the Marburg envelope GP. An email was immediately sent to the PI requesting cessation of the unapproved work pending submission of an amended IBC protocol.

All pseudotyping experiments were performed at the UNL laboratory of Dr. Xiang, under approved BSL-2 containment. His graduate students assisted with pseudovirus production. These experiments began in March 2018 and continued until enough virions were created to complete the inhibition experiments.

Dr. Xiang received NIH Guidelines training in 2012 in addition to refresher training in 2018 and 2019.

Dr. Xiang submitted an updated amendment on 2-5-2020 that included the Marburg env GP gene and the experiments described above. This work will be reviewed by the IBC at the March 9th IBC meeting.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☑YES ☐NO
Please describe the root cause of this incident:	PI was not aware that all new genes of interest to be used in recombinant experiments must be registered with the IBC, even if they are related by taxonomic family.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As mentioned above, the PI has already submitted an amendment to his IBC protocol to cover the work.

PI was provided refresher training about research under the purview of the IBC, protocol maintenance, sections of the NIH guidelines that require IBC approval prior to initiation and non-compliance policy on 6/18/2019.

The IBC was notified of the non-compliance at the February 10, 2020 meeting and the committee determined that the PI will be required to complete the full EHS Biosafety Research Compliance training module by Feb 18, which covers the above topics in more detail and also outlines Roles and Responsibilities.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Matt Anderson <manderson11@unl.edu>
Sent: Wednesday, February 12, 2020 2:48 PM
To: NIH guidelines
Cc: Shi-Hua Xiang; Amit Mitra; Dan Hoyt; Clayton Kelling
Subject: Report of Non-compliance at UNL
Attachments: Xiang non-compliance HIV Marburg GP pseudovirus 2020.docx

Office of Science Policy,

Please find attached to this email a report of non-compliance with the NIH Guidelines related to work being conducted without approval by the IBC.

Please contact me if further information is required or with questions/comments.

Sincerely,

Matt

IN OUR GRIT, OUR GLORY.

Matthew A. Anderson, PhD, RBP(ABSA), CBSP(ABSA)
Biosafety Officer/ARO
University of Nebraska–Lincoln
Environmental Health & Safety
3630 East Campus Loop
Lincoln, NE 68583-0824
manderson11@unl.edu
Tel: 402.472.9554
Fax: 402.472.9650

"Wisdom is not a product of schooling but of the lifelong attempt to acquire it." — Albert Einstein

Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Rengarajan, Kalpana; NIH guidelines
Cc: Lyon III, G Marshall; Thomaston, Scott W; Lawley, John; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report
Date: Friday, March 27, 2020 4:07:04 PM

Dear Dr. Kalpana Rengarajan,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Rengarajan, Kalpana <krengar@emory.edu>
Sent: Wednesday, March 11, 2020 4:34 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; Lyon III, G Marshall <gmlyon@emory.edu>; Thomaston, Scott W <scott.thomaston@emory.edu>; Lawley, John <jlawley@emory.edu>
Subject: Incident report

Good afternoon. Please find attached a detailed incident report. The initial report was sent on 2/13/2020. Please contact me if you have any questions.

With regards
Kalpana

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office

Obtained via FOIA by Judicial Watch Inc.

1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

You may visit www.ehso.emory.edu for updated information.

From: Rengarajan, Kalpana
Sent: Thursday, February 13, 2020 12:11 PM
To: NIHGuidelines@od.nih.gov
Cc: HarrisKath@mail.nih.gov; Lyon III, G Marshall <gmlyon@emory.edu>; Thomaston, Scott W <scott.thomaston@emory.edu>
Subject: RE: Incident report

This is to report that there was a spill of HeLa derived cell-line (TZM-GFPs) infected with HIV at BSL2+ . A detailed report will be sent within 30 days.

Thank you
Kalpana

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

You may visit www.ehso.emory.edu for updated information.

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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

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Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

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A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Emory University
Date of Report:	Initial Report: 2/13/2020 Detailed Report: 3/12 /2020
Reporter name and position:	Kalpana Rengarajan Director Research Safety/Biosafety Officer
Telephone number:	404-727-8863
Email address:	krengar@emory.edu
Reporter mailing address:	1762 Clifton Road Suite 1200 Atlanta, GA 30322
Date of incident:	2/11/20
Name of Principal Investigator:	Dr. Stefan Sarafianos
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* NIH R01 AI076119, R01 AI120860, R01 AI121315, R01 GM118012, U54 AI150472, R01 AI148382, R01 AI146017 *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☒Spill ☐Other (please describe): The student accidentally dropped a 96 well plate in the BSL2+ as she was trying to put it back into the incubator after reading the plate on the bench. It fell on the floor, the lid came off and contents spilled on the floor. The culture spilled contained HeLa derived cell-line (TZM-GFPs) infected with HIV adapted strain NL43 (MOI approx 0.05).
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 12/13/2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	• Section III-A-1 • Section III-D-1 • Section III-D-2 • Section III-D-3 • Section III-E • Section III-E-1 • Section III-F-1

Obtained via FOIA by Judicial Watch Inc.

	• Section III-F-2 • Section III-F-3 • Section III-F-5 • Section III-F-8
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA **Not applicable**
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The culture spilled contained HeLa derived cell-line (TZM-GFPs) infected with HIV adapted strain NL43 (MOI approximately 0.05).

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
  Lab
- Who was involved in the incident/violation, including others present at the incident location?
  Graduate student

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event

Obtained via FOIA by Judicial Watch Inc.

The student cleaned the spill, notified her supervisor and a colleague who came in to check on the spill clean-up. Student informed Biosafety office and filed an incident report.

- The training received by the individual(s) involved and the date(s) the training was conducted
  - Research Lab Safety training completed on 8/6/2019
  - Blood borne pathogen training completed on 8/6/2019
  - Biosafety Training completed on 8/19/2019
  - BSL2 Enhanced training completed on 12/12/2019

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
  No

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
  No

- The personal protective equipment in use at the time of the incident/violation

  Gown, double gloves, booties, goggles, mask

- The occupational health requirements for laboratory personnel involved in the research
  No

- Any medical surveillance provided or recommended after the incident
  No

- Any injury or illness associated with the incident
  No

- Equipment failures **No**

DESCRIPTION OF INCIDENT: (use additional space as necessary)

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)

Obtained via FOIA by Judicial Watch Inc.

The student accidentally dropped a 96 well plate in the BSL2+ as she was trying to put it back into the incubator after reading the plate on the bench. It fell on the floor, the lid came off and contents spilled on the floor. The culture spilled contained HeLa derived cell-line (TZM-GFPs) infected with HIV adapted strain NL43 (MOI approx 0.05). The incubator is at eye level and the shelf where it would have been placed is below eye level. There were no trip hazards. The student picked it up, and put the plate in a bucket of bleach and followed the BSL2+ spill protocol. Although the contents did not visibly spill on her PPE, she removed all PPE (gown, double gloves, booties, goggles, mask), and donned a new set. She placed bleach (undiluted) soaked paper towels down over the spilled media. The contact time was 30 minutes. Contaminated paper towels were disposed of into the biohazard waste bin. A second wipe of the floor and immediate areas was conducted with cavicide. Then the student removed her PPE and disposed of in the biohazardous waste. The student notified her supervisor and a colleague who came in to check on the spill clean- up. The student described that she has experience doing this experiment, that particular day she was reading eight plates, each plate is read by the machine for about 20 minutes, the plate that spilled was plate #6.

Has the IBC reviewed this incident?	☐YES ☒NO will be presented on March 12th, 2020 Meeting
Please describe the root cause of this incident:	Loss of focus on the task at hand

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary)

1. Consider running experiments with less number of plates
2. Revise Safety SOP for the BSL2+ to include a reference for transferring tissue culture plates between incubator and plate reader. Discuss this step with other users so they are aware that culture plates may be dropped.
3. Consider carrying and storing cultures (e.g., bottles and plates) in racks and spill-proof containers (to prevent dropping and breakage).

Obtained via FOIA by Judicial Watch Inc.

Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

From: Rengarajan, Kalpana
To: NIH guidelines
Cc: Harris, Kathryn (NIH/OD) [C]; Lyon III, G Marshall; Thomaston, Scott W; Lawley, John
Subject: Incident report
Date: Wednesday, March 11, 2020 4:34:34 PM
Attachments: rDNA_Incident_Dr Sarafianos_2020.pdf

Good afternoon. Please find attached a detailed incident report. The initial report was sent on 2/13/2020. Please contact me if you have any questions.

With regards
Kalpana

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

You may visit www.ehso.emory.edu for updated information.

From: Rengarajan, Kalpana
Sent: Thursday, February 13, 2020 12:11 PM
To: NIHGuidelines@od.nih.gov
Cc: HarrisKath@mail.nih.gov; Lyon III, G Marshall <gmlyon@emory.edu>; Thomaston, Scott W <scott.thomaston@emory.edu>
Subject: RE: Incident report

This is to report that there was a spill of HeLa derived cell-line (TZM-GFPs) infected with HIV at BSL2+ . A detailed report will be sent within 30 days.

Thank you
Kalpana

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Emory University
Date of Report:	Initial Report: 2/13/2020 Detailed Report: 3/12 /2020
Reporter name and position:	Kalpana Rengarajan Director Research Safety/Biosafety Officer
Telephone number:	404-727-8863
Email address:	krengar@emory.edu
Reporter mailing address:	1762 Clifton Road Suite 1200 Atlanta, GA 30322
Date of incident:	2/11/20
Name of Principal Investigator:	Dr. Stefan Sarafianos
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* NIH R01 AI076119, R01 AI120860, R01 AI121315, R01 GM118012, U54 AI150472, R01 AI148382, R01 AI146017 *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☒Spill ☐Other (please describe): The student accidentally dropped a 96 well plate in the BSL2+ as she was trying to put it back into the incubator after reading the plate on the bench. It fell on the floor, the lid came off and contents spilled on the floor. The culture spilled contained HeLa derived cell-line (TZM-GFPs) infected with HIV adapted strain NL43 (MOI approx 0.05).
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 12/13/2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	• Section III-A-1 • Section III-D-1 • Section III-D-2 • Section III-D-3 • Section III-E • Section III-E-1 • Section III-F-1

Obtained via FOIA by Judicial Watch Inc.

	• Section III-F-2 • Section III-F-3 • Section III-F-5 • Section III-F-8
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA **Not applicable**
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The culture spilled contained HeLa derived cell-line (TZM-GFPs) infected with HIV adapted strain NL43 (MOI approximately 0.05).

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
  Lab
- Who was involved in the incident/violation, including others present at the incident location?
  Graduate student

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event

Obtained via FOIA by Judicial Watch Inc.

The student cleaned the spill, notified her supervisor and a colleague who came in to check on the spill clean-up. Student informed Biosafety office and filed an incident report.

- The training received by the individual(s) involved and the date(s) the training was conducted
  - Research Lab Safety training completed on 8/6/2019
  - Blood borne pathogen training completed on 8/6/2019
  - Biosafety Training completed on 8/19/2019
  - BSL2 Enhanced training completed on 12/12/2019

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
  No

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
  No

- The personal protective equipment in use at the time of the incident/violation

  Gown, double gloves, booties, goggles, mask

- The occupational health requirements for laboratory personnel involved in the research
  No

- Any medical surveillance provided or recommended after the incident
  No

- Any injury or illness associated with the incident
  No

- Equipment failures **No**

DESCRIPTION OF INCIDENT: (use additional space as necessary)

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)

Obtained via FOIA by Judicial Watch Inc.

The student accidentally dropped a 96 well plate in the BSL2+ as she was trying to put it back into the incubator after reading the plate on the bench. It fell on the floor, the lid came off and contents spilled on the floor. The culture spilled contained HeLa derived cell-line (TZM-GFPs) infected with HIV adapted strain NL43 (MOI approx 0.05). The incubator is at eye level and the shelf where it would have been placed is below eye level. There were no trip hazards. The student picked it up, and put the plate in a bucket of bleach and followed the BSL2+ spill protocol. Although the contents did not visibly spill on her PPE, she removed all PPE (gown, double gloves, booties, goggles, mask), and donned a new set. She placed bleach (undiluted) soaked paper towels down over the spilled media. The contact time was 30 minutes. Contaminated paper towels were disposed of into the biohazard waste bin. A second wipe of the floor and immediate areas was conducted with cavicide. Then the student removed her PPE and disposed of in the biohazardous waste. The student notified her supervisor and a colleague who came in to check on the spill clean- up. The student described that she has experience doing this experiment, that particular day she was reading eight plates, each plate is read by the machine for about 20 minutes, the plate that spilled was plate #6.

Has the IBC reviewed this incident?	☐YES ☒NO will be presented on March 12th, 2020 Meeting
Please describe the root cause of this incident:	Loss of focus on the task at hand

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary)

1. Consider running experiments with less number of plates
2. Revise Safety SOP for the BSL2+ to include a reference for transferring tissue culture plates between incubator and plate reader. Discuss this step with other users so they are aware that culture plates may be dropped.
3. Consider carrying and storing cultures (e.g., bottles and plates) in racks and spill-proof containers (to prevent dropping and breakage).

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Obtained via FOIA by Judicial Watch Inc.

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If you have received this message in error, please contact the sender by reply e-mail message and destroy all copies of the original message (including attachments).

Obtained via FOIA by Judicial Watch Inc.

From: Rengarajan, Kalpana
To: NIH guidelines
Cc: Harris, Kathryn (NIH/OD) [C]; Lyon III, G Marshall; Thomaston, Scott W
Subject: RE: Incident report
Date: Thursday, February 13, 2020 12:11:08 PM

This is to report that there was a spill of HeLa derived cell-line (TZM-GFPs) infected with HIV at BSL2+ . A detailed report will be sent within 30 days.

Thank you
Kalpana

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

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If you have received this message in error, please contact the sender by reply e-mail message and destroy all copies of the original message (including attachments).

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, February 21, 2020 9:42 AM
To: Tower, Nichole A.; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: OSP Incident Report 12FEB2020

Dear Nichole Tower,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Tower, Nichole A. <ntower@southernresearch.org>
Sent: Friday, February 14, 2020 10:25 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: OSP Incident Report 12FEB2020

Good Morning,
Please find attached to this email for a potential OSP reportable event. If you have any additional questions or concerns, please contact me.
Thank you,
Nichole

Nichole A. Tower
Corporate Biosafety Officer, EHS, ARO
2000 Ninth Ave. South
Birmingham, AL 35205
205-581-2341 office
Redacted by agreement mobile

Obtained via FOIA by Judicial Watch Inc.

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Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Southern Research
Date of Report:	12 Feb 2020
Reporter name and position:	Steven Orr, Mgr Biosafety & Compliance, Responsible Official, Nichole Tower, Corporate Biosafety Officer, Alternate Responsible Official, IBC Chair Jeremy Miller, EHS Operations Leader
Telephone number:	205-581-2203 (Steven Orr) 205-581-2341 (Nichole Tower) 301-228-2175 (Jeremy Miller)
Email address:	sorr@southernresearch.org ntower@southernresearch.org jmiller@southernresearch.org
Reporter mailing address:	2000 Ninth Ave. South Birmingham, AL 35205
Date of incident:	12 February 2020
Name of Principal Investigator:	Raj Kalkeri, PhD, MBA
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:*

Obtained via FOIA by Judicial Watch Inc.

	NIH funding institute or center: *NIH program officer (name, email address):*

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 11 April 2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-2 and III-D-3
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in	*AAV-HBV (Adeno-associated virus Hepatitis B virus)*

Obtained via FOIA by Judicial Watch Inc.

incident (strain, attenuation, etc.)	

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
  - ABSL-2

- Who was involved in the incident/violation, including others present at the incident location?
  - Female Senior In Vivo Technician
  - Male Associate In Vivo Technician

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.

  - The employee scrubbed the area of the bite with a chlorhexidine scrub brush for approximately 15 minutes and called EH&S for guidance. At which point the employee evacuated the area and proceeded to seek medical evaluation at occupational health clinic (Frederick Health Employer Solutions).

- The training received by the individual(s) involved and the date(s) the training was conducted
  - Refresher training on submandibular blood collection on 5/12/19
  - Bloodborne Pathogen Awareness Training on 6/19/19
  - Viral Vectors Safety Training on 6/20/19

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation

Obtained via FOIA by Judicial Watch Inc.

- There was no deviation from SOPs or training at the time of the incident.

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
  - The work that was being conducted as it had been approved by the IBC on the 11 April 2019.

- The personal protective equipment in use at the time of the incident/violation
  - The following PPE was being used at the time of the incident: Shoe covers, Tyvek coveralls, hair bonnet, safety glasses, splash shield, 2 pairs of gloves, and a N95 mask.

- The occupational health requirements for laboratory personnel involved in the research -
  - HBV vaccination and yearly medical surveillance for work in ABSL-2.

- Any medical surveillance provided or recommended after the incident –
  - A follow up appointment is scheduled for Friday (14Feb 2020), but there was no treatment provided by the Occupational Health Clinic.

- Any injury or illness associated with the incident
  - To date, there has been no illness reported.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On 12 February 2020, Southern Research (SR) employee A and another SR employee B were conducting routine blood collections as part of a recombinant hepatitis B virus antiviral study. Employee A was attempting to stop a mouse from bleeding after a submandibular blood collection in the A/BSL2 by applying gauze to the area and was bitten by the mouse that had been treated with recombinant. The employees followed the SR First Aid Instructions for Biological Exposure and immediately began scrubbing the area with a chlorohexidine scrub brush for 15 minutes and called EHS for additional guidance. Employee A was instructed to seek medical evaluation at Occupational Health Clinic. The employee was up to date on the medical surveillance and had previously received the Hepatitis B vaccination series which when tested had a positive titer. Therefore, there was no additional follow-up medical treatment provided at the Occupational Health Clinic at the time of the incident and Employee A was cleared to perform all job functions after a follow-up appointment effective 14 February 2020.

Obtained via FOIA by Judicial Watch Inc.

Employee A followed SOPs and training procedures for the submandibular mouse bleed as well as the follow-up response for first aid instructions for biological exposure incidents. Employee A, as do all of the animal care technicians, receive initial and on-going training for procedures. The submandibular bleeding refresher training that employee A received had last been conducted on 12 May 2019. Additional refresher safety trainings include Bloodborne Pathogen Awareness Training on 19 June 2019 and Viral Vector Safety Training on 20 June 2019.

The study that the mouse was assigned to had received a tail vein injection of Adeno-Associated Vector Hepatitis B Virus (AAV-HBV). This model is used to evaluate antivirals or therapeutics for Hepatitis B. Submandibular or retro orbital blood collection occurs every three days to measure HBV replication via serum antigen levels. The bite occurred at Day 14 of the study and the likelihood of the presence of the recombinant material still circulating in the bloodstream of the mouse and being transmitted to employee A is negligible.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	The employee was providing animal care to stop bleeding with a piece of gauze and her finger was within reach of the mouse to bite. As a follow-up preventative measure, it has been determined that forceps will be used to apply gauze and light pressure to minimize bleeding.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

It has been recommended to use forceps or an instrument to hold the gauze next to the bleed site of the mouse in the future.

Obtained via FOIA by Judicial Watch Inc.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Tower, Nichole A. <ntower@southernresearch.org>
Sent: Friday, February 14, 2020 10:25 AM
To: NIH guidelines
Subject: OSP Incident Report 12FEB2020
Attachments: OSP Incident Report 12FEB2020.docx

Good Morning,
Please find attached to this email for a potential OSP reportable event. If you have any additional questions or concerns, please contact me.
Thank you,
Nichole

Nichole A. Tower
Corporate Biosafety Officer, EHS, ARO
2000 Ninth Ave. South
Birmingham, AL 35205
205-581-2341 office
Redacted by agreement mobile

Confidentiality Notice · The information contained in this communication and its attachments is intended solely for the use of the individual to whom it is addressed and may contain information that is legally privileged, confidential, or exempt from disclosure. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication and its attachments is strictly prohibited. If you have received this communication in error, please notify Southern Research at postmaster@southernresearch.org or (205) 581-2999, and immediately delete the communication and its attachments permanently without retaining any copies. Thank you.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 10:17 AM
To: Marketon, Melanie; NIH guidelines
Cc: Parkison, Valerie; cthorpe@tuftsmedicalcenter.org; Taylor, Mali; Gipson-Cosier, Heather; Linz, Brandon; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: lab accident on 2/13/2020

Dear Dr. Melanie Marketon,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information is needed at this time, however we note that the Principal Investigator (PI) bears ultimate responsibility for ensuring that safe work practices are properly implemented, to include ensuring the availability and use of appropriate PPE, posting laboratory signage with necessary entry requirements and evaluation of personnel by a qualified medical care provider following potential exposures. We recommend that the PI be reminded these responsibilities and undergo additional training on the requirements of the *NIH Guidelines*, including the need ensure that all personnel are appropriately trained and that appropriate PPE is available prior to beginning laboratory work. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Thursday, February 27, 2020 4:20 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Parkison, Valerie <Valerie.Parkison@tufts.edu>; cthorpe@tuftsmedicalcenter.org; Taylor, Mali <Mali.Taylor@tufts.edu>; Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>; Linz, Brandon <Brandon.Linz@tufts.edu>
Subject: RE: lab accident on 2/13/2020

Hello,

Please find the attached incident report documents for the influenza spill incident described below. Note that my initial notification incorrectly stated the strain as H2N2, when it was actually an H3N2 strain. The attached report provides the correct strain information. The incident was discussed at today's IBC meeting.

Please let me know if there are any questions.

Obtained via FOIA by Judicial Watch Inc.

Best,
Melanie

From: Marketon, Melanie
Sent: Friday, February 14, 2020 9:20 AM
To: NIHGuidelines@od.nih.gov
Cc: Parkison, Valerie <Valerie.Parkison@tufts.edu>; Thorpe, Cheleste <cthorpe@tuftsmedicalcenter.org>; Taylor, Mali <Mali.Taylor@tufts.edu>; Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>
Subject: lab accident on 2/13/2020

Hello,

I am writing to give immediate notification of an incident that occurred last evening. A 10 ml stock of influenza A H2N2 was spilled while working in the BSC, and some of it landed in the front grille of the BSC. The worker and a nearby person were not wearing N95 masks because they had run out and were waiting for the order to be filled due to the mask shortage problem. The BSC was decontaminated with bleach and the personnel were advised to go to the ER last night to be evaluated. The influenza stock was made by transfecting cells with multiple plasmids carrying viral genome segments, so this is recombinant work, but the viral genome was "wild type".

I will follow up with a complete report, but please let me know if there are questions in the meantime.

Best,
Melanie

Melanie M. Marketon, PhD
Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621
Boston, MA 02111
Boston office (617) 636-0969
cell Redacted by agreement

Office of the Vice Provost for Research
BIOSAFETY OFFICE
BI SMART SAFE

http://viceprovost.tufts.edu/biosafety/

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Tufts University
Date of Report:	2/27/20
Reporter name and position:	Melanie Marketon
Telephone number:	617-636-0969
Email address:	Melanie.marketon@tufts.edu
Reporter mailing address:	75 Kneeland St. Room 621 Boston, MA 02111
Date of incident:	2/13/20
Name of Principal Investigator:	Marta Gaglia
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) NIH R01AI37358; NIAID

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☒Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☒Spill ☒Other (please describe): Failure to wear proper PPE
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 1/31/2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-3
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☒State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Influenza A H3N2 wild type viral culture, generated from an 8-plasmid, recombinant DNA rescue system for viral packaging. See attached for full details.

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Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	See attached document.

See attached document for full incident description and root cause analysis.

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Incident Report

Brief Description of Incident:

A graduate student was collecting influenza A viral supernatant from infected cells and spilled the culture on the front grille of the BSC.

Description of Events:

Date of Incident: Thursday, February 13, 2020 @ ~3:45 PM

A junior graduate student (student #1) in the laboratory of Marta Gaglia was working within a biosafety cabinet in the M&V 429 tissue culture facility. Approximately 1 week prior, the student had transfected 293T cells with an 8-plasmid rescue system encoding a wildtype Influenza A/Perth/16/2009 H3N2. Following incubation, the student was attempting to collect the supernatant for titer and downstream infection and experimental work. After placing the ~10 ml of culture in a 15ml conical tube, the student dropped and spilled the culture on the front grille of the biosafety cabinet.

Student #1 sprayed the spill and grille with 70% ethanol and left the sash to the cabinet open with the blower running. The student then wiped up the ethanol with absorbent material and applied more bleach. Another graduate student (student #2) in the Heldwein lab was working in a biosafety cabinet behind student #1 and was wearing gloves and lab coat (as described in the Heldwein IBC registration). Student #1 informed student #2, the PI, and two other students (students #3 and #4) in the main lab area (M&V 405) of the spill and asked for assistance. Students #3, #4, and the PI entered wearing no PPE as all equipment is stored in M&V 429. The PI gathered information on the spill cleanup and informed personnel to contact the Biosafety Office for assistance. The PI then left the facility for a non-related meeting.

Students #3 and #4 donned PPE prior (gloves, lab coat, fit-tested respiratory protection) to fully cleaning and decontaminating the biosafety cabinet, including cleaning under the work surface and grille. The work surface was lifted, and a 20% bleach solution applied and allowed to sit for 10 minutes. Absorbent materials were applied and disposed of, followed by a second round of 20% bleach for 20 minutes. After absorbent material application, 70% ethanol was used.

At ~4:30 PM, Student #1 called and spoke to Melanie Marketon (Biosafety Manager) who advised on how to properly clean a spill under the worksurface and grille, but not large enough to fully contaminate the basin. The student informed Dr. Marketon that they were not wearing respiratory protection during the spill due to their fit-tested mask being on backorder. At this time, Dr. Marketon advised student #1 to complete an accident/incident report form and to seek medical attention. However, Dr. Marketon was unclear on the time sensitivity of being medically evaluated following Influenza A exposure, thus Dr. Marketon consulted Dr. Cheleste Thorpe (IBC Chair and TMC Infectious Disease Attending Physician). Dr. Thorpe recommended immediate medical evaluation to all exposed personnel. Dr. Marketon

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immediately informed the lab that all exposed personnel should seek immediate medical attention at the TMC Emergency Department.

Students #1 and #2 went to the Partner's Urgent Care clinic at 137 Stuart St. as it was their understanding that this would be a quicker and cheaper option for them opposed to TMC Emergency Department. Both students were prescribed Tamiflu.

Student #3 called Chester Pediatrics/Allied Physicians Group's Telehealth Service for medical consultation and was prescribed a 10-day course of oseltamivir.

Student #4 decided not to be medically evaluated but was advised when speaking to Dr. Brandon Linz (Biosafety Officer) to seek medical treatment should they desire it or if they begin to feel ill.

The PI, after returning to the lab at ~6:30 PM and speaking with personnel called Dr. Marketon to confirm that exposed personnel should go to the ER. Dr. Gaglia was informed that since she had been exposed without respiratory protection prior to letting aerosol particles fully settle, she should be seen. Dr. Gaglia also went to the Partner's Urgent Care clinic where she received a Tamiflu prescription.

Notification:

On Friday morning, Dr. Marketon summarized events in a message to the laboratory group and asked Dr. Linz to follow up for Biosafety and reporting requirements. Dr. Marketon also immediately informed the NIH and Boston Public Health Commission (BPHC) as required. Dr. Simon Muchohi (BPHC Director of Biological Safety) acknowledged receipt and asked for clarification of the laboratory's biosafety level and IBC requirements for respiratory protection and use.

Dr. Gaglia and student #1 completed and submitted incident reports to Risk Management (Debopam Mitra) on Friday (2/14/20).

Dr. Linz met with student #1 in person on Tuesday to discuss the incident, to gather the above information, and to discuss issues with PPE requirements, spill cleanup, and reporting (see below follow up items).

Students #2 and #3 submitted reports on Tuesday (2/18/20) and student #4 submitted a report on Wednesday (2/19/20).

Safety precautions in place during the experiment:

- Student #1 was wearing gloves and lab coat but no respiratory protection. The student had undergone BSL-2 training on 3/6/2018 and is listed on the associated IBC registration (2018-BR84).
- Student #2 was wearing gloves and lab coat but no respiratory protection. The student had undergone NIH/BSL2 training on 8/2/2019 and is listed on the Heldwein IBC registration (2019-BR14) and not the Gaglia registration as they are not associated personnel.
- Students #3 and #4 were initially wearing no PPE upon entering the tissue culture facility, but donned gloves, lab coat, and respiratory protection while cleaning the spill. Both students

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underwent training on 10/4/19 (BSL2/BBP) and 11/21/17 (BSL2) respectively. Both students are listed on the Gaglia IBC registration.

- The PI was wearing no PPE upon entering the facility to inquire as to the nature of the spill. The PI underwent BSL2 training on 1/4/17. The work was funded and performed under the PI's grant (NIH R01AI37358).
- Incident report forms were completed by all four students and the PI.
- Appropriate notification of the incident occurred, including notification of the Biosafety Office.
- All personnel had received influenza vaccination from private health care providers (not employer provided).

Summary of incident response:

The student ceased work after the spill and notified proximate and nearby personnel and the PI. Personnel were not wearing appropriate PPE, nor was signage in place to inform those entering the facility of the PPE requirement.

Inappropriate time was given to allow aerosols to settle. While disinfectants were applied to the spill, personnel did not apply absorbent materials and sprayed ethanol onto the spill, potentially causing more aerosol generation.

Students and PI were unaware of need to be medically treated following exposure as dictated by the IBC registration and were not fully evaluated by an occupational health provider.

Personnel quickly contacted the Biosafety Office for advice and follow-up and all eventually submitted incident reports following prompting.

As the agent involved in this incident is both recombinant and is a RG2 infectious agent, this incident is reportable to both the NIH and BPHC. Immediate notification was sent within 24 hours to both agencies by Melanie Marketon.

Risk Assessment and Potential for Infection:

M&V 429 BSL-2 is a containment lab for manipulation and work with infectious viral agents and mammalian cell lines. Two separate laboratory groups share this space working on different viruses.

1. The Influenza A H3N2 in use had been transfected into the rescue cell line.
2. The culture in use had not been titered, but similar cultures usually have a titer lower than 5x10^6 pfu/ml.
3. As the spill occurred onto the front grille of the biosafety cabinet, most viral particles should have flowed under the work surface and into the duct work and HEPA filter. However, because of the laminar flow in the Class II A2 cabinet, some particles may have been blown directly onto student #1 there is a high chance the student received an infectious dose (ID50 for Influenza A H3N2 is not known) from the inhalation exposure as they were wearing no respiratory protection. However, the student did receive the yearly influenza vaccination which contains the H3N2 subtype.

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4. Student #2 was not wearing respiratory protection but was nearby when the spill occurred. As they were not directly in the path of the exposure, potential is low but still present for them to develop an infection.
5. Students #3 and #4 entered the facility ~30 minutes after the spill but were not wearing respiratory protection initially. Potential for infection is lower than Student #2, but still present as aerosols may not have had a chance to fully settle.
6. The PI entered the facility before allowing aerosols to fully settle and was not wearing respiratory protection. Potential for infection is lower than Student #2, but still present as aerosols may not have had a chance to fully settle.

Lessons learned & follow-up observations:

- Personnel were:
    - Instructed that all work and established safety precautions cannot deviate from the IBC registration.
    - Informed that they could be fit-tested on a variety of available respirators to limit the chances of a fitted respirator not being available and were directed to TU EHS' Industrial Hygienist.
    - Informed to contact the Biosafety Office if no respiratory protection is immediately available and to work with a Biosafety Officer for an appropriate solution (e.g. temporary use of a PAPR).
    - Reminded that all personnel exposed should be seen by a medical and occupational health professional for incidents that occur in a workspace.
    - Informed that a walk-in clinic and personally affiliated medical providers are not an appropriate substitute for a full medical evaluation (i.e. TMC ER with an infectious disease consult).
    - Reminded of proper spill cleanup procedures (e.g. allowing aerosols settle for 30 minutes, application of absorbent materials, use of approved disinfectants).
    - Reminded to maintain timely safety training and advised of the new combined BBP and BSL2 online training.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Thursday, February 27, 2020 4:20 PM
To: NIH guidelines
Cc: Parkison, Valerie; cthorpe@tuftsmedicalcenter.org; Taylor, Mali; Gipson-Cosier, Heather; Linz, Brandon
Subject: RE: lab accident on 2/13/2020
Attachments: NIH Incident Report_Gaglia_2020.docx; Gaglia - Biosafety Incident Report to Feb IBC 2020.docx

Hello,

Please find the attached incident report documents for the influenza spill incident described below. Note that my initial notification incorrectly stated the strain as H2N2, when it was actually an H3N2 strain. The attached report provides the correct strain information. The incident was discussed at today's IBC meeting.

Please let me know if there are any questions.

Best,
Melanie

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Sent: Friday, February 14, 2020 9:20 AM
To: NIHGuidelines@od.nih.gov
Cc: Parkison, Valerie <Valerie.Parkison@tufts.edu>; Thorpe, Cheleste <cthorpe@tuftsmedicalcenter.org>; Taylor, Mali <Mali.Taylor@tufts.edu>; Gipson-Cosier, Heather <Heather.Cosier@tufts.edu>
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I will follow up with a complete report, but please let me know if there are questions in the meantime.

Best,
Melanie

Melanie M. Marketon, PhD
Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621
Boston, MA 02111
Boston office (617) 636-0969

Obtained via FOIA by Judicial Watch Inc.

cell Redacted by agreement

Office of the Vice Provost for Research
BIOSAFETY OFFICE

BIO SMART SAFE

http://viceprovost.tufts.edu/biosafety/

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Marketon, Melanie <Melanie.Marketon@tufts.edu>
Sent: Friday, February 14, 2020 9:20 AM
To: NIH guidelines
Cc: Parkison, Valerie; cthorpe@tuftsmedicalcenter.org; Taylor, Mali; Gipson-Cosier, Heather
Subject: lab accident on 2/13/2020

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Melanie M. Marketon, PhD
Biosafety Manager, Office of the Vice Provost for Research
Responsible Official, Select Agent and Toxins Program
Research Assistant Professor, Department of Molecular Biology and Microbiology
Tufts University
75 Kneeland St, Room 621
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Office of the Vice Provost for Research
BIOSAFETY OFFICE
BIOSMART SAFE

http://viceprovost.tufts.edu/biosafety/

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, February 21, 2020 10:24 AM
To: ca2511@cumc.columbia.edu; NIH guidelines
Cc: Dosunmu, Aderemi S.; Crowley, Kathleen A.; Morse, Stephen S.; Cameron, Cody; Danino, Tal; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Potential rDNA exposure - NIH incident report

Dear Dr. Christopher Aston,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information is required at this time. However, we note that the incident occurred on January 24, 2020, and was not reported to NIH OSP until February 14, 2020. Please note that under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), incidents occurring at biosafety level 2 that result in an overt exposure are required to be reported immediately. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: ca2511@cumc.columbia.edu <ca2511@cumc.columbia.edu>
Sent: Friday, February 14, 2020 10:04 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Cc: Dosunmu, Aderemi S. <ad3241@cumc.columbia.edu>; Crowley, Kathleen A. <kc298@cumc.columbia.edu>; Morse, Stephen S. <ssm20@cumc.columbia.edu>; Cameron, Cody <cc4282@cumc.columbia.edu>; Danino, Tal <td2506@columbia.edu>
Subject: Potential rDNA exposure - NIH incident report

Kathryn and colleagues
Please find attached an incident report for a potential rDNA exposure related to a needle stick. Our IBC reviewed the accident on Feb 11th.
Sincerely

Obtained via FOIA by Judicial Watch Inc.



Christopher Aston, PhD
Associate Director, Biological Safety Programs
Environmental Health & Safety
Columbia University
www.ehs.columbia.edu
Phone: 212-305-1506
Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Columbia University
Date of Report:	02/14/2020
Reporter name and position:	Christopher Aston, PhD Associate Director, Biological Safety Programs
Telephone number:	212-305-1506
Email address:	ca2511@columbia.edu
Reporter mailing address:	630 W. 168th Street Box 8 NY, NY 10032
Date of incident:	01/24/2020
Name of Principal Investigator:	Tal Danino
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 01/14/2020
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-E-1, III-D-1-a
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Strain of *Mycobacterium marinum (M. marinum)* has been transformed with plasmid DNA encoding gene for fluorescent reporter gene tdTomato. *M. marinum* is utilized for granuloma formation in murine models of the tumor microenvironment.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of

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the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

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Incident occurred on 01/24/2020 at approximately 12:00pm on the 8th floor laboratory of Tal Danino in the Northwest Corner Building at the Morningside Campus. The incident involved a Research Assistant (RA) in the Biomedical Engineering Department. The RA has over 3 years of laboratory experience in this laboratory as an undergraduate and then as a full-time employee. The RA was performing a series of disaggregation procedures for clumping cultures of *M. marinum,* using sterile needles for the procedure. The laboratory has a written SOP maintained in a laboratory notebook. The lab's protocol is based on published papers on standard macrophage phagocytosis assays. The RA was wearing personal protective equipment (PPE) consisting of a single pair of gloves and a lab coat. The procedure, involved in this instance was strictly an *in vitro* procedure involving the co-culture of macrophages and *M. marinum.* The co-culture experiment was performed inside a certified biosafety cabinet. The RA was uncapping a sterile syringe and needle (BD precision glide 27.5 G). The syringe was not yet filled with any mycobacteria. The cap of the needle was hard to remove and their hand recoiled as the cap was removed and the needle punctured their other gloved hand. The gloved hands had been used for *M. marinum* culturing and may have been contaminated with the mycobacteria. The RA immediately removed their glove and examined the site of the puncture. A small droplet of blood was expressed from the tip of their left middle finger. The RA bandaged their finger, notified their laboratory manager of the incident and traveled directly to Workforce Health and Safety; Columbia's Occupational Health Services. Of note, they did not wash wound. The wound was washed at WHS and first aid administered. They were counseled on how to monitor the wound for potential erythema/granuloma formation or non-specific symptoms from a potential systemic infection, and instructed to return for chemoprophylaxis should this occur. To date (2/14/20), the RA reports no ill effects following the exposure. Based on the requirement to report rDNA exposures, NIH is being notified of this exposure because the *M. marinum* strain being utilized was transfected with a plasmid to express the fluorescent reporter gene tdTomato. The maximum concentration of the *M. marinum* bacterial culture does not exceed 1 x 10^6 – 10^9 CFU/mL. The RA is current on the following requisite safety trainings: BSC Training (12/20/2019) and Bio Safety/Bloodborne Pathogen (12/20/2019). RA was identified as personnel on the protocol that was reviewed by the IBC 01/14/2020.

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Has the IBC reviewed this incident?	☐YES ☒NO The IBC reviewed the incident at the 2/11/20 meeting.
Please describe the root cause of this incident:	RA attempting to forcefully uncap a tightly fastened syringe needle cap.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

1. EH&S Biosafety Officer reviewed an alternate disaggregation method with the RA and managers. Another method besides needles, such as sonication, can be used for disaggregation procedures. This was not adopted because of concerns it would reduce the viability of the mycobacteria. The lab will use blunt needles in the future which are less likely to cause an injury.
2. EH&S Biosafety Officer reviewed whether a surface-mounted needle uncapper can be utilized instead e.g. https://www.delasco.com/needle-safe-ii-needle-uncapper-recapper-syringe-holder/ . Lab was agreeable to purchase and test one.
3. EH&S Biosafety Officer reviewed incident response procedures with the laboratory since the RA did not wash their hands after the exposure.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: ca2511@cumc.columbia.edu
Sent: Friday, February 14, 2020 10:04 AM
To: NIH guidelines; Harris, Kathryn (NIH/OD) [C]
Cc: Dosunmu, Aderemi S.; Crowley, Kathleen A.; Morse, Stephen S.; Cameron, Cody; Danino, Tal
Subject: Potential rDNA exposure - NIH incident report
Attachments: Danino lab M. marinum 02-14-2020.pdf

Kathryn and colleagues
Please find attached an incident report for a potential rDNA exposure related to a needle stick. Our IBC reviewed the accident on Feb 11th.
Sincerely

Chris

Christopher Aston, PhD
Associate Director, Biological Safety Programs
Environmental Health & Safety
Columbia University
www.ehs.columbia.edu
Phone: 212-305-1506
Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:37 AM
To: Preston, Francine [JRDUS]; NIH guidelines
Cc: Niven, Patrick [JRDUS]; Hammonds, Elizabeth [JRDUS]; Link, David [JRDUS]; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Janssen Incident Report

Dear Francine Preston,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to these incidents appear appropriate.

No further information is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Preston, Francine [JRDUS] <FPreston@its.jnj.com>
Sent: Saturday, February 29, 2020 11:07 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Cc: Niven, Patrick [JRDUS] <PNiven1@its.jnj.com>; Hammonds, Elizabeth [JRDUS] <EHammond@its.jnj.com>; Link, David [JRDUS] <DLink@its.jnj.com>
Subject: RE: Janssen Incident Report

Hello Kathryn –
Attached you will find the January 7 -8, 2020 incident report for failure to follow approved containment conditions and accessing a closed laboratory. A BSL2 laboratory was unexpectedly closed for air handler repairs. Several workers went into the space without authorization during this closure.

Please let me know if you have any questions or concerns.

Thanks,
Francine

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Friday, February 14, 2020 1:18 PM
To: Preston, Francine [JRDUS] <FPreston@its.jnj.com>
Subject: RE: Janssen Incident Report

Obtained via FOIA by Judicial Watch Inc.

Thanks Francine. Sorry I was a bit rushed on the call.

Regards,

Kathryn

From: Preston, Francine [JRDUS] <FPreston@its.jnj.com>
Sent: Friday, February 14, 2020 12:07 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Hammonds, Elizabeth [JRDUS] <EHammond@its.jnj.com>; Niven, Patrick [JRDUS] <PNiven1@its.jnj.com>
Subject: Janssen Incident Report

Hello Dr. Harris –

Thank you for speaking with me today regarding the an incident that occurred in a Janssen BSL2 lab. EHSS was informed that the lab exhaust was not functioning properly and the lab airflow was positive to the outside hallway. EHSS promptly closed the lab and scientists accessed the space during the time the lab was closed. The ventilation failure occurred on January 7, 2020 and was promptly repaired on January 8, 2020.

As we discussed, I will be submitting a report with details regarding this incident in the next 2 weeks.

Please let me know if you have any questions or concerns.

Kind regards,
Francine

Francine Preston, CBSP, RBP, CSP
Principal Biosafety Specialist
Environment Health Safety & Sustainability
Janssen Pharmaceuticals, Inc.
1400 McKean Road
Spring House, PA 19477

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://osp.od.nih.gov/sites/default/files/resources/Adverse_Event_Template_.docx

Does this incident involve research subject to the *NIH Guidelines*?	☒ YES ☐ NO If no, this incident does not have to be reported to OBA
Institution name:	Janssen Pharmaceuticals, LLC
Date of report:	29 Feb 2020
Reporter name and position:	Francine Preston, Principal Biosafety Specialist (IBC Chair)
Reporter telephone:	610-574-9556
Reporter email:	fpreston@its.jnj.com
Reporter mailing address:	1400 McKean Road Spring House, PA 19477
Date of incident:	7 January 2020
Name of principal investigator:	Ravi Bhatia
Is this an NIH funded project?	☐ YES ☒ NO
If yes, please provide:	NIH grant or contract number:
	NIH funding institute or center:
	NIH program officer contact information (name, email etc):
What was the **nature** of incident?	☐ Personnel exposure ☐ Spill ☐ Loss of containment ☐ Loss of transgenic animal ☐ Failure to obtain IBC approval ☒ Failure to follow approved containment conditions ☒ Other - please describe: A BSL2 laboratory exhaust fan failed causing the directional airflow in the laboratory to reverse. EHS&S and the lab manager closed the laboratory until repairs could be made. EHS&S and the lab manager were later informed that scientists worked in the lab during closure.

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Did the Institutional Biosafety Committee (IBC) approve this research	☒ YES ☐ NO If yes, on what date?
If yes, please provide:	Approval date: 4 February 2019
	Approved biosafety level(s) for the research: BSL2
	Additional approval requirements: Directional air flow, medical surveillance
What section(s) of the *NIH Guidelines* is the research subject to?	Section III: D-1
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	☐ CDC ☐ USDA ☐ FDA ☐ EPA ☐ OSHA ☐ Research Funding Agency/Sponsor: (name)_____ ☐ State/Local Public Health ☐ Federal/State/Local Law Enforcement ☐ Other – please describe:
Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc. as relevant.)	Patient-derived T cells transduced with lentiviral vector encoding Chimeric Antigen Receptors (CAR). Cells were transduced with 3rd Generation SIN Lentivirus – VSVG pseudotyped. No work with lentivirus occurred during this lab closure.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:
The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space).

- The incident occurred in BSL2 invitro lab.

Who was involved in the incident/violation, including others present at the incident location? **Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker).**

24 unauthorized scientists and support staff accessed the lab without approval during the laboratory closure.
Lab manager was unable to identify anyone who started work with biological materials during these entries. He indicated entries were to:

- inform people lab was closed,
- remove data from computer,
- place material in cold storage or incubator,
- take materials out of this lab to work in other lab spaces,
- check liquid nitrogen levels,
- get dry ice and
- remove lab waste.

Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.

- EHSS and the IBC Chair were informed the laboratory ventilation for the space was not working properly and the room was positive to the outside.
- EHSS and the IBC Chair determined the lab should be closed because it no longer met the company requirements for BSL2 containment.
- IBC Chair emailed the people leaders of the lab closure and requirements to safely stop work and evacuate the lab until repairs were made and lab returned to normal operating conditions.

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- Lab manager went to the lab and told scientists to safely stop work and evacuate the lab.
- A scientist posted a sign indicated "Lab closed, until signage is removed" on the outside door.
- EHSS and the BSO were informed people accessed lab during closure
- IBC was informed of the event on January 9, 2020. IBC requested an incident investigation and to determine if this is an NIH reportable Incident
- Security provided badge access report
- IBC Chair and EHSS evaluated the list and people leaders were contacted regarding incident.
- Lab manager returned list to and EHSS, and BSO determined it is also necessary to revoke laboratory badge access during future closures.

The training received by the individual(s) involved and the date(s) the training was conducted.

Title	Lab waste staff (AWRS)	All staff working with biohazardous materials	All other support staff with authorized access to space
Hazard Communication			Annually
Chemical Hygiene training		January and February 2020	
HAZWOPER training	Annually		
Biosafety Training		Annually	
Bloodborne pathogen	Annually	January and February 2020	Annually
BSL2 plus viral vector biosafety training	Annually	Annually	

The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.

- Biosafety Manual
- Exposure Control Plan

Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.

- Workers accessed the BSL2 space after it was closed for ventilation repairs.

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The personal protective equipment in use at the time of the incident/violation.

- Lab coat, nitrile gloves, and safety glasses.

The occupational health requirements for laboratory personnel involved in the research.

- Hepatitis B vaccine offer/declination
- Annual biosafety medical surveillance

Any medical advice/treatment/surveillance provided or recommended after the incident.

- None - No exposure occurred during this incident

Any injury or illness associated with the incident.

- None

Medical surveillance results (if not available at the time of initial report please indicate when results will be available).

- N/A

Equipment failures.

- Laboratory building exhaust fan failure.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

January 7th approximately 2:08 PM, EHSS circulated a message indicating that Building 13 labs 1088/1089 were closed until repairs on the air handler could be made. Signage was placed on the lab doors indicating the lab is closed at approximately 2:30 PM. Repairs were complete and the lab was approved for operation on January 8th at approximately 10:45 AM. Unfortunately, EHSS and the BSO were informed that several people knowingly entered the lab after it was closed. Security records also indicate the lab was accessed by several people during this time that were not involved in the facility repairs.

Has the IBC reviewed this incident?	☐ YES ☒ NO January 9, 2020 IBC was informed of incident and requested an

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	investigation. This report will be reviewed at the next IBC meeting. If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.
Has a root cause for this incident been identified?	☒ YES ☐ NO If yes please describe: • Inadequate communication and training o Email communicating the lab was closed because it no longer met the biosafety requirements to work safely in the space was sent to lab personnel only and did not include service personnel or their representatives. This includes Allied Universal, Avantor, Eurofins and AWRS. This did not enable communication to a wider audience. o Lab personnel created generic signage that did not effectively stand out or communicate the situation / hazard within the space. A white 8.5x 11" piece of paper stating "lab closed" was used. The signage was not seen and understood by all personnel.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)

Workers attending Janssen Bloodborne Pathogen training or BSL2+ Viral Vector training are informed of the NIH reporting requirements and this incident. Every manager of the workers who violated the posted signage informed their staff of the need to read signage posted on the door. If there is anything that they do not understand, they are to contact their manager for instruction and not make assumptions.

Any future lab closures will include:

- a more robust signage system or caution tape across the door.
- If laboratory requires additional card access (GMP or BSL2+ labs), EHS&S or the lab manager will instruct security to suspend card access during closure.

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- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Preston, Francine [JRDUS] <FPreston@its.jnj.com>
Sent: Saturday, February 29, 2020 11:07 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Niven, Patrick [JRDUS]; Hammonds, Elizabeth [JRDUS]; Link, David [JRDUS]
Subject: RE: Janssen Incident Report
Attachments: Janssen Incident Reporting January 7-8, 2020 .pdf

Hello Kathryn –
Attached you will find the January 7 -8, 2020 incident report for failure to follow approved containment conditions and accessing a closed laboratory. A BSL2 laboratory was unexpectedly closed for air handler repairs. Several workers went into the space without authorization during this closure.

Please let me know if you have any questions or concerns.

Thanks,
Francine

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Friday, February 14, 2020 1:18 PM
To: Preston, Francine [JRDUS] <FPreston@its.jnj.com>
Subject: RE: Janssen Incident Report

Thanks Francine. Sorry I was a bit rushed on the call.

Regards,

Kathryn

From: Preston, Francine [JRDUS] <FPreston@its.jnj.com>
Sent: Friday, February 14, 2020 12:07 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Hammonds, Elizabeth [JRDUS] <EHammond@its.jnj.com>; Niven, Patrick [JRDUS] <PNiven1@its.jnj.com>
Subject: Janssen Incident Report

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As we discussed, I will be submitting a report with details regarding this incident in the next 2 weeks.

Please let me know if you have any questions or concerns.

Kind regards,
Francine

Obtained via FOIA by Judicial Watch Inc.

Francine Preston, CBSP, RBP, CSP
Principal Biosafety Specialist
Environment Health Safety & Sustainability
Janssen Pharmaceuticals, Inc.
1400 McKean Road
Spring House, PA 19477



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Preston, Francine [JRDUS] <FPreston@its.jnj.com>
Sent: Friday, February 14, 2020 12:07 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Hammonds, Elizabeth [JRDUS]; Niven, Patrick [JRDUS]
Subject: Janssen Incident Report

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Kind regards,
Francine

Francine Preston, CBSP, RBP, CSP
Principal Biosafety Specialist
Environment Health Safety & Sustainability
Janssen Pharmaceuticals, Inc.
1400 McKean Road
Spring House, PA 19477

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, April 13, 2020 12:06 PM
To: Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident Report - Preliminary

Hi Kathryn

Hope you're doing good during these challenging times!

Based on our subsequent email conversations on 2/18 and 2/19, we had determined that this incident was not reportable to the NIH OSP since the research involved work with exempt mice during the conduct of research that was not subject to the Guidelines.

Kind regards.
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Monday, April 13, 2020 10:54 AM
To: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Subject: RE: NIH Incident Report - Preliminary

Hi Garry:

Just following up on this incident. Do you have any update?

I apologize if I missed the final report come in.

Regards,

Kathryn

Obtained via FOIA by Judicial Watch Inc.

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, February 17, 2020 5:16 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of a potential exposure to recombinant DNA involving a worker in a BSL-2+ laboratory. Our initial investigation indicates a researcher received a mouse bite from a triple-knockout transgenic BL1 mouse (C57BL/6 *Rag2*$^{-/-}\gamma_c^{-/-}$*CD47*$^{-/}$) that had been implanted with primary rhesus macaque tissues. The Researcher has reported to the Occupational Health Clinic, and been evaluated and treated by the Medical Director as per protocol.

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, February 17, 2020 5:16 PM
To: NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.
Subject: NIH Incident Report - Preliminary

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We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 27, 2020 4:16 PM
To: McFarland Christine Tetzlaff; NIH guidelines
Cc: Rojo del Busto, Katherine; Institutional Biosafety Committee; Gonzalez, Carlos F; Bourquin, Jessica; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Final Report - Texas A&M University

Dear Dr. Christine Tetzlaff McFarland,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: McFarland Christine Tetzlaff <ctmcfarland@tamu.edu>
Sent: Tuesday, March 17, 2020 3:33 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Rojo del Busto, Katherine <krdb@tamu.edu>; Institutional Biosafety Committee <ibc@tamu.edu>; Gonzalez, Carlos F <cf-gonzalez@tamu.edu>; Bourquin, Jessica <jrbourquin@tamu.edu>
Subject: Final Report - Texas A&M University

Dear NIH OSP,

Per Section IV-B-1-j of the NIH Guidelines, and on behalf of Texas A&M University (TAMU) and the College Station – TAMU Institutional Biosafety Committee (IBC), I am writing to provide a final report regarding a disruption in the functionality of one of our BSL-3 facilities, where work with recombinantly modified RG3 organisms takes place. As I reported initially on February 18, 2020, during daily remote monitoring of the laboratories on February 17, 2020, we discovered that the Building Automation System (BAS) capabilities in one of our BSL-3 lab suites was disrupted and that the required interlock between the supply and exhaust fans was inoperable. We further determined that this loss of functionality began on Friday, February 14, 2020. Without this interlock, the labs did not meet BSL-3 requirements and thus research operations were suspended. Researchers were immediately notified and instructed to halt all research activities until the BAS was restored.

Fortunately, we did not experience a fan failure between February 14 and February 17, the interlock was not required, and there was no reversal of airflow. Working closely with Utilities & Energy Services (UES) on campus, the BAS was

Obtained via FOIA by Judicial Watch Inc.

quickly restored, alarms were tested, trending capabilities resumed, and we were able to lift the research suspension on February 18, 2020, when we it was determined that the air handling system was working as designed and as required.

Since then, we have focused our efforts on determining how this disruption in services came about and what can be done to prevent a recurrence at this location or at another of our BSL-3 facilities.

In this specific case, we learned that TAMU Information Technology (IT) planned for upgrades to multiple network switches (MAC bridges) that serve the College of Veterinary Medicine (CVM). This plan was communicated to CVM IT personnel as an internet outage. The people who received this message did not fully appreciate the scope of the impact that an internet outage would have on the BAS and so did not alert UES, who is responsible for BAS operations. When the switches were replaced, the IP addresses changed, and no downstream equipment could communicate through the switches. This meant that multiple control panels within the CVM facility could not communicate with one another or with remote monitoring interfaces. The controls for the supply and exhaust fans were isolated from one another, so the programming for the interlock could not function.

This incident allowed us to identify a gap in the communication between TAMU IT and local facility personnel in buildings that house our BSL-3 laboratories. Following discussions with TAMU IT's Associate Director of Information Security, UES representatives, CVM's Director of Facilities, CVM IT, and representatives from the Office of Biosafety, three corrective actions were identified and will be implemented:

1. During the next annual, preventative maintenance period (scheduled for August of 2020), the need for internet communication between building automation system components in the CVM BSL-3 suite will be eliminated by creating a hardware connection between the components. This solution will ensure that the supply/exhaust interlock at the CVM BSL-3 will not be affected by network switch changes.

2. UES and TAMU IT will identify all switches and other components on campus that are connected to equipment and controls systems serving BSL-3 labs so that any proposed changes to these components will automatically alert IT to the need to communicate with Biosafety before any changes are implemented. This project is underway and we expect it to be completed within the next two weeks.

3. Physical IT components that could disrupt BSL-3 labs will be labeled as critical hardware and include contact information (i.e. names and phone numbers of key Biosafety personnel) to prevent inadvertent interruption of operations. This project is underway and we expect it to be completed within the next two to three weeks.

Implementation of items 2 and 3 will ensure that Biosafety staff are consulted before changes to systems responsible for the proper operations of our high containment laboratories are implemented. Together, these solutions should prevent a similar issue from happening in the future.

Please let me know if there are any questions or a need for additional information.
Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety
Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
Office: 979-845-6475 | Cell: Redacted by agreement Fax: 979-458-2669 | ctmcfarland@tamu.edu | http://rcb.tamu.edu

---

From: McFarland Christine Tetzlaff
Sent: Tuesday, February 18, 2020 4:41 PM
To: 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>

Obtained via FOIA by Judicial Watch Inc.

Cc: Rojo del Busto, Katherine <krdb@tamu.edu>; Institutional Biosafety Committee <ibc@tamu.edu>; 'Carlos' <cf-gonzalez@tamu.edu>; Bourquin, Jessica <jrbourquin@tamu.edu>
Subject: Initial Notification - Texas A&M University
Importance: High

Dear NIH OSP,

Per Section IV-B-1-j of the NIH Guidelines, and on behalf of Texas A&M University, I am writing to provide an initial notification regarding a disruption in the functionality of one of our BSL-3 facilities, where work with recombinantly modified RG3 organisms takes place. On February 17, 2020, during weekly inspection of the laboratories, we discovered that the Building Automation System (BAS) capabilities in this location were disrupted and that the required interlock between the supply and exhaust fans was inoperable. We have since determined that this loss of functionality began on Friday, February 14, 2020. Without this interlock, the labs do not meet BSL-3 requirements and thus research operations were suspended. Researchers were immediately notified and instructed to halt all research activities until the BAS is restored.

Fortunately, we did not experience a fan failure over the weekend, the interlock was not required, and there was no reversal of airflow. We are working closely with Utilities & Energy Services (UES) on campus to restore the BAS and will lift the research suspension as soon as we are certain that the air handling system is working as designed and as required. This afternoon, we were informed that the interlock programming is once again functional and back under full control of our UES server. Alarms were tested and trending capabilities have resumed. Nevertheless, we will focus our efforts on determining how this disruption in services was allowed to happen and what must be done to prevent a recurrence. A final report will be submitted as soon as we have more information and within the thirty day reporting timeline.

Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety
Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
Office: 979-845-6475 | Cell: Redacted by agreement | Fax: 979-458-2669 | ctmcfarland@tamu.edu | http://rcb.tamu.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McFarland Christine Tetzlaff <ctmcfarland@tamu.edu>
Sent: Tuesday, March 17, 2020 3:33 PM
To: NIH guidelines
Cc: Rojo del Busto, Katherine; Institutional Biosafety Committee; Gonzalez, Carlos F; Bourquin, Jessica
Subject: Final Report - Texas A&M University

Dear NIH OSP,

Per Section IV-B-1-j of the NIH Guidelines, and on behalf of Texas A&M University (TAMU) and the College Station – TAMU Institutional Biosafety Committee (IBC), I am writing to provide a final report regarding a disruption in the functionality of one of our BSL-3 facilities, where work with recombinantly modified RG3 organisms takes place. As I reported initially on February 18, 2020, during daily remote monitoring of the laboratories on February 17, 2020, we discovered that the Building Automation System (BAS) capabilities in one of our BSL-3 lab suites was disrupted and that the required interlock between the supply and exhaust fans was inoperable. We further determined that this loss of functionality began on Friday, February 14, 2020. Without this interlock, the labs did not meet BSL-3 requirements and thus research operations were suspended. Researchers were immediately notified and instructed to halt all research activities until the BAS was restored.

Fortunately, we did not experience a fan failure between February 14 and February 17, the interlock was not required, and there was no reversal of airflow. Working closely with Utilities & Energy Services (UES) on campus, the BAS was quickly restored, alarms were tested, trending capabilities resumed, and we were able to lift the research suspension on February 18, 2020, when we it was determined that the air handling system was working as designed and as required.

Since then, we have focused our efforts on determining how this disruption in services came about and what can be done to prevent a recurrence at this location or at another of our BSL-3 facilities.

In this specific case, we learned that TAMU Information Technology (IT) planned for upgrades to multiple network switches (MAC bridges) that serve the College of Veterinary Medicine (CVM). This plan was communicated to CVM IT personnel as an internet outage. The people who received this message did not fully appreciate the scope of the impact that an internet outage would have on the BAS and so did not alert UES, who is responsible for BAS operations. When the switches were replaced, the IP addresses changed, and no downstream equipment could communicate through the switches. This meant that multiple control panels within the CVM facility could not communicate with one another or with remote monitoring interfaces. The controls for the supply and exhaust fans were isolated from one another, so the programming for the interlock could not function.

This incident allowed us to identify a gap in the communication between TAMU IT and local facility personnel in buildings that house our BSL-3 laboratories. Following discussions with TAMU IT's Associate Director of Information Security, UES representatives, CVM's Director of Facilities, CVM IT, and representatives from the Office of Biosafety, three corrective actions were identified and will be implemented:

1. During the next annual, preventative maintenance period (scheduled for August of 2020), the need for internet communication between building automation system components in the CVM BSL-3 suite will be eliminated by creating a hardware connection between the components. This solution will ensure that the supply/exhaust interlock at the CVM BSL-3 will not be affected by network switch changes.

2. UES and TAMU IT will identify all switches and other components on campus that are connected to equipment and controls systems serving BSL-3 labs so that any proposed changes to these components will automatically

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alert IT to the need to communicate with Biosafety before any changes are implemented. This project is underway and we expect it to be completed within the next two weeks.

3. Physical IT components that could disrupt BSL-3 labs will be labeled as critical hardware and include contact information (i.e. names and phone numbers of key Biosafety personnel) to prevent inadvertent interruption of operations. This project is underway and we expect it to be completed within the next two to three weeks.

Implementation of items 2 and 3 will ensure that Biosafety staff are consulted before changes to systems responsible for the proper operations of our high containment laboratories are implemented. Together, these solutions should prevent a similar issue from happening in the future.

Please let me know if there are any questions or a need for additional information.
Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety
Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
Office: 979-845-6475 | Cell: Redacted by agreement Fax: 979-458-2669 | ctmcfarland@tamu.edu | http://rcb.tamu.edu

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From: McFarland Christine Tetzlaff
Sent: Tuesday, February 18, 2020 4:41 PM
To: 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
Cc: Rojo del Busto, Katherine <krdb@tamu.edu>; Institutional Biosafety Committee <ibc@tamu.edu>; 'Carlos' <cf-gonzalez@tamu.edu>; Bourquin, Jessica <jrbourquin@tamu.edu>
Subject: Initial Notification - Texas A&M University
Importance: High

Dear NIH OSP,

Per Section IV-B-1-j of the NIH Guidelines, and on behalf of Texas A&M University, I am writing to provide an initial notification regarding a disruption in the functionality of one of our BSL-3 facilities, where work with recombinantly modified RG3 organisms takes place. On February 17, 2020, during weekly inspection of the laboratories, we discovered that the Building Automation System (BAS) capabilities in this location were disrupted and that the required interlock between the supply and exhaust fans was inoperable. We have since determined that this loss of functionality began on Friday, February 14, 2020. Without this interlock, the labs do not meet BSL-3 requirements and thus research operations were suspended. Researchers were immediately notified and instructed to halt all research activities until the BAS is restored.

Fortunately, we did not experience a fan failure over the weekend, the interlock was not required, and there was no reversal of airflow. We are working closely with Utilities & Energy Services (UES) on campus to restore the BAS and will lift the research suspension as soon as we are certain that the air handling system is working as designed and as required. This afternoon, we were informed that the interlock programming is once again functional and back under full control of our UES server. Alarms were tested and trending capabilities have resumed. Nevertheless, we will focus our efforts on determining how this disruption in services was allowed to happen and what must be done to prevent a recurrence. A final report will be submitted as soon as we have more information and within the thirty day reporting timeline.

Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety

Obtained via FOIA by Judicial Watch Inc.

Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
Office: 979-845-6475 | Cell: Redacted by agreement Fax: 979-458-2669 | ctmcfarland@tamu.edu | http://rcb.tamu.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McFarland Christine Tetzlaff <ctmcfarland@tamu.edu>
Sent: Tuesday, February 18, 2020 5:41 PM
To: NIH guidelines
Cc: Rojo del Busto, Katherine; Institutional Biosafety Committee; Gonzalez, Carlos F; Bourquin, Jessica
Subject: Initial Notification - Texas A&M University

Importance: High

Dear NIH OSP,

Per Section IV-B-1-j of the NIH Guidelines, and on behalf of Texas A&M University, I am writing to provide an initial notification regarding a disruption in the functionality of one of our BSL-3 facilities, where work with recombinantly modified RG3 organisms takes place. On February 17, 2020, during weekly inspection of the laboratories, we discovered that the Building Automation System (BAS) capabilities in this location were disrupted and that the required interlock between the supply and exhaust fans was inoperable. We have since determined that this loss of functionality began on Friday, February 14, 2020. Without this interlock, the labs do not meet BSL-3 requirements and thus research operations were suspended. Researchers were immediately notified and instructed to halt all research activities until the BAS is restored.

Fortunately, we did not experience a fan failure over the weekend, the interlock was not required, and there was no reversal of airflow. We are working closely with Utilities & Energy Services (UES) on campus to restore the BAS and will lift the research suspension as soon as we are certain that the air handling system is working as designed and as required. This afternoon, we were informed that the interlock programming is once again functional and back under full control of our UES server. Alarms were tested and trending capabilities have resumed. Nevertheless, we will focus our efforts on determining how this disruption in services was allowed to happen and what must be done to prevent a recurrence. A final report will be submitted as soon as we have more information and within the thirty day reporting timeline.

Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety
Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:48 AM
To: lydia SOHN; NIH guidelines
Cc: Chips Hoai; Brandon DEFRANCISCI; Biosafety Program Departmental; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: recombinant DNA accident

Dear Dr. Lydia Sohn,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: lydia SOHN <sohn@berkeley.edu>
Sent: Sunday, February 23, 2020 12:21 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chips Hoai <chips@berkeley.edu>; Brandon DEFRANCISCI <defran@berkeley.edu>; Biosafety Program Departmental <bso@berkeley.edu>; lydia SOHN <sohn@berkeley.edu>
Subject: recombinant DNA accident

Dear Dr. Harris,

I would like to report an incident in the lab of Dr. Richard Kramer at UC Berkeley. On February 04, 2020, a Staff Research Associate (SRA) sustained a scratch on the back of her right hand by a needle used for injection of AAV9 expressing Green Fluorescent protein (GFP). The needle had been left in the stereotaxic injection equipment by a previous user in another lab. A detailed incident report is attached.

If you have any questions, or need additional information, please do not hesitate to contact me.

Thank you.

Sincerely yours,

Obtained via FOIA by Judicial Watch Inc.

Lydia Sohn

****

Lydia L. Sohn
CLEB Chair
Chancellor's Professor
Dept. of Mechanical Engineering
Faculty Assistant to the Vice Chancellor for Research
UC Berkeley

Core Member
UCSF-UC Berkeley Joint Graduate Program in Bioengineering
Berkeley, CA 94720-1740

5118 Etcheverry Hall
Berkeley, CA 94720-1740
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http://srl.berkeley.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of California, Berkeley
Date of Report:	February 21, 2020
Reporter name and position:	Chips Hoai Biosafety Officer
Telephone number:	510-849-7142
Email address:	chips@berkeley.edu
Reporter mailing address:	317 University Hall #1150 Office of Environment, Health & Safety UC Berkeley Berkeley, CA 94720
Date of incident:	February 04, 2020
Name of Principal Investigator:	Richard Kramer
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: September 04, 2018
What was the approved biosafety level of the research?	☒BL1 ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-4-a
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	serotype AAV9 expressing Green Fluorescent protein (GFP)

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of

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the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

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On February 04, 2020 around 1 pm, a Staff Research Associate (SRA) sustained a scratch that bled on the back of her right hand through the glove when she reached to unplug the power cord. There was a needle from a previous injection that was not removed at the end of experimentation the day before. The incident occurred in a shared procedure facility, but there was no one else present at the time. The SRA immediately washed her hands with running water for 15 minutes, then 70% ethanol for 5 minutes. She then went to the Occupational Health Clinic to have her hand examined. After further investigation, it was determined someone from another lab forgot to take out the needle after a stereotaxic injection with AAV9 expressing Green Fluorescent protein (GFP). The SRA was wearing a labcoat, gloves and hair bonnet at the time of incident. She was trained for doing intravitreal injections and certified by a campus veterinarian.

Has the IBC reviewed this incident?	☐YES ☒NO
Please describe the root cause of this incident:	The used needle was not removed and disposed of properly by a previous user in the facility. The root cause of the incident was failure to follow SOPs.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Both labs have updated and posted the SOP in the shared procedure room for the neonatal injection procedure. The SOP now has a mandatory checklist to follow after procedure(s) are complete. After procedures are completed, surfaces will be decontaminated with a 10% commercial bleach solution, all sharps will be disposed of in a rigid sharps container and all equipment will be turned off.

Members of the lab that will be performing this procedure were trained on this SOP on February 14, 2020. A record of this training will be located in the Lab Safety Manual SOP section.

In addition, lab members will be obtaining their OLAC re-certification on the neonatal brain injection February 21, 2020.

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- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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Hunter, Renee (NIH/OD) [C]

From: lydia SOHN <sohn@berkeley.edu>
Sent: Sunday, February 23, 2020 12:21 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Chips Hoai; Brandon DEFRANCISCI; Biosafety Program Departmental; lydia SOHN
Subject: recombinant DNA accident
Attachments: Kramer - NIH report - 2020.02.docx

Dear Dr. Harris,

I would like to report an incident in the lab of Dr. Richard Kramer at UC Berkeley. On February 04, 2020, a Staff Research Associate (SRA) sustained a scratch on the back of her right hand by a needle used for injection of AAV9 expressing Green Fluorescent protein (GFP). The needle had been left in the stereotaxic injection equipment by a previous user in another lab. A detailed incident report is attached.

If you have any questions, or need additional information, please do not hesitate to contact me.

Thank you.

Sincerely yours,

Lydia Sohn

****
Lydia L. Sohn
CLEB Chair
Chancellor's Professor
Dept. of Mechanical Engineering
Faculty Assistant to the Vice Chancellor for Research
UC Berkeley

Core Member
UCSF-UC Berkeley Joint Graduate Program in Bioengineering
Berkeley, CA 94720-1740

5118 Etcheverry Hall
Berkeley, CA 94720-1740
Redacted by agreement (cell)
http://srl.berkeley.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:46 AM
To: Mark Bouchard; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Salk NIH Incident (2020 0130) Report

Dear Mark Bouchard,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to these incidents appear appropriate.

No further information is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Mark Bouchard <mbouchard@salk.edu>
Sent: Monday, February 24, 2020 11:29 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Salk NIH Incident (2020 0130) Report

Dear NIH, Please see the attached incident report for a potential low risk exposure to Pseudorabies Virus (PRV).

Please send any question, concerns, or require further action.

Best Regards, -Mark

Mark Bouchard, MPH
DIRECTOR, ENVIRONMENTAL HEALTH & SAFETY

salk

Salk Institute for Biological Studies
10010 N Torrey Pines Rd • La Jolla, CA 92037

Obtained via FOIA by Judicial Watch Inc.

PH (858) 453-4100 x1319 • **FX** (858) 824-1962
M Redacted by agreement **E** mbouchard@salk.edu
WWW.SALK.EDU
TWITTER • FACEBOOK • YOUTUBE • LINKEDIN

Note: This email message (including any attachments) is for the sole use of the intended recipient(s) and may contain confidential, proprietary and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy the original message along with any and all copies.

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National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	The Salk Institute for Biological Studies
Date of Report:	2020 0220
Reporter name and position:	Mark Bouchard, Director EH&S and Biosafety Officer
Telephone number:	858-583-3094
Email address:	mbouchard@salk.edu
Reporter mailing address:	10010 N Torrey Pines Rd La Jolla, CA 92037
Date of incident:	2020 0130
Name of Principal Investigator:	Sam Pfaff, Ph.D.
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☒ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒ YES ☐ NO If yes, date of approval: 2019 1002
What was the approved biosafety level of the research?	☐ BL1 ☒ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1 Experiments using RG2 Agents as host vector systems III-D-4 Experiments involving whole animals
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Psuedorabies viral strains (PRV-152 and PRV-614). Replication competent viruses purchased through CNNV (The Center for Neuroanatomy with Neurotropic Viruses). See description of incident for additional information.

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A graduate student sustained a small puncture wound from dissection scissors to her right thumb while performing minor surgeries on a mouse. The scissors were used to make an incision in the leg of the mouse to expose a muscle; the muscle was then injected with pseudorabies viral strain (PRV-152). A second incision was made on the same leg and then a different PRV strain (PRV-614) was injected into the 2nd exposed muscle. The researcher sustained a small puncture wound prior to the 2nd PRV injection while adjusting the scope with the dissection scissors in her hand. This resulted in an accidental puncture from the tip of the scissors to her right thumb. The scissors were not decontaminated between PRV injections; however, they were decontaminated between individual animal surgeries.

The incident occurred in the CRAF Animal Biohazard Suite procedure room at 7 pm on 2020 0130. There were no witnesses present when the incident occurred. The minor puncture to researcher's right thumb was immediately cleaned for 15 minutes and was bandaged by the researcher. Once her animals were returned to the husbandry room the researcher reported to UCSD Thornton Hospital Emergency Room for care and treatment.

PRV, a neurotropic herpesvirus, has a wide host range, including several mammalian species, but is nonpathogenic for humans. Biosafety Level 2 practices and facilities are required per Salk's IBC. PRV strains used in this experiment were purchased through The Center for Neuroanatomy with Neurotropic Viruses (CNNV), an NIH-supported national resource based at the University of Pittsburgh. The two strains utilized in the experiment are listed below.

1. PRV-152: PRV-Bartha containing the CMV-EGFP reporter gene cassette inserted into the gG locus of the viral genome. The CMV promoter drives expression of the EGFP gene and the virus is selectively transported retrogradely. Demmin, GL et al. 2001 J. Virol. 75(22): 10856-69. Smith, BN et al. 2000. Proc. Natl. Acad. Sci. 97:9264-69.
2. PRV-614: PRV-Bartha containing CMV-mRFP reporter gene cassette inserted into the gG locus of the viral genome. Isogenic with PRV-152. Often used with PRV-152 in dual-infection studies. Banfield, BW et al. 2003. J. Virol. 77(18): 10106-12.

The researcher was wearing appropriate Personal Protective Equipment (PPE) required within the Biohazard Suite. The required PPE included a biohazard gown, head cover, shoe covers, double pair of gloves, face mask, and eye protection.

A contributing factor involved the use of new scissors that were sharper than the pair the researcher normally uses. The researcher stated this would not have happened with her previous pair of scissors since the tip of the scissors were not as sharp as the new pair. There were no deviations from standard operating procedures or from ABSL2 containment requirements.

The researcher was current on her tetanus vaccination (within 10 yrs). No other medical surveillance is required for this type of experiment.

The researcher started at Salk as a rotation student in Sept 2016 and was officially hired at Salk on May 30, 2017. Please see below for a list of completed trainings.

Date	Training	Training Group
2016 0921	New Hire Safety Orientation	EH&S
2017 0602	Biohazard ABSL2 training	EH&S & Animal Resources Dept (ARD)
2017 0508	Viral Vector Training	Viral Vector Core
2018 0619	2018 EH&S Annual Refresher	EH&S
2019 0814	2019 EH&S Annual Refresher	EH&S

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Has the IBC reviewed this incident?	☐YES ☒NO Incident will be reviewed at the next IBC meeting on March 4, 2020.
Please describe the root cause of this incident:	New equipment was a contributing factor. New scissors were sharper than the pair normally in use.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The injured researcher was counseled on the safe use of sharps in the work area on 2020 0206 by the Director of EH&S.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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Hunter, Renee (NIH/OD) [C]

From: Mark Bouchard <mbouchard@salk.edu>
Sent: Monday, February 24, 2020 11:29 AM
To: NIH guidelines
Subject: Salk NIH Incident (2020 0130) Report
Attachments: NIH Incident Report Salk Institute 2020 0130.pdf

Dear NIH, Please see the attached incident report for a potential low risk exposure to Pseudorabies Virus (PRV).

Please send any question, concerns, or require further action.

Best Regards, -Mark

Mark Bouchard, MPH
DIRECTOR, ENVIRONMENTAL HEALTH & SAFETY

salk.

Salk Institute for Biological Studies
10010 N Torrey Pines Rd • La Jolla, CA 92037
PH (858) 453-4100 x1319 • **FX** (858) 824-1962
M Redacted by agreement **E** mbouchard@salk.edu
WWW.SALK.EDU
TWITTER • FACEBOOK • YOUTUBE • LINKEDIN

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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:50 AM
To: Judge,Sharon; NIH guidelines
Cc: Gulig,Paul A; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report

Dear Dr. Sharon Judge,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Judge,Sharon <sjudge@ehs.ufl.edu>
Sent: Tuesday, February 25, 2020 3:05 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Gulig,Paul A <gulig@UFL.EDU>
Subject: Incident report

Dear Dr. Harris:

Attached is an incident report related to a potential exposure to recombinant DNA that occurred at UF on 2/11/20. Please let me know if you have questions or require any additional information.

Thank you,
Sharon

Sharon Judge, PhD, RBP
Biosafety Officer
University of Florida
Division of Environmental Health & Safety
Building 179, 916 Newell Drive
PO Box 112190
Gainesville, FL 32611-2190
Tel: 352-392-1591

Obtained via FOIA by Judicial Watch Inc.

Fax: 352-392-3647
Email: sjudge@ehs.ufl.edu

Obtained via FOIA by Judicial Watch Inc.

UF UNIVERSITY of FLORIDA

Business Affairs
Division of Environmental Health & Safety
Biological Safety Office

Building 179
PO Box 112190
Gainesville, FL 32611-2190
352-392-1591
352-392-3647 Fax
www.ehs.ufl.edu
bso@ehs.ufl.edu

February 25, 2020

Kathryn Harris, PhD, RBP
Senior Outreach and Education Specialist
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
Phone: 301-496-9838
Fax: 301-496-9839
Email: harriskath@od.nih.gov

Dear Dr. Harris,

I am writing to report an incident at the University of Florida involving a *potential exposure* to rDNA. The incident occurred in the afternoon on February 11th when a UF scientist received a mouse bite to the left index finger. The mouse had been placed on the wire-cage top and the scientist was using her left hand to restrain it so she could check the ID tag prior to weighing the animal when the mouse turned her head and bit the scientist. The mouse had received an intravenous injection of AAV9 expressing MBNL1 (41kD isoform) on January 9, 2020.

The scientist removed her gloves and thoroughly washed the wound with soap and water and then applied isopropanol. When she returned to the lab, she notified the lab manager who then called me to report the incident. I spoke with the injured worker and directed her to contact AmeriSys, the State of Florida's medical case management vendor, to report the incident. AmeriSys instructed the scientist to seek treatment at Emergency Physicians Medical Center where she was prescribed antibiotics. A follow-up appointment was scheduled for 2/25/20 but the scientist said the wound was mostly healed as of 2/17.

The scientist was wearing gloves, lab coat and shoe covers when the incident occurred. We discussed ways to mitigate a future incident but ultimately agreed that this was a random incident that could not have been prevented. Mice are routinely picked up to be weighed and this was the first time an incident such as this has occurred. The scientist indicated she could try wearing double gloves in the future but worried it may limit her dexterity.

The mouse had been injected with 9.5×10^{10} vector genomes AAV9 expressing muscleblind like splicing regulator 1 which modulates alternative splicing of pre-mRNAs. Myotonic dystrophy type 1 (DM1) is a microsatellite expansion disease caused by CTG expansion in the 3" UTR of the DMPK gene. The CUG repeats bind and sequester MBNL1 creating problems with pre-mRNA splicing. The PI stated that this is an endogenous protein that occurs in humans and the very small amount that might possibly be transmitted by a mouse bite should have no deleterious impact. Furthermore, the AAV vectors were produced in the absence of helper virus, are replication defective, and are not known to cause any disease in humans or animals.

The recombinant AAV involved is part of a project appropriately registered through the IBC. *In vitro* work was approved at BSL-1 in December 2015 under section III-E-1 for experiments involving the formation of recombinant or synthetic nucleic acids molecules containing no more than 2/3 of the genome of any eukaryotic virus. Animal experiments were added to the scope of work and approved at ABSL-1 by the IBC in November 2018 under section III-D-4-a of the NIH Guidelines. The PI updates the project annually

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and whenever new constructs are added. I believe all the relevant information you need about the incident has been provided here, but if you would like to discuss this further, or if I can provide more information, please don't hesitate to contact me.

Sincerely,

Redacted by agreement

Sharon Judge, PhD, RBP
Biosafety Officer
University of Florida
Division of Environmental Health & Safety
Building 179, 916 Newell Drive
PO Box 112190
Gainesville, FL 32611
T: 352-392-1591
F: 352-392-3647
E: sjudge@ehs.ufl.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Judge,Sharon <sjudge@ehs.ufl.edu>
Sent: Tuesday, February 25, 2020 3:05 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Gulig,Paul A
Subject: Incident report
Attachments: Reportable NIH Incident 2-11-20.pdf

Dear Dr. Harris:

Attached is an incident report related to a potential exposure to recombinant DNA that occurred at UF on 2/11/20. Please let me know if you have questions or require any additional information.

Thank you,
Sharon

Sharon Judge, PhD, RBP
Biosafety Officer
University of Florida
Division of Environmental Health & Safety
Building 179, 916 Newell Drive
PO Box 112190
Gainesville, FL 32611-2190
Tel: 352-392-1591
Fax: 352-392-3647
Email: sjudge@ehs.ufl.edu

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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:52 AM
To: Hynes, Steve; NIH guidelines
Cc: Stich, Roger W.; Hoffman, Sunny J.; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident Report - University of Missouri

Dear Steve Hynes,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Hynes, Steve <hyness@missouri.edu>
Sent: Wednesday, February 26, 2020 11:35 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Stich, Roger W. <stichrw@missouri.edu>; Hoffman, Sunny J. <hoffmansj@missouri.edu>
Subject: NIH Incident Report - University of Missouri

Attached is an incident report from the University of Missouri. Please let me know if you need any additional information.

Thanks,

Steve Hynes, RBP
Biosafety Officer
Responsible Official, Select Agent Program
University of Missouri
180 General Services Building
Columbia, MO 65211
hyness@missouri.edu
http://ehs.missouri.edu/

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	[X]YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Missouri
Date of Report:	2/25/2020
Reporter name and position:	Steve Hynes, Biosafety Officer
Telephone number:	573-882-7018
Email address:	hyness@missouri.edu
Reporter mailing address:	900 E. Stadium Blvd. Columbia, MO 65211
Date of incident:	1/28/2020
Name of Principal Investigator:	Bing Zhang, PhD
Is this an NIH-funded project?	☐YES [X]NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions [X] Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES [X] NO If yes, date of approval:
What was the approved biosafety level of the research?	[X]BL1 ☐ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-4-a
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Modified *Drosophila melanogaster*

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

On January 28, 2020, a member of our Laboratory Safety team and I visited the laboratory of the named Principal Investigator and found a student working with modified *Drosophila*. This investigator has previously had an approved protocol on file with the IBC, but let it expire. At the time of expiration, he said he was no longer doing the work described on his expired protocol. The student in the laboratory during the inspection visit described their work with *Drosophila* and TTX (exempt amounts), including the creation of crosses with modified flies obtained from prior collaborations.

Has the IBC reviewed this incident?	☐ YES [X] NO Will review at next IBC. IBC Chair is aware of the incident.
Please describe the root cause of this incident:	PI stated that he didn't think that this work fell under the *NIH Guidelines* any longer. However, back in 2014 he was cited for this very same issue.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

We promptly met with our Director, the Assistant Vice Chancellor for Research, and the investigator's Department Head. During this meeting, it was agreed upon that the investigator must immediately cease his work and either destroy or transfer his flies to an approved investigator.

He has complied; another investigator with IBC approval for work with transgenic Drosophila has submitted an amendment form to assume responsibility. The investigator is working on a new IBC protocol application and understands that research cannot commence until the application is reviewed and approved by the IBC. This includes the completion of all required training (Laboratory Safety and Recombinant Materials). The PI has confirmed that he now fully understands that his work fall under the *NIH Guidelines* and will comply in the future.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Hynes, Steve <hyness@missouri.edu>
Sent: Wednesday, February 26, 2020 11:35 AM
To: NIH guidelines
Cc: Stich, Roger W.; Hoffman, Sunny J.
Subject: NIH Incident Report - University of Missouri
Attachments: 20200225 NIH Incident Report - University of Missouri.pdf

Attached is an incident report from the University of Missouri. Please let me know if you need any additional information.

Thanks,

Steve Hynes, RBP
Biosafety Officer
Responsible Official, Select Agent Program
University of Missouri
180 General Services Building
Columbia, MO 65211
hyness@missouri.edu
http://ehs.missouri.edu/

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Anju Subba <asubba@uci.edu>
Sent: Monday, March 2, 2020 4:05 PM
To: NIH guidelines
Cc: Institutional Biosafety Committee
Subject: RE: Potential injury involving transgenic mouse

Hello,

After investigation we have confirmed that this incident involved non-transgenic mouse. The mouse involved was wild type C57BL6/J mice.

Best regards,

Anju Subba, MS, MS EMAP
Biosafety Officer
Biosafety & IBC, Environmental Health & Safety
Office: (949) 824-4365, Fax: (949) 824-1325
asubba@uci.edu

University of California, Irvine
4600 Health Sciences Rd
Irvine, CA 92697-2725



From: Anju Subba
Sent: Friday, February 28, 2020 4:16 PM
To: NIHGuidelines@od.nih.gov
Cc: Institutional Biosafety Committee <ibc@uci.edu>
Subject: Potential injury involving transgenic mouse

Hello,

We would like to report an injury (a mouse bite) to a researcher caused by a potential transgenic mouse. The incident occurred about 15 minutes ago. After investigation on Monday, we will submit a report if the incident involved any recombinant nucleic acids/transgenic mouse.

Best regards,

Anju Subba, MS, MS EMAP
Biosafety Officer
Biosafety & IBC, Environmental Health & Safety
Office: (949) 824-4365, Fax: (949) 824-1325
asubba@uci.edu

University of California, Irvine
4600 Health Sciences Rd
Irvine, CA 92697-2725

Obtained via FOIA by Judicial Watch Inc.



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Anju Subba <asubba@uci.edu>
Sent: Friday, February 28, 2020 7:16 PM
To: NIH guidelines
Cc: Institutional Biosafety Committee
Subject: Potential injury involving transgenic mouse

Hello,

We would like to report an injury (a mouse bite) to a researcher caused by a potential transgenic mouse. The incident occurred about 15 minutes ago. After investigation on Monday, we will submit a report if the incident involved any recombinant nucleic acids/transgenic mouse.

Best regards,

Anju Subba, MS, MS EMAP
Biosafety Officer
Biosafety & IBC, Environmental Health & Safety
Office: (949) 824-4365, Fax: (949) 824-1325
asubba@uci.edu

University of California, Irvine
4600 Health Sciences Rd
Irvine, CA 92697-2725



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 27, 2020 4:04 PM
To: Kirchhoff, Louis; NIH guidelines
Cc: Mortensen, Nyree E; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report of incident involving recombinant lentivirus - University of Iowa

Dear Dr. Louis Kirchhoff,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kirchhoff, Louis <louis-kirchhoff@uiowa.edu>
Sent: Thursday, March 19, 2020 1:50 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Mortensen, Nyree E <nyree-mortensen@uiowa.edu>
Subject: Report of incident involving recombinant lentivirus - University of Iowa

Dear Sir or Madam:

Attached please find a report of an incident involving recombinant lentivirus that occurred at the University of Iowa. The information regarding this incident was entered in the attached Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* provided on your website.

For your convenience, a copy of the immediate notification sent to your office via email on February 28th by Nyree Mortensen, PhD, RBP, BSO, is also attached.

Please be in touch if you have any comments or questions.

Best regards,

Louis

Obtained via FOIA by Judicial Watch Inc.

Louis V. Kirchhoff, MD, MPH
Chair, Institutional Biosafety Committee (IBC)

Professor of Internal Medicine (Infectious Diseases),
Psychiatry, and Epidemiology
Carver College of Medicine and College of Public Health
University of Iowa
Iowa City, Iowa
☎ Cell: Redacted by agreement
☎ Office: 319-356-7227
☎ Fax: 641-323-4537
: louis-kirchhoff@uiowa.edu

From: Mortensen, Nyree E
Sent: Friday, February 28, 2020 12:20 PM
To: NIHGuidelines@od.nih.gov
Subject: Potential Exposure to rDNA - Immediate Notification

We were notified this morning of an incident involving a potential eye exposure to replication defective recombinant lentivirus, which occurred on 02/25/2020. This email serves as our immediate notification.

We will begin working with all parties involved to complete and submit the incident report within 30 days.

Please feel free to contact me if you need any further information.

Thank you,

Nyree Mortensen, PhD, RBP
Biological Safety Officer, Select Agent Responsible Official
Environmental Health & Safety
University of Iowa
122 Grand Avenue Court, Iowa City, IA 52242
Office (319) 353-5679 | *Fax* (319) 384-3120
https://ehs.research.uiowa.edu/

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Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Does this incident involve research subject to the *NIH Guidelines*?	X YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	The University of Iowa
Date of Report:	
Reporter name and position:	Louis V. Kirchhoff, MD, MPH; IBC Chair
Telephone number:	319-356-7227
Email address:	louis-kirchhoff@uiowa.edu
Reporter mailing address:	UIHC SW54 GH Department of Internal Medicine 200 Hawkins Dr Iowa City, IA 52242
Date of incident:	02/25/2020
Name of Principal Investigator:	Eric B. Taylor, PhD
Is this an NIH-funded project?	X YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* RO1 DK104998 05 *NIH funding institute or center:* NIDDK *NIH program officer (name, email address):* Teff, Karen L.; teffk@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	X Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal X Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	X YES ☐NO If yes, date of approval: 05/16/2019
What was the approved biosafety level of the research?	☐ BL1 X BL2 ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Partially bleached supernatant from a culture of human cells transduced with a replication defective, HIV-based lentivirus expressing Cas9 and a guide RNA targeting a human gene thought to be involved in heme synthesis.

Obtained via FOIA by Judicial Watch Inc.

INCIDENT DESCRIPTION

On February 25, 2020, a graduate student was conducting an experiment with cells transduced with a replication defective lentivirus inside a biosafety cabinet (BSC). Per lab SOP, all pipette tips from the work were discarded into a receptacle containing a 10% bleach solution inside the BSC. Upon completion of the work, the graduate student removed the receptacle from the BSC and placed it near a sink in the BSL2 lab to allow for at least 20 minutes disinfection prior to discarding the liquid waste and the tips.

Upon inspection of the receptacle, the student noted that one pipette tip appeared to still contain a small amount (estimated 250 uL) of crude lentiviral cell supernatant, as evidenced by the pink color of the liquid inside of the tip. The student thought the filter in the tip was preventing the bleach solution from filling the tip. He decided to pick up the tip with his gloved hands and bend the tip to try and get it to fill with bleach. During this process, some of the liquid was expelled from the tip. The student believes some of the liquid contacted his left wrist and right eyelid, he does not believe that any of the liquid contacted his cornea.

At the time of the incident the student was wearing gloves, but no additional PPE. Immediately following the incident, the student washed his hands and wrists, but did not use an eyewash.

The student reported the incident to his supervisor on February 26, 20020 and contacted University of Iowa Occupational Health for medical follow up. The Biosafety Officer (BSO) and IBC Chair were notified of the incident on February 28, 2020. An Occupational Health physician concluded that the event was a low risk of exposure that did not require any diagnostic measures or treatment. Antiviral medications were offered to the student but were declined. No signs or symptoms related to this event have been reported.

Commented [k1]: It's not clear what the student did "to bend the tip," and an attentive reader is left wondering if he grabbed it with his fingers, a forceps, or whatever. You may want to clarify this, and also I suggest that you indicate specifically that the student stated that the supernatant did not contaminate his cornea.

Commented [MNE2R1]: I did confirm in the initial interview that he doesn't think it contacted his eyeball, which is why he didn't do an eyewash. I will follow up to get more details surrounding the bending of the tip.

Commented [MNE3R1]: Updated to state that he picked up the tip with gloved hands.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	xYES ☐NO
Please describe the root cause of this incident:	Not following proper protocol for disinfecting tip waste.

MEASURES TAKEN BY THE INSTITUTION TO MITIGATE ANY PROBLEMS IDENTIFIED.

On 2/26/2020 the PI and the lab safety officer discussed the incident in detail with the student and proposed the two corrective actions: 1) If an employee is ever uncertain about how to safely decontaminate materials, the employee should ask the PI, lab safety officer, or other more experience lab members for guidance; 2) Lentiviral decontamination should always occur in the BSC. The lab safety officer also re-reviewed exposure control training with the student.

During a follow up meeting on 3/4/2020 the BSO reminded the student of the requirement to immediately report exposures to his supervisor, University of Iowa Occupational Heath, and EHS Biosafety staff. The BSO also reminded the student that the minimum PPE for work in a BSL2 lab includes gloves, a lab coat, and eye protection (if a splash potential exists).The BSO also suggested: 1) aspirating the 10 % bleach solution into pipette tips prior to ejecting them from the pipetter and discarding them into the bleach solution; and 2) leaving the tip receptacle in the BSC for at least 20minutes to allow the submerged tips to obtain the appropriate contact time with the bleach solution. Only after the appropriate contact time is reached, should the receptacle be removed from the BSC.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kirchhoff, Louis <louis-kirchhoff@uiowa.edu>
Sent: Thursday, March 19, 2020 1:50 AM
To: NIH guidelines
Cc: Mortensen, Nyree E
Subject: Report of incident involving recombinant lentivirus - University of Iowa
Attachments: 200317 Report for OSP re Taylor rLentivirus incident .docx

Dear Sir or Madam:

Attached please find a report of an incident involving recombinant lentivirus that occurred at the University of Iowa. The information regarding this incident was entered in the attached Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* provided on your website.

For your convenience, a copy of the immediate notification sent to your office via email on February 28th by Nyree Mortensen, PhD, RBP, BSO, is also attached.

Please be in touch if you have any comments or questions.

Best regards,

Louis

Louis V. Kirchhoff, MD, MPH
Chair, Institutional Biosafety Committee (IBC)

Professor of Internal Medicine (Infectious Diseases),
Psychiatry, and Epidemiology
Carver College of Medicine and College of Public Health
University of Iowa
Iowa City, Iowa
☎ Cell: Redacted by agreement
☎ Office: 319-356-7227
☎ Fax: 641-323-4537
: louis-kirchhoff@uiowa.edu

From: Mortensen, Nyree E
Sent: Friday, February 28, 2020 12:20 PM
To: NIHGuidelines@od.nih.gov
Subject: Potential Exposure to rDNA - Immediate Notification

We were notified this morning of an incident involving a potential eye exposure to replication defective recombinant lentivirus, which occurred on 02/25/2020. This email serves as our immediate notification.

We will begin working with all parties involved to complete and submit the incident report within 30 days.

Please feel free to contact me if you need any further information.

Obtained via FOIA by Judicial Watch Inc.

Thank you,

Nyree Mortensen, PhD, RBP
Biological Safety Officer, Select Agent Responsible Official
Environmental Health & Safety
University of Iowa
122 Grand Avenue Court, Iowa City, IA 52242
Office (319) 353-5679 | *Fax* (319) 384-3120
https://ehs.research.uiowa.edu/

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Mortensen, Nyree E <nyree-mortensen@uiowa.edu>
Sent: Friday, February 28, 2020 1:20 PM
To: NIH guidelines
Subject: Potential Exposure to rDNA - Immediate Notification

We were notified this morning of an incident involving a potential eye exposure to replication defective recombinant lentivirus, which occurred on 02/25/2020. This email serves as our immediate notification.

We will begin working with all parties involved to complete and submit the incident report within 30 days.

Please feel free to contact me if you need any further information.

Thank you,

Nyree Mortensen, PhD, RBP
Biological Safety Officer, Select Agent Responsible Official
Environmental Health & Safety
University of Iowa
122 Grand Avenue Court, Iowa City, IA 52242
Office (319) 353-5679 | *Fax* (319) 384-3120
https://ehs.research.uiowa.edu/

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 13, 2020 8:56 AM
To: Zara Llewellyn; NIH guidelines
Cc: Katia Harb; Andre Lieber; Thea L Brabb; Steve Libby; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report - University of Washington

Dear Dr. Zara Llewellyn,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Zara Llewellyn <zaral@uw.edu>
Sent: Friday, February 28, 2020 7:48 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Katia Harb <kharb@uw.edu>; Zara Llewellyn <zaral@uw.edu>; Andre Lieber <lieber00@uw.edu>; Thea L Brabb <thea@uw.edu>; Steve Libby <slibby@uw.edu>
Subject: Incident report - University of Washington

Dear NIH,

Please find attached an incident report involving an employee performing research subjected to the NIH Section III-D guidelines.

Please let me know if you have any questions or need additional information.

Sincerely,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager

Obtained via FOIA by Judicial Watch Inc.

Alternate Responsible Official
Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
Direct: 206.221.2676 | Main: 206.221.7770 | Fax: 206.221.3068
zaral@uw.edu | www.ehs.washington.edu

UNIVERSITY of WASHINGTON

This information is intended for the individual named above. If you are not the intended recipient, any disclosure, copying, distribution, or use of the contents of this information is prohibited. Please notify the sender by reply email and then destroy all copies of the message and any attachments.

The above email may contain patient identifiable or confidential information. Because email is not secure, please be aware of associated risk of email transmission. If you are a patient, communication to a UW Medicine (or applicable) Provider via email implies your agreement to email communication; see http://uwmedicine.washington.edu/Global/Compliance/Pages/Notice-Of-Privacy-Practices.aspx .

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Washington
Date of Report:	February 28,2020 First reported via email to NIH on February 7,2020
Reporter name and position:	Zara Llewellyn, PhD, RBP Assistant Director for Research and Occupational Safety
Telephone number:	206-221-2676
Email address:	zaral@uw.edu
Reporter mailing address:	University of Washington Environmental Health and Safety Department Research and Occupational Safety Section 1705 NE Pacific Street T287 UW Box 357165 Seattle, WA 98195-7165
Date of incident:	February 6, 2020
Name of Principal Investigator:	Andre Lieber, MD, PhD
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* NIH R01HL141781 *NIH funding institute or center:* NHLBI *NIH program officer (name, email address):* Qasba, Pankaj, qasbap@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: February 20, 2019.
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☒OSHA: Reported on Institution's OSHA log.
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The recombinant is a gutless human adenovirus based on serotype 5 and containing chimeric Ad35 fibers. The vector expressed a human factor VIII from an erythroid specific promoter.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On February 6, 2020 a research scientist was handling a male C57BL/6 mouse that had been inoculated on December 13, 2019 with bone marrow lineage-negative cells after lethal irradiation. The lineage negative cells were harvested from a mouse at week 16 after a gutless adenovirus injection. The gutless human adenovirus contains chimeric Ad35 fibers expressing the human factor VIII from an erythroid specific promoter. The expression of FVIII in secondary recipients is not known to have biological effects.

The mouse was located in a BSL-2 animal laboratory vivarium at the University of Washington. The scientist was handling the mouse to perform a clinical exam and to trim the toe nails. The mouse had dermal lesions on the back, shoulders, and head. It was housed with five mice in the cage, of which three mice presented lesions. The mouse's left eye was dried shut from discharge. While scruffing the neck of the mouse lightly, the research scientist went to touch the eye and the mouse bit the scientist on the thumb side of the right index finger near the first knuckle. The scientist was wearing standard personal protective equipment that included facility scrubs, laboratory gown, nitrile gloves (single pair), dedicated facility shoes, and hair bonnet.

The scientist noticed a small amount of blood from the site of the wound. The scientist removed the gloves and washed the hands with soap and water for approximately 15 minutes. The employee followed up with the University Employee Health Clinic the following day on February 7, 2020 for medical counseling and monitoring.

The scientist had completed the following training:

Course	Completion Date	Expiration Date
Animal Technician Sick Animal Recognition & Reporting	6/10/2005	
Lab-Managed Sick Rodent Recognition	6/15/2005	
Mouse Hands-On Laboratory	9/23/2010	
Orbital Bleed, Mouse Anesthetized	12/21/2005	
Orbital Injection, Mouse Anesthetized	12/21/2005	
Animal Use Laws & Regulations	3/13/2018	3/13/2023
*Biosafety for animal handlers	7/30/2015	7/30/2018
Occupational health for animal handlers	7/30/2015	

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*The scientist will be taking the biosafety for animal handler's course as the current training has expired.

Has the IBC reviewed this incident?	☒YES ☐NO The incident was reviewed at the February 19, 2020 IBC meeting.
Please describe the root cause of this incident:	The mouse was not restrained properly and securely enough to perform a clinical exam on the left eye of the mouse.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The research scientist will not be performing an eye exam with the same clinical signs and symptoms on a mouse without properly scruffing and securing the hold on the mouse; or the research scientist will use a device, such as a cotton swab or similar device to prevent the person's finger from being in close proximity to the mouse's eye or mouth.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Zara Llewellyn <zaral@uw.edu>
Sent: Friday, February 28, 2020 7:48 PM
To: NIH guidelines
Cc: Katia Harb; Zara Llewellyn; Andre Lieber; Thea L Brabb; Steve Libby
Subject: Incident report - University of Washington
Attachments: NIH incident report_UW_Lieber_Feb_2020.pdf

Dear NIH,

Please find attached an incident report involving an employee performing research subjected to the NIH Section III-D guidelines.

Please let me know if you have any questions or need additional information.

Sincerely,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager
Alternate Responsible Official
Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
Direct: 206.221.2676 | Main: 206.221.7770 | Fax: 206.221.3068
zaral@uw.edu | www.ehs.washington.edu

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From: McKinney, Michelle (NIH/OD) [E]
To: Rengarajan, Kalpana; NIH guidelines
Cc: Thomaston, Scott W; Lyon III, G Marshall; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Lab Incident
Date: Friday, April 17, 2020 3:01:41 PM
Attachments: image001.jpg

Dear Dr. Kalpana Rengarajan,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Rengarajan, Kalpana <krengar@emory.edu>
Sent: Thursday, April 2, 2020 3:09 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Cc: Thomaston, Scott W <scott.thomaston@emory.edu>; Lyon III, G Marshall <gmlyon@emory.edu>
Subject: RE: Lab Incident

Good afternoon. Please find attached the detailed report of the incident that was reported initially on March 3rd, 2020. Please feel free to contact me if you have any questions
With regards
Kalpana

Wash your Hands and Stay safe

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)



PLEASE
WASH
YOUR
HANDS

FOIA by Judic

Obtained via FOIA by Judicial Watch Inc.

Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

You may visit www.ehso.emory.edu for updated information.

From: Rengarajan, Kalpana
Sent: Tuesday, March 3, 2020 2:33 PM
To: NIHguidelines@od.nih.gov; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Thomaston, Scott W <scott.thomaston@emory.edu>; Lyon III, G Marshall <gmlyon@emory.edu>
Subject: Lab Incident
Importance: High

Good afternoon. This is an initial report that a lab personnel had a needle stick while using Needle/syringe containing OS17 human osteosarcoma cells transduced (lentivirus) with firefly luciferase.

A detailed report will eb submitted within 30 days

Kalpana

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

You may visit www.ehso.emory.edu for updated information.

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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Emory University
Date of Report:	Initial Report: 3/3/2020 Detailed Report: 4/2/2020
Reporter name and position:	Kalpana Rengarajan Director Research Safety/Biosafety Officer
Telephone number:	404-727-8863
Email address:	krengar@emory.edu
Reporter mailing address:	1762 Clifton Road Suite 1200 Atlanta, GA 30322
Date of incident:	3/3/20
Name of Principal Investigator:	Dr. Edwin Horwitz
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 8/21/2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	• Section III-D-4-a • Section III-D-4-c-(2) • Section III-E • Section III-F-1 • Section III-F-2 • Section III-F-3 • Section III-F-4 • Section III-F-5 • Section III-F-6 • Section III-F-7 • F-Appendix C-VII • F-Appendix C-VIII

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Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA **Not applicable**
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	**Human osteosarcoma cells (OS17) transduced using a pHIV-luciferase self-inactivating 3rd generation lentiviral vector system.**

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
  Vivarium

- Who was involved in the incident/violation, including others present at the incident location?
  Research Specialist

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
  Removed the gloves, washed with soap and water for 15 minutes.

- The training received by the individual(s) involved and the date(s) the training was conducted
  - Research Lab Safety training completed on 7/28/2019 (required annually)
  - Blood borne pathogen training completed on 7/28/2019 (required annually)

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- Biosafety Training completed on 8/22/2018 (required every three years)

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
  No

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
  No

- The personal protective equipment in use at the time of the incident/violation

  Lab coat, nitrile gloves, surgical mask

- The occupational health requirements for laboratory personnel involved in the research
  No

- Any medical surveillance provided or recommended after the incident
  No

- Any injury or illness associated with the incident
  No

- Equipment failures **No**

DESCRIPTION OF INCIDENT: (use additional space as necessary)

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
  A mouse was secured in a restrainer to conduct the tail vein injection. Individual was holding loaded syringe with needle attached in right hand and reached for mouse's tail with left hand. Mouse flicked its tail, and the needle moved into individual's left thumb resulting in a puncture wound with minor bleeding. Individual removed gloves, washed the wound with soap and water for 15 minutes.

Has the IBC reviewed this	

Obtained via FOIA by Judicial Watch Inc.

incident?	☒YES Presented on March 12th, 2020 Meeting
Please describe the root cause of this incident:	Performing steps sequentially

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary)

Recommendations:

1. Avoid combining procedure steps
2. The loaded syringe should be set aside
3. The tail should have been secured with left hand and then the syringe should have been picked with right hand
4. Practice the process with veterinary staff
5. Consider using a safer needle safe device

Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

From: Rengarajan, Kalpana
To: NIH guidelines; Harris, Kathryn (NIH/OD) [C]
Cc: Thomaston, Scott W; Lyon III, G Marshall
Subject: RE: Lab Incident
Date: Thursday, April 2, 2020 3:09:51 PM
Attachments: image002.jpg
rDNA_Incident_Dr Horwitz_2020.pdf

Good afternoon. Please find attached the detailed report of the incident that was reported initially on March 3rd, 2020. Please feel free to contact me if you have any questions
With regards
Kalpana

Wash your Hands and Stay safe

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

You may visit www.ehso.emory.edu for updated information.

From: Rengarajan, Kalpana
Sent: Tuesday, March 3, 2020 2:33 PM
To: NIHguidelines@od.nih.gov; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Thomaston, Scott W <scott.thomaston@emory.edu>; Lyon III, G Marshall <gmlyon@emory.edu>
Subject: Lab Incident
Importance: High

Good afternoon. This is an initial report that a lab personnel had a needle stick while using Needle/syringe containing OS17 human osteosarcoma cells transduced (lentivirus) with firefly luciferase.

A detailed report will eb submitted within 30 days

Kalpana



PLEASE
WASH
YOUR
HANDS

FOIA by Judic

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Emory University
Date of Report:	Initial Report: 3/3/2020 Detailed Report: 4/2/2020
Reporter name and position:	Kalpana Rengarajan Director Research Safety/Biosafety Officer
Telephone number:	404-727-8863
Email address:	krengar@emory.edu
Reporter mailing address:	1762 Clifton Road Suite 1200 Atlanta, GA 30322
Date of incident:	3/3/20
Name of Principal Investigator:	Dr. Edwin Horwitz
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 8/21/2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	• Section III-D-4-a • Section III-D-4-c-(2) • Section III-E • Section III-F-1 • Section III-F-2 • Section III-F-3 • Section III-F-4 • Section III-F-5 • Section III-F-6 • Section III-F-7 • F-Appendix C-VII • F-Appendix C-VIII

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Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA **Not applicable**
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	**Human osteosarcoma cells (OS17) transduced using a pHIV-luciferase self-inactivating 3rd generation lentiviral vector system.**

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
  Vivarium

- Who was involved in the incident/violation, including others present at the incident location?
  Research Specialist

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
  Removed the gloves, washed with soap and water for 15 minutes.

- The training received by the individual(s) involved and the date(s) the training was conducted
  - Research Lab Safety training completed on 7/28/2019 (required annually)
  - Blood borne pathogen training completed on 7/28/2019 (required annually)

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- Biosafety Training completed on 8/22/2018 (required every three years)

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
  No

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
  No

- The personal protective equipment in use at the time of the incident/violation

  Lab coat, nitrile gloves, surgical mask

- The occupational health requirements for laboratory personnel involved in the research
  No

- Any medical surveillance provided or recommended after the incident
  No

- Any injury or illness associated with the incident
  No

- Equipment failures **No**

DESCRIPTION OF INCIDENT: (use additional space as necessary)

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
  A mouse was secured in a restrainer to conduct the tail vein injection. Individual was holding loaded syringe with needle attached in right hand and reached for mouse's tail with left hand. Mouse flicked its tail, and the needle moved into individual's left thumb resulting in a puncture wound with minor bleeding. Individual removed gloves, washed the wound with soap and water for 15 minutes.

Has the IBC reviewed this	

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incident?	☒YES Presented on March 12th, 2020 Meeting
Please describe the root cause of this incident:	Performing steps sequentially

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary)

Recommendations:

1. Avoid combining procedure steps
2. The loaded syringe should be set aside
3. The tail should have been secured with left hand and then the syringe should have been picked with right hand
4. Practice the process with veterinary staff
5. Consider using a safer needle safe device

Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

You may visit www.ehso.emory.edu for updated information.

This e-mail message (including any attachments) is for the sole use of the intended recipient(s) and may contain confidential and privileged information. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this message (including any attachments) is strictly prohibited.

If you have received this message in error, please contact the sender by reply e-mail message and destroy all copies of the original message (including attachments).

Obtained via FOIA by Judicial Watch Inc.

From: Rengarajan, Kalpana
To: NIH guidelines; Harris, Kathryn (NIH/OD) [C]
Cc: Thomaston, Scott W; Lyon III, G Marshall
Subject: Lab Incident
Date: Tuesday, March 3, 2020 2:33:23 PM
Importance: High

Good afternoon. This is an initial report that a lab personnel had a needle stick while using Needle/syringe containing OS17 human osteosarcoma cells transduced (lentivirus) with firefly luciferase.

A detailed report will eb submitted within 30 days

Kalpana

Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
FAX: (404) 727-9778

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This e-mail message (including any attachments) is for the sole use of the intended recipient(s) and may contain confidential and privileged information. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this message (including any attachments) is strictly prohibited.

If you have received this message in error, please contact the sender by reply e-mail message and destroy all copies of the original message (including attachments).

Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Frothingham, Richard; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report: AAV needle stick exposure
Date: Friday, March 27, 2020 4:30:03 PM

Dear Dr. Richard Frothingham,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. However, we understand the incident occurred on January 28, 2020. A report was not sent to NIH OSP until March 6, 2020. We would like to remind you that, as required by the *NIH Guidelines*, incidents involving an overt exposure at BL2 must be immediately reported to NIH. Investigators and research staff should also be reminded of this requirement. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Richard Frothingham, M.D. <richard.frothingham@duke.edu>
Sent: Friday, March 6, 2020 12:58 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Report: AAV needle stick exposure

NIH Office of Science Policy
Email: NIHGuidelines@od.nih.gov
Report: AAV needle stick exposure

I am writing to report a needle stick exposure of a Duke researcher to tissue potentially containing an AAV vector.

Event: The research involves perfusion of a porcine donor heart with an AAV vector, then implanting the donor heart into a porcine recipient. Here are event descriptions from Researcher A and the PI with minor edits:

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Researcher A: During the porcine heterotypic heart transplant surgery, I got a stick to my right fourth finger with a suture needle while holding pig's bowel. I went and washed my hands thoroughly with chlorhexidine.

PI: The AAV viral vector was administered to a donor heart through an ex vivo perfusion. After two hours of perfusion, the donor heart was flushed and implanted into the abdomen of the recipient in a heterotopic fashion. Only the donor heart received the AAV vector expressing the luciferase transgene. The needle that stuck Researcher A was used to sew the donor organ into the recipient. Researcher A was holding the intestines while the surgeon was sewing in the donor heart.

Recombinant DNA material description and risk assessment: The AAV vector contained a luciferase gene but no *rep* or *cap* genes. The suture needle had contacted heart tissue that had recently been perfused with the AAV vector. The tissue contained cells transfected by the vector; it may have contained some intact AAV vector. The needle stick exposure may have involved porcine cells and a small amount of intact AAV vector. The AAV vector is expected to efficiently infect human cells with expression of the transgene. The luciferase transgene is not expected to cause specific adverse effects.

Clinical evaluation and management: The researcher completed an incident report and was contacted by Duke Employee Occupational Health and Wellness (EOHW). No laboratory tests or treatment were recommended. The researcher was advised to contact employee health if any symptoms or signs arise at the needle stick site, or if the researcher had further questions.

Safety evaluation: This research was covered by an approved rDNA registration with an accompanying SOP describing BSL2/ABSL2 containment for the surgical procedure. The exposure is not expected to cause significant adverse effects.

Corrective action: The investigator and biological safety officer will consider possible modifications to operative procedures that might reduce the risk for suture needle exposures.

IBC review: This event was reviewed by the Duke IBC. The IBC agreed that this exposure did not pose a meaningful risk to Researcher A, and affirmed the corrective action plan.

Please contact me with any questions.

Best,
Rich Frothingham
Co-chair, Duke IBC

Richard Frothingham, MD
Associate Professor of Medicine
Co-chair, Institutional Biosafety Committee
Duke University Medical Center
Phone: 919 684 5455
Cell: Redacted by agreement
Email: richard.frothingham@duke.edu

Obtained via FOIA by Judicial Watch Inc.

Obtained via FOIA by Judicial Watch Inc.

From: NIH guidelines
To: "Richard Frothingham, M.D."
Subject: RE: Report: AAV needle stick exposure
Date: Tuesday, March 24, 2020 4:30:00 PM

Dear Dr. Frothingham:

Thank you for your report. Sorry if I am missing this, but can you please confirm the date the incident took place?

Regards,

Dr. Kathryn Harris

From: Richard Frothingham, M.D. <richard.frothingham@duke.edu>
Sent: Friday, March 6, 2020 12:58 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Report: AAV needle stick exposure

NIH Office of Science Policy
Email: NIHGuidelines@od.nih.gov
Report: AAV needle stick exposure

I am writing to report a needle stick exposure of a Duke researcher to tissue potentially containing an AAV vector.

Event: The research involves perfusion of a porcine donor heart with an AAV vector, then implanting the donor heart into a porcine recipient. Here are event descriptions from Researcher A and the PI with minor edits:

Researcher A: During the porcine heterotypic heart transplant surgery, I got a stick to my right fourth finger with a suture needle while holding pig's bowel. I went and washed my hands thoroughly with chlorhexidine.

PI: The AAV viral vector was administered to a donor heart through an ex vivo perfusion. After two hours of perfusion, the donor heart was flushed and implanted into the abdomen of the recipient in a heterotopic fashion. Only the donor heart received the AAV vector expressing the luciferase transgene. The needle that stuck Researcher A was used to sew the donor organ into the recipient. Researcher A was holding the intestines while the surgeon was sewing in the donor heart.

Recombinant DNA material description and risk assessment: The AAV vector contained a luciferase gene but no *rep* or *cap* genes. The suture needle had contacted heart tissue that had recently been perfused with the AAV vector. The tissue contained cells transfected by the vector; it may have contained some intact AAV vector. The needle stick exposure may have involved porcine cells and a small amount of intact AAV vector. The AAV vector is expected to efficiently infect human cells with expression of the transgene. The luciferase transgene is not expected to cause specific adverse effects.

Obtained via FOIA by Judicial Watch Inc.

Clinical evaluation and management: The researcher completed an incident report and was contacted by Duke Employee Occupational Health and Wellness (EOHW). No laboratory tests or treatment were recommended. The researcher was advised to contact employee health if any symptoms or signs arise at the needle stick site, or if the researcher had further questions.

Safety evaluation: This research was covered by an approved rDNA registration with an accompanying SOP describing BSL2/ABSL2 containment for the surgical procedure. The exposure is not expected to cause significant adverse effects.

Corrective action: The investigator and biological safety officer will consider possible modifications to operative procedures that might reduce the risk for suture needle exposures.

IBC review: This event was reviewed by the Duke IBC. The IBC agreed that this exposure did not pose a meaningful risk to Researcher A, and affirmed the corrective action plan.

Please contact me with any questions.

Best,
Rich Frothingham
Co-chair, Duke IBC

_____

Richard Frothingham, MD
Associate Professor of Medicine
Co-chair, Institutional Biosafety Committee
Duke University Medical Center
Phone: 919 684 5455
Cell: Redacted by agreement
Email: richard.frothingham@duke.edu

Obtained via FOIA by Judicial Watch Inc.

From: Richard Frothingham, M.D.
To: NIH guidelines
Subject: RE: Report: AAV needle stick exposure
Date: Tuesday, March 24, 2020 4:40:10 PM

Hello Dr. Harris,

The incident occurred on January 28, 2020. Let me know if you have other questions.

Best,
Rich

_____

Richard Frothingham, MD
Associate Professor of Medicine
Co-chair, Institutional Biosafety Committee
Duke University Medical Center
Phone: 919 684 5455
Cell: Redacted by agreement
Email: richard.frothingham@duke.edu

From: NIH guidelines <NIHguidelines@od.nih.gov>
Sent: Tuesday, March 24, 2020 4:30 PM
To: Richard Frothingham, M.D. <richard.frothingham@duke.edu>
Subject: RE: Report: AAV needle stick exposure

Dear Dr. Frothingham:

Thank you for your report. Sorry if I am missing this, but can you please confirm the date the incident took place?

Regards,

Dr. Kathryn Harris

From: Richard Frothingham, M.D. <richard.frothingham@duke.edu>
Sent: Friday, March 6, 2020 12:58 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Report: AAV needle stick exposure

NIH Office of Science Policy
Email: NIHGuidelines@od.nih.gov
Report: AAV needle stick exposure

I am writing to report a needle stick exposure of a Duke researcher to tissue potentially containing an AAV vector.

Obtained via FOIA by Judicial Watch Inc.

Event: The research involves perfusion of a porcine donor heart with an AAV vector, then implanting the donor heart into a porcine recipient. Here are event descriptions from Researcher A and the PI with minor edits:

Researcher A: During the porcine heterotypic heart transplant surgery, I got a stick to my right fourth finger with a suture needle while holding pig's bowel. I went and washed my hands thoroughly with chlorhexidine.

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Clinical evaluation and management: The researcher completed an incident report and was contacted by Duke Employee Occupational Health and Wellness (EOHW). No laboratory tests or treatment were recommended. The researcher was advised to contact employee health if any symptoms or signs arise at the needle stick site, or if the researcher had further questions.

Safety evaluation: This research was covered by an approved rDNA registration with an accompanying SOP describing BSL2/ABSL2 containment for the surgical procedure. The exposure is not expected to cause significant adverse effects.

Corrective action: The investigator and biological safety officer will consider possible modifications to operative procedures that might reduce the risk for suture needle exposures.

IBC review: This event was reviewed by the Duke IBC. The IBC agreed that this exposure did not pose a meaningful risk to Researcher A, and affirmed the corrective action plan.

Please contact me with any questions.

Best,
Rich Frothingham
Co-chair, Duke IBC

Richard Frothingham, MD
Associate Professor of Medicine
Co-chair, Institutional Biosafety Committee
Duke University Medical Center

Obtained via FOIA by Judicial Watch Inc.

Phone: 919 684 5455
Cell: Redacted by agreement
Email: richard.frothingham@duke.edu

Obtained via FOIA by Judicial Watch Inc.

From: Richard Frothingham, M.D.
To: NIH guidelines
Subject: Report: AAV needle stick exposure
Date: Friday, March 6, 2020 12:58:07 PM

NIH Office of Science Policy
Email: NIHGuidelines@od.nih.gov
Report: AAV needle stick exposure

I am writing to report a needle stick exposure of a Duke researcher to tissue potentially containing an AAV vector.

Event: The research involves perfusion of a porcine donor heart with an AAV vector, then implanting the donor heart into a porcine recipient. Here are event descriptions from Researcher A and the PI with minor edits:

Researcher A: During the porcine heterotypic heart transplant surgery, I got a stick to my right fourth finger with a suture needle while holding pig's bowel. I went and washed my hands thoroughly with chlorhexidine.

PI: The AAV viral vector was administered to a donor heart through an ex vivo perfusion. After two hours of perfusion, the donor heart was flushed and implanted into the abdomen of the recipient in a heterotopic fashion. Only the donor heart received the AAV vector expressing the luciferase transgene. The needle that stuck Researcher A was used to sew the donor organ into the recipient. Researcher A was holding the intestines while the surgeon was sewing in the donor heart.

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Clinical evaluation and management: The researcher completed an incident report and was contacted by Duke Employee Occupational Health and Wellness (EOHW). No laboratory tests or treatment were recommended. The researcher was advised to contact employee health if any symptoms or signs arise at the needle stick site, or if the researcher had further questions.

Safety evaluation: This research was covered by an approved rDNA registration with an accompanying SOP describing BSL2/ABSL2 containment for the surgical procedure. The exposure is not expected to cause significant adverse effects.

Corrective action: The investigator and biological safety officer will consider possible modifications to operative procedures that might reduce the risk for suture needle exposures.

IBC review: This event was reviewed by the Duke IBC. The IBC agreed that this exposure did not pose a meaningful risk to Researcher A, and affirmed the corrective action plan.

Obtained via FOIA by Judicial Watch Inc.

Please contact me with any questions.

Best,
Rich Frothingham
Co-chair, Duke IBC

_____
Richard Frothingham, MD
Associate Professor of Medicine
Co-chair, Institutional Biosafety Committee
Duke University Medical Center
Phone: 919 684 5455
Cell: Redacted by agreement
Email: richard.frothingham@duke.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 27, 2020 4:09 PM
To: Matt Anderson; NIH guidelines
Cc: Amit Mitra; Dan Hoyt; Brenda Osthus; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report of Non-compliance incident at UNL

Dear Dr. Matthew Anderson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Matt Anderson <manderson11@unl.edu>
Sent: Monday, March 9, 2020 4:50 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Amit Mitra <amitra1@unl.edu>; Dan Hoyt <dhoyt2@unl.edu>; Brenda Osthus <bosthus1@unl.edu>
Subject: Report of Non-compliance incident at UNL

Office of Science Policy,

Please find attached to this email a report of non-compliance with the NIH Guidelines related to work being conducted without approval by the IBC.

Please contact me if further information is required or with questions/comments.

Sincerely,

Matt

Obtained via FOIA by Judicial Watch Inc.

IN OUR GRIT, OUR GLORY.

Matthew A. Anderson, PhD, RBP(ABSA), CBSP(ABSA)
Biosafety Officer/ARO
University of Nebraska–Lincoln
Environmental Health & Safety
3630 East Campus Loop
Lincoln, NE 68583-0824
manderson11@unl.edu
Tel: 402.472.9554
Fax: 402.472.9650

"Wisdom is not a product of schooling but of the lifelong attempt to acquire it." — Albert Einstein

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☑YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Nebraska – Lincoln
Date of Report:	March 9, 2020
Reporter name and position:	Matthew Anderson, Biosafety Officer
Telephone number:	402-472-9554
Email address:	Manderson11@unl.edu
Reporter mailing address:	3630 East Campus Loop Lincoln, NE 68583-0824
Date of incident:	This incident came to the attention of the BSO on 2/12/2020. The unapproved study occurred from 12/17/19 to 1/21/20.
Name of Principal Investigator:	Eric Weaver, PhD
Is this an NIH-funded project?	☐YES ☑NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☑ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES ☑ NO ☐ If yes, date of approval: The creation of adenoviral-based Influenza vaccine vectors and use in mice was approved on 3/13/2017, but the use of these vectors in pigs was not approved at the time the experiments were conducted. An amendment to Dr. Weaver's IBC protocol has been submitted and will be reviewed at the March 9th, 2020 IBC meeting.
What was the approved biosafety level of the research?	☐ BL1 ☑ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	The work falls under Section III-D-4-a.
Has a report of this incident been made to other agencies? If so, please indicate No Report made to other agencies	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Replication-defective adenovirus viral vectors (based Ad5) expressing wildtype H1 genes from Swine Influenza A and mosaic/consensus sequence hemagglutinin proteins was tested in pigs for immune response in comparison to commercially available Influenza vaccines.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On February 12th, it was discovered that a pilot study injecting pigs with adenoviral vector-based swine influenza vaccines was conducted by the PI from 12-17-2019 through 1-21-2020. Upon further investigation and interview of the PI, this work was approved by the IACUC on 9/23/2019 and the PI was informed on 9/10/2019 by the attending veterinarian that an update to his IBC protocol would be needed for the work. An amendment to the IBC protocol was not submitted prior to the work starting. The work was conducted by a graduate student in the PI's lab and animal care workers at the animal facility on campus. Blood collection was performed as part of this study, but **no** challenge with infectious influenza virus was done.

The PI received initial training on the NIH Guidelines in 2015 and took refresher training on the NIH Guidelines on 12-5-2018.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☑ YES ☐ NO The incident was reviewed by the IBC at the March 9th 2020 IBC meeting
Please describe the root cause of this incident:	The PI was confused about what information needed to be included in his IBC protocol vs. his IACUC protocol and did not realize the administration of recombinant organisms to pigs needed to be explicitly described in his IBC protocol and approved by the IBC.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As the pilot study has already been completed, the PI was informed to not start new experiments with pigs until the protocol amendment describing the work has been reviewed by the IBC. The protocol was reviewed and approved at the March 9th IBC meeting.

The BSO explained to the PI about the need to have overlap between the IBC and IACUC protocols and that the IBC must be notified of all work with recombinant organisms and microbes and some work must be approved by the IBC prior to initiation.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Matt Anderson <manderson11@unl.edu>
Sent: Monday, March 9, 2020 4:50 PM
To: NIH guidelines
Cc: Amit Mitra; Dan Hoyt; Brenda Osthus
Subject: Report of Non-compliance incident at UNL
Attachments: Weaver Incident Report 2-12-20.docx

Office of Science Policy,

Please find attached to this email a report of non-compliance with the NIH Guidelines related to work being conducted without approval by the IBC.

Please contact me if further information is required or with questions/comments.

Sincerely,

Matt

IN OUR GRIT, OUR GLORY.

Matthew A. Anderson, PhD, RBP(ABSA), CBSP(ABSA)
Biosafety Officer/ARO
University of Nebraska–Lincoln
Environmental Health & Safety
3630 East Campus Loop
Lincoln, NE 68583-0824
manderson11@unl.edu
Tel: 402.472.9554
Fax: 402.472.9650

"Wisdom is not a product of schooling but of the lifelong attempt to acquire it." — Albert Einstein

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, March 27, 2020 4:14 PM
To: Cook, Susan; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report

Dear Susan Cook,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Cook, Susan <shcook@wustl.edu>
Sent: Thursday, March 12, 2020 1:15 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Incident report

Attached, please find a report of a potential occupational exposure. Please let me know if you have any questions or need any additional information.

-Susan

Susan Cook, PhD, CBSP
Director, Office of Biological Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: shcook@wustl.edu; Web: ehs.wustl.edu
(pronouns: she/her/hers)

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	XYES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Washington University in St. Louis, School of Medicine
Date of Report:	March 12. 2020
Reporter name and position:	Susan Cook, Biological Safety Officer
Telephone number:	314-747-0309
Email address:	shcook@wustl.edu
Reporter mailing address:	Campus Box 8229 660 South Euclid Avenue Saint Louis, MO 63110
Date of incident:	March 10, 2020
Name of Principal Investigator:	Christina Stallings
Is this an NIH-funded project?	XYES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number: U19AI142784* *NIH funding institute or center: NIAID* *NIH program officer (name, email address): Michael Schaeffer,*michael.schaefer@nih.gov

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal X Personnel exposure ☐ Spill X Other (please describe): Bitten by mouse infected with Mycobacterium tuberculosis
Did the Institutional Biosafety Committee (IBC) approve this research?	XYES ☐NO If yes, date of approval: 8/26/2015
What was the approved biosafety level of the research?	☐ BL1 ☐ BL2 ☐BL2+ (describe specific enhancement in report) X BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-4
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Mycobacterium tuberculosis Erdman strain transformed with an episomal plasmid expressing the GFP protein and a kanamycin resistance cassette.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

The research technician was scruffing a mouse that had been infected with a GFP expressing Mycobacterium tuberculosis strain. The mouse turned around and bit his left thumb, puncturing through the two layers of gloves, but the bite did not draw blood. The incident occurred in the animal BSL3 facility and the technician was following the approved protocols and wearing the approved personal protective equipment. The technician will undergo a diagnostic IGRA blood test in 2 months to determine if they have been exposed to M. tuberculosis. The individual is fully trained in working in the BSL3 and with mice, and is regularly monitored for exposure to M. tuberculosis. The risk of exposure due to this incident is considered minimal.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	X YES ☐NO The incident was reported to the IBC chairs on March 12 and will be discussed with the full committee at the next convened meeting on March 18.
Please describe the root cause of this incident:	Inadequate restraint of a research animal.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

EH&S is working with vendors and researchers to trial gloves to find a cut-resistant glove that does not negatively impact dexterity.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Cook, Susan <shcook@wustl.edu>
Sent: Thursday, March 12, 2020 1:15 PM
To: NIH guidelines
Subject: Incident report
Attachments: Incident-Report-WUSTL-200310.pdf

Attached, please find a report of a potential occupational exposure. Please let me know if you have any questions or need any additional information.

-Susan

Susan Cook, PhD, CBSP
Director, Office of Biological Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: shcook@wustl.edu; Web: ehs.wustl.edu
(pronouns: she/her/hers)

Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Chris Doyle; NIH guidelines
Cc: Karen McCulloch; "Juan.Varela.MD@AdventHealth.com"; "felipe.valerio@adventhealth.com"; "Rob.Herzog@AdventHealth.com"; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: IBC Incident Report - AdventHealth Orlando Infusion Center
Date: Thursday, April 2, 2020 2:33:45 PM
Attachments: image001.jpg

Dear Chris Doyle,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Chris Doyle <cdoyle@wirb.com>
Sent: Friday, March 20, 2020 4:02 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Karen McCulloch <KMcCulloch@wcgclinical.com>; 'Juan.Varela.MD@AdventHealth.com' <Juan.Varela.MD@AdventHealth.com>; 'felipe.valerio@adventhealth.com' <felipe.valerio@adventhealth.com>; 'Rob.Herzog@AdventHealth.com' <Rob.Herzog@AdventHealth.com>
Subject: IBC Incident Report - AdventHealth Orlando Infusion Center

To Whom it May Concern,

Please see the attached incident report, related to the use of facilities prior to IBC approval. The IBC has since reviewed the facilities and approved them for use in the future. Please feel free to reach out with any questions or if I can provide any additional details.

Best,
Chris

Obtained via FOIA by Judicial Watch Inc



The Trusted Partner in Ethical Review

Obtained via FOIA by Judicial Watch Inc.

Christopher Doyle, PhD | IBC Chair
WCG - WIRB
1019 39th Avenue SE
Suite 120
Puyallup, WA 98374
o/ +1 360.570.1386
cdoyle@wirb.com | **www.wirb.com**
www.wcgclinical.com



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Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Advent Health Orlando Infusion Center
Date of Report:	03-20-2020
Reporter name and position:	Christopher Doyle, PhD IBC Chair
Telephone number:	(360) 570-1386
Email address:	cdoyle@wirb.com
Reporter mailing address:	1019 39th Ave SE, Suite 120 Puyallup, WA 98374
Date of incident:	03-09-2020
Name of Principal Investigator:	Juan Carlos Varela, MD
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☒Other (please describe): Dosing in a location not approved by the IBC.
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 05-29-2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-C
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	CD19-targeted CAR T cells (lentivirus-modified)

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Unforeseen, subject-specific circumstances.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident

Obtained via FOIA by Judicial Watch Inc.

- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary):

In line with clinical trial-specified procedures, the IBC approved dosing in an outpatient area at the site. However, a subject with an underlying medical condition requiring hospitalization had to be dosed in an inpatient area rather than the outpatient area approved by the IBC. Other than the dosing location, all IBC-approved practices were adhered to and the incident did not result in any exposures, injuries, or illnesses.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The institution notified the IBC of the event in a timely manner. The IBC has reviewed the inpatient area and approved it for use as needed going forward.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

From:	Chris Doyle
To:	NIH guidelines
Cc:	Karen McCulloch; "Juan.Varela.MD@AdventHealth.com"; "felipe.valerio@adventhealth.com"; "Rob.Herzog@AdventHealth.com"
Subject:	IBC Incident Report - AdventHealth Orlando Infusion Center
Date:	Friday, March 20, 2020 4:03:18 PM
Attachments:	image001.jpg OSP Incident Report, Varela, dated 03-20-2020.pdf

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To Whom it May Concern,

Please see the attached incident report, related to the use of facilities prior to IBC approval. The IBC has since reviewed the facilities and approved them for use in the future. Please feel free to reach out with any questions or if I can provide any additional details.

Best,
Chris

Christopher Doyle, PhD | IBC Chair
WCG - WIRB
1019 39th Avenue SE
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Puyallup, WA 98374
o/ +1 360.570.1386
cdoyle@wirb.com | **www.wirb.com**
www.wcgclinical.com



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Obtained via FOIA by Judicial Watch Inc



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Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Advent Health Orlando Infusion Center
Date of Report:	03-20-2020
Reporter name and position:	Christopher Doyle, PhD IBC Chair
Telephone number:	(360) 570-1386
Email address:	cdoyle@wirb.com
Reporter mailing address:	1019 39th Ave SE, Suite 120 Puyallup, WA 98374
Date of incident:	03-09-2020
Name of Principal Investigator:	Juan Carlos Varela, MD
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☒Other (please describe): Dosing in a location not approved by the IBC.
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 05-29-2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-C
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	CD19-targeted CAR T cells (lentivirus-modified)

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Unforeseen, subject-specific circumstances.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident

Obtained via FOIA by Judicial Watch Inc.

- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary):

In line with clinical trial-specified procedures, the IBC approved dosing in an outpatient area at the site. However, a subject with an underlying medical condition requiring hospitalization had to be dosed in an inpatient area rather than the outpatient area approved by the IBC. Other than the dosing location, all IBC-approved practices were adhered to and the incident did not result in any exposures, injuries, or illnesses.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The institution notified the IBC of the event in a timely manner. The IBC has reviewed the inpatient area and approved it for use as needed going forward.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, April 17, 2020 4:01 PM
To: Institutional Biosafety Committee; NIH guidelines
Cc: Chow, Samson; Tafoya, Christine; Perkins, Jennifer; Powell, Trevor; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Final Report: 3/20/2020 UCLA Needle stick Incident - PI: Zack

Dear Christine Bruton,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. However, it is recommended that you consider using inactivated or non-infectious materials (and animals) while conducting training. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Institutional Biosafety Committee <ibc@research.ucla.edu>
Sent: Wednesday, April 15, 2020 1:56 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chow, Samson <schow@mednet.ucla.edu>; Tafoya, Christine <ctafoya@ehs.ucla.edu>; Perkins, Jennifer <JPerkins@research.ucla.edu>; Powell, Trevor <trevor.powell@research.ucla.edu>
Subject: Final Report: 3/20/2020 UCLA Needle stick Incident - PI: Zack

Dear OSP,

Please find the attached final report related to this incident. Of note, the incident description has been updated since the initial report.

Best,

Christine Bruton
IBC Manager
Email: christine.bruton@research.ucla.edu

Obtained via FOIA by Judicial Watch Inc.

Phone: 310.794.0474
Need extra help with the IBC process or safetyNet?
Stop by during weekly in-person office hours on campus.
Wednesdays, 2pm-5pm in CHS 17-132A

From: Institutional Biosafety Committee <ibc@research.ucla.edu>
Sent: Friday, March 20, 2020 4:46 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Tafoya, Christine <ctafoya@ehs.ucla.edu>; Chow, Samson <schow@mednet.ucla.edu>; Perkins, Jennifer <JPerkins@research.ucla.edu>
Subject: 3/20/2020 UCLA Needle stick Incident - PI: Zack

Dear OSP,

Our office has been notified of the following incident:

Date of Incident
3/20/2020

Incident Description:
An SRA II was training a new graduate student to do subcutaneous injections on an HIV positive mouse. The mouse had been involved in a challenge study and was given rHIV NL4-3 and had also been administered anti-retroviral drugs. They were using a needle with PBS to practice the injection. The graduate student had injected the mouse, but did so incorrectly, when the grad student was handing over the needle and the mouse to the SRA II and they accidentally stuck the SRA II with the contaminated needle. Lab data shows that the viral load in the animal is suppressed and lab members expressed that they considered this a low risk HIV exposure. The SRA II was seen at Occupational Health and given anti-retroviral treatments. The root cause of this incident was poor needle handling etiquette. The needle should have been placed down for the SRA to pick up. The SRA did not effectively communicate good needle handling to the student.

Containment:
BSL2+

A final report is forthcoming.

Regards,

Christine Bruton

Obtained via FOIA by Judicial Watch Inc.

IBC Manager

Email: christine.bruton@research.ucla.edu

Phone: 310.794.0474

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	***UCLA***
Date of Report:	***4/13/2020***
Reporter name and position:	***Christine Bruton, IBC Manager***
Telephone number:	***310-794-0474***
Email address:	***Christine.bruton@research.ucla.edu***
Reporter mailing address:	***UCLA- IBC Administrative Office 10889 Wilshire Blvd., Suite 600 Los Angeles, CA 90095-1406***
Date of incident:	***3/20/2020***
Name of Principal Investigator:	***Jerome Zack***
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) NIH - NATIONAL INSTITUTES OF HEALTH AI124843 Development of SMAC mimetics as latency-

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			reversing agents
		NIH - NATIONAL INSTITUTES OF HEALTH	AI124743	HIV Latency Reversal through Novel, Potent PKC Modulators
		NIH - NATIONAL INSTITUTES OF HEALTH	AI124763	Novel method for evaluating HIV latency and persistence in vivo
		NIH - NATIONAL INSTITUTES OF HEALTH	U19 AI117941	Anti-HIV Gene Therapy: Defend and Attack
		NIH - NATIONAL INSTITUTES OF HEALTH	UL1TR001881	: UCLA Clinical and Translational Science Institute (Intramural Award to Matthew Marsden, Ph.D: Evaluating HIV latency and persistence in vivo using genetically barcoded virus)
		NIH - NATIONAL INSTITUTES OF HEALTH	UL1TR000124	: UCLA Clinical and Translational Science Institute (Intramural Award to Matthew Marsden,

Obtained via FOIA by Judicial Watch Inc.

			Ph.D: Evaluating HIV latency and persistence in vivo using genetically barcoded virus)
	NIH - NATIONAL INSTITUTES OF HEALTH	AI028697	The UCLA Center for AIDS Research (CFAR)
	NIH - NATIONAL INSTITUTES OF HEALTH	HD080474	Early Antiretroviral Therapy and HIV Remission in Perinatal Infection
	NIH - NATIONAL INSTITUTES OF HEALTH	P01 AI131294	Defining Factors Controlling HIV Rebound

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: ***6/13/2018***

Obtained via FOIA by Judicial Watch Inc.

What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☒BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	***III-D, III-E***
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	***Needle contaminated from mouse that had been injected with rHIV NL4-3 and had also been administered anti-retroviral drugs.***

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A Staff Research Associate II (SRAII) was training a new graduate student to do subcutaneous injections on an HIV positive mouse. The mouse had been involved in a challenge study and was given rHIV NL4-3 and had also been administered anti-retroviral drugs. The graduate student was using a needle to inject Lactated Ringers solution per veterinary advice. The graduate student had injected the mouse, but did so incorrectly. When the grad student was handing over the needle and the mouse to the SRA II, the needle was still in the grad student's hand and the SRA II didn't see it and ran their hand into it. Lab data shows that the viral load in the animal is suppressed and lab members expressed that they considered this a low risk HIV exposure. The SRA II was seen at Occupational Health and given anti-retroviral treatments.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	***The root cause of this incident was poor needle handling etiquette. The needle should have been placed down for the SRA to pick up. The SRA did not effectively communicate good needle handling to the student.***

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Proper needle handling reinforcement and training. Implement "Needles Down" methodology, to be discussed at lab group meeting. To address the repeated needlestick injuries in the lab, Dr Zack is including more rigorous training for individuals working with mice. This will include: documented hands-on practice and needles safety, evaluating training stages and reassigning when a new person will start handling HIV+ animals. Approval for the research team to work individually will be approved by the lab's Sr personnel and the manager of the humanized mouse core facility.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Institutional Biosafety Committee <ibc@research.ucla.edu>
Sent: Wednesday, April 15, 2020 1:56 PM
To: NIH guidelines
Cc: Chow, Samson; Tafoya, Christine; Perkins, Jennifer; Powell, Trevor
Subject: Final Report: 3/20/2020 UCLA Needle stick Incident - PI: Zack
Attachments: UCLA Incident Zack 3_20_2020.docx

Dear OSP,

Please find the attached final report related to this incident. Of note, the incident description has been updated since the initial report.

Best,

Christine Bruton
IBC Manager
Email: christine.bruton@research.ucla.edu
Phone: 310.794.0474
Need extra help with the IBC process or safetyNet?
Stop by during weekly in-person office hours on campus.
Wednesdays, 2pm-5pm in CHS 17-132A

From: Institutional Biosafety Committee <ibc@research.ucla.edu>
Sent: Friday, March 20, 2020 4:46 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Tafoya, Christine <ctafoya@ehs.ucla.edu>; Chow, Samson <schow@mednet.ucla.edu>; Perkins, Jennifer <JPerkins@research.ucla.edu>
Subject: 3/20/2020 UCLA Needle stick Incident - PI: Zack

Dear OSP,

Our office has been notified of the following incident:

Date of Incident
3/20/2020

Incident Description:
An SRA II was training a new graduate student to do subcutaneous injections on an HIV positive mouse. The mouse had been involved in a challenge study and was given rHIV NL4-3 and had also been administered anti-retroviral drugs. They were using a needle with PBS to practice the injection. The

Obtained via FOIA by Judicial Watch Inc.

graduate student had injected the mouse, but did so incorrectly, when the grad student was handing over the needle and the mouse to the SRA II and they accidentally stuck the SRA II with the contaminated needle. Lab data shows that the viral load in the animal is suppressed and lab members expressed that they considered this a low risk HIV exposure. The SRA II was seen at Occupational Health and given anti-retroviral treatments. The root cause of this incident was poor needle handling etiquette. The needle should have been placed down for the SRA to pick up. The SRA did not effectively communicate good needle handling to the student.

Containment:
BSL2+

A final report is forthcoming.

Regards,

Christine Bruton

IBC Manager

Email: christine.bruton@research.ucla.edu

Phone: 310.794.0474

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Institutional Biosafety Committee <ibc@research.ucla.edu>
Sent: Friday, March 20, 2020 7:46 PM
To: NIH guidelines
Cc: Tafoya, Christine; Chow, Samson; Perkins, Jennifer
Subject: 3/20/2020 UCLA Needle stick Incident - PI: Zack

Dear OSP,

Our office has been notified of the following incident:

Date of Incident
3/20/2020

Incident Description:
An SRA II was training a new graduate student to do subcutaneous injections on an HIV positive mouse. The mouse had been involved in a challenge study and was given rHIV NL4-3 and had also been administered anti-retroviral drugs. They were using a needle with PBS to practice the injection. The graduate student had injected the mouse, but did so incorrectly, when the grad student was handing over the needle and the mouse to the SRA II and they accidentally stuck the SRA II with the contaminated needle. Lab data shows that the viral load in the animal is suppressed and lab members expressed that they considered this a low risk HIV exposure. The SRA II was seen at Occupational Health and given anti-retroviral treatments. The root cause of this incident was poor needle handling etiquette. The needle should have been placed down for the SRA to pick up. The SRA did not effectively communicate good needle handling to the student.

Containment:
BSL2+

A final report is forthcoming.

Regards,

Christine Bruton
IBC Manager
Email: christine.bruton@research.ucla.edu
Phone: 310.794.0474

Obtained via FOIA by Judicial Watch Inc.

From:	McKinney, Michelle (NIH/OD) [E]
To:	Ghosh, Sajal K; NIH guidelines
Cc:	Auerbach, Michelle; Hutchinson, Jennifer M; IBC; Mellouk, Kathryn M.; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject:	RE: Boston University Assistant Professor finger laceration with razor blade while mincing transgenic mouse tissue
Date:	Friday, March 27, 2020 4:02:36 PM

Dear Dr. Sajal Ghosh,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Ghosh, Sajal K <sajal@bu.edu>
Sent: Friday, March 20, 2020 3:40 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Auerbach, Michelle <ma1@bu.edu>; Hutchinson, Jennifer M <jhutch@bu.edu>; IBC <IBC@bu.edu>; Mellouk, Kathryn M. <kateski@bu.edu>; Ghosh, Sajal K <sajal@bu.edu>
Subject: Boston University Assistant Professor finger laceration with razor blade while mincing transgenic mouse tissue

NIH Office of Science Policy

To Whom It May Concern,

Please find attached an incident report for an incident that occurred on March 3, 2020 at the Boston University.

Sincerely,

Sajal K. Ghosh, Ph.D.

Obtained via FOIA by Judicial Watch Inc.

Senior Research Compliance Specialist
Institutional Biosafety Committee,
Boston University,
85 East Newton Street, Room 810 G
Boston, MA 02118
Ph: 617-358-7910 (new number), FAX: 617-358-7888
Email: sajal@bu.edu; ibc@bu.edu

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Boston University
Date of Report:	3/20/2020
Reporter name and position:	Sajal Ghosh, Ph.D., Senior Compliance Specialist, Safety and Quality Assurance Program
Telephone number:	617-358-7910
Email address:	IBC@bu.edu
Reporter mailing address:	85 East Newton Street, Suite 810 Boston, MA 02118
Date of incident:	3/3/2020
Name of Principal Investigator:	Darrell Kotton, Ph.D.
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant or contract number: 2R01- HL095993-10* *NIH funding institute or center: NHLBI* *NIH program officer (name, email address): Sara Lin (sara.lin@nih.gov)*

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this	☒YES ☐NO

Obtained via FOIA by Judicial Watch Inc.

research?	If yes, date of approval: 05/07/2018
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Sections III-D-1, III-D-4: Appendix-B-II, Appendix G-II-B-1
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☒State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Tissue from a transgenic mouse. The animal contained a knocked in green fluorescence protein reporter gene in the NKX2-1 locus.

DESCRIPTION OF INCIDENT:

On March 3, 2020, an assistant professor (AP) visited Research Occupational Health a few minutes after sustaining a shallow laceration to his left middle finger, through a single protective glove. The AP was mincing mouse tissue with a razor in a 3.5mm petri dish and immediately removed the glove, sprayed with ethanol, then washed the wound with soap and water for a few minutes before visiting Research Occupational Health. He is up-to-date with his tetanus vaccinations and returned to work with no restrictions.

The incident took place on the BU Medical Campus, 75 East Newton Street, in a BSL-2 room (E-602). The AP's Laboratory Safety Training and medical clearance are current. A report was sent to the Boston Public Health Commission.

Has the IBC reviewed this incident?	☐YES ☒NO Will be reviewed at the April 2020 IBC meeting.
Please describe the root cause of this incident:	Lack of conscientiousness and Equipment was insufficient (petri dish was not of sufficient size).

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation:

- On 03/4/2020, the AP completed Sharps Safety Training.
- On 03/05/2020, the AP was retrained to use the appropriate size petri dish for mincing tissues (per the standard operating procedure).

Obtained via FOIA by Judicial Watch Inc.

From: Ghosh, Sajal K
To: NIH guidelines
Cc: Auerbach, Michelle; Hutchinson, Jennifer M; IBC; Mellouk, Kathryn M.; Ghosh, Sajal K
Subject: Boston University Assistant Professor finger laceration with razor blade while mincing transgenic mouse tissue
Date: Friday, March 20, 2020 3:40:19 PM
Attachments: BU Incident Report 3.3.2020.pdf

NIH Office of Science Policy

To Whom It May Concern,

Please find attached an incident report for an incident that occurred on March 3, 2020 at the Boston University.

Sincerely,

Sajal K. Ghosh, Ph.D.
Senior Research Compliance Specialist
Institutional Biosafety Committee,
Boston University,
85 East Newton Street, Room 810 G
Boston, MA 02118
Ph: 617-358-7910 (new number), FAX: 617-358-7888
Email: sajal@bu.edu; ibc@bu.edu

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Boston University
Date of Report:	3/20/2020
Reporter name and position:	Sajal Ghosh, Ph.D., Senior Compliance Specialist, Safety and Quality Assurance Program
Telephone number:	617-358-7910
Email address:	IBC@bu.edu
Reporter mailing address:	85 East Newton Street, Suite 810 Boston, MA 02118
Date of incident:	3/3/2020
Name of Principal Investigator:	Darrell Kotton, Ph.D.
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant or contract number: 2R01- HL095993-10* *NIH funding institute or center: NHLBI* *NIH program officer (name, email address): Sara Lin (sara.lin@nih.gov)*

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this	☒YES ☐NO

Obtained via FOIA by Judicial Watch Inc.

research?	If yes, date of approval: 05/07/2018
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Sections III-D-1, III-D-4: Appendix-B-II, Appendix G-II-B-1
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☒State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Tissue from a transgenic mouse. The animal contained a knocked in green fluorescence protein reporter gene in the NKX2-1 locus.

DESCRIPTION OF INCIDENT:

On March 3, 2020, an assistant professor (AP) visited Research Occupational Health a few minutes after sustaining a shallow laceration to his left middle finger, through a single protective glove. The AP was mincing mouse tissue with a razor in a 3.5mm petri dish and immediately removed the glove, sprayed with ethanol, then washed the wound with soap and water for a few minutes before visiting Research Occupational Health. He is up-to-date with his tetanus vaccinations and returned to work with no restrictions.

The incident took place on the BU Medical Campus, 75 East Newton Street, in a BSL-2 room (E-602). The AP's Laboratory Safety Training and medical clearance are current. A report was sent to the Boston Public Health Commission.

Has the IBC reviewed this incident?	☐YES ☒NO Will be reviewed at the April 2020 IBC meeting.
Please describe the root cause of this incident:	Lack of conscientiousness and Equipment was insufficient (petri dish was not of sufficient size).

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation:

- On 03/4/2020, the AP completed Sharps Safety Training.
- On 03/05/2020, the AP was retrained to use the appropriate size petri dish for mincing tissues (per the standard operating procedure).

Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Karen McCulloch; NIH guidelines
Cc: Chris Doyle (cdoyle@wirb.com); abalmanoukian@theangelesclinic.org; namini@theangelesclinic.org; ohamid@theangelesclinic.org; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: IBC Incident Report - The Angeles Clinic and Research Institute
Date: Friday, April 17, 2020 3:17:17 PM
Attachments: image001.jpg

Dear Karen McCulloch,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Karen McCulloch <KMcCulloch@wcgclinical.com>
Sent: Thursday, March 26, 2020 4:11 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chris Doyle (cdoyle@wirb.com) <cdoyle@wirb.com>; abalmanoukian@theangelesclinic.org; namini@theangelesclinic.org; ohamid@theangelesclinic.org
Subject: IBC Incident Report - The Angeles Clinic and Research Institute

To Whom it May Concern,

Please see the attached incident report, related to the use of facilities prior to IBC approval. The IBC is scheduled to review the facilities during an IBC review meeting scheduled for Friday, March 27, 2020. Please feel free to reach out with any questions or if

Obtained via FOIA by Judicial Watch Inc.

WCG™ WIRB®

The Trusted Partner in Ethical Review

Obtained via FOIA by Judicial Watch Inc.

I can provide any additional details.

Best,
Karen

Karen A. McCulloch | IBC Chair
WCG - WIRB
1019 39th Avenue SE
Suite 120
Puyallup, WA 98374
o/ +1 651.429.1058
m/ Redacted by agreement
kmcculloch@wcgclinical.com | **www.wirb.com**
www.wcgclinical.com

WCG_WIRB_Clinical_Logo_Tagline (002)

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Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒ YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	The Angeles Clinic and Research Institute 11818 Wilshire Blvd. Los Angeles, CA 90025
Date of Report:	03-26-2020
Reporter name and position:	Karen McCulloch, BS IBC Chair, The Angeles Clinic and Research Institute
Telephone number:	651-429-1058
Email address:	kmcculloch@wcgclinical.com
Reporter mailing address:	1019 39th Ave SE, Suite 120 Puyallup, WA 98374
Date of incident:	03-04-2020
Name of Principal Investigator:	Ani Balmanoukian, MD
Is this an NIH-funded project?	☐YES ☒ NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☒ Other (please describe): Use of new/renovated agent preparation and dosing locations prior to IBC approval.
Did the Institutional Biosafety Committee (IBC) approve this research?	☒ YES ☐NO If yes, date of approval: Initial: 10-26-2017 Reapproved: 11-09-2018
What was the approved biosafety level of the research?	☒ BL1+ ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-C
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Lipoplex-encased mRNA encoding 10 tumor neoantigens (subject-specific)

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
    - The location the violation occurred was in the preparation area (pharmacy) and administration areas (infusion).

- Who was involved in the incident/violation, including others present at the incident location?
    - The pharmacists and infusion nurses and are all female.

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.
    - Directive taken from IBC services to submit an updated site map and revised SOP for the protocol. Additionally, a phone call was held on March 10, 2020 with the IBC Chairs, the Principle Investigator and Site Representative to review the violation and the tasks required in order to become compliant. The annual IBC Review meeting has also been scheduled for March 27, 2020.
    - This violation did not cause any health or environmental consequences.

- The training received by the individual(s) involved and the date(s) the training was conducted.
    - After our scheduled annual IBC review meeting, and approval of the revised SOP all clinical staff will be retrained.

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.
    - There were no deviations from the SOPs or protocol at the time of the violation, just a renovation of the designated space.
    -
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
    - No.

Obtained via FOIA by Judicial Watch Inc.

- The personal protective equipment in use at the time of the incident/violation
  - The personal protective equipment stated in the Biosafety SOP and the Biohazard sign were utilized.

- The occupational health requirements for laboratory personnel involved in the research.
  - Not applicable.

- Any medical surveillance provided or recommended after the incident
  - None were recommended or provided.

- Any injury or illness associated with the incident
  - No.

- Equipment failures
  - No.

DESCRIPTION OF INCIDENT:

On March 4, 2020, the IBC was informed that HGT research occurred in renovated facilities at The Angeles Clinic and Research Institute. Preparation of recombinant agent occurred in a renovated Pharmacy and dosing of this agent occurred in renovated exam rooms. Pharmacy renovations were completed on January 9, 2019, study agent was prepared and a subject was dosed on March 25, 2019, and 6 additional subjects have been dosed to date. The institution failed to obtain IBC approval prior to using these renovated areas for HGT research activities. An IBC meeting is scheduled for March 27, 2020 to review active HGT research and the renovations to the Pharmacy and exam rooms where recombinant agent is handled.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☐YES ☒ NO
Please describe the root cause of this incident:	Failure of the Institution to notify the IBC of facility changes.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

In the future, the Institutional Representative of the Institution will inform the IBC of any relocations or renovations to existing areas at least one month prior to the move.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

From:	Karen McCulloch
To:	NIH guidelines
Cc:	Chris Doyle (cdoyle@wirb.com); abalmanoukian@theangelesclinic.org; namini@theangelesclinic.org; ohamid@theangelesclinic.org
Subject:	IBC Incident Report - The Angeles Clinic and Research Institute
Date:	Thursday, March 26, 2020 4:11:30 PM
Attachments:	image002.jpg OSP Incident Report, Dr. Balmanoukian, dated 03-26-2020.pdf

To Whom it May Concern,

Please see the attached incident report, related to the use of facilities prior to IBC approval. The IBC is scheduled to review the facilities during an IBC review meeting scheduled for Friday, March 27, 2020. Please feel free to reach out with any questions or if I can provide any additional details.

Best,
Karen

Karen A. McCulloch | IBC Chair
WCG - WIRB
1019 39th Avenue SE
Suite 120
Puyallup, WA 98374
o/ +1 651.429.1058
m/ Redacted by agreement
kmcculloch@wcgclinical.com | www.wirb.com
www.wcgclinical.com

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Obtained via FOIA by Judicial Watch Inc.

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Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒ YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	The Angeles Clinic and Research Institute 11818 Wilshire Blvd. Los Angeles, CA 90025
Date of Report:	03-26-2020
Reporter name and position:	Karen McCulloch, BS IBC Chair, The Angeles Clinic and Research Institute
Telephone number:	651-429-1058
Email address:	kmcculloch@wcgclinical.com
Reporter mailing address:	1019 39th Ave SE, Suite 120 Puyallup, WA 98374
Date of incident:	03-04-2020
Name of Principal Investigator:	Ani Balmanoukian, MD
Is this an NIH-funded project?	☐YES ☒ NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☒ Other (please describe): Use of new/renovated agent preparation and dosing locations prior to IBC approval.
Did the Institutional Biosafety Committee (IBC) approve this research?	☒ YES ☐NO If yes, date of approval: Initial: 10-26-2017 Reapproved: 11-09-2018
What was the approved biosafety level of the research?	☒ BL1+ ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-C
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Lipoplex-encased mRNA encoding 10 tumor neoantigens (subject-specific)

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

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- Who was involved in the incident/violation, including others present at the incident location?
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  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

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- The training received by the individual(s) involved and the date(s) the training was conducted.
    - After our scheduled annual IBC review meeting, and approval of the revised SOP all clinical staff will be retrained.

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    - There were no deviations from the SOPs or protocol at the time of the violation, just a renovation of the designated space.
    -
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
    - No.

Obtained via FOIA by Judicial Watch Inc.

- The personal protective equipment in use at the time of the incident/violation
  - The personal protective equipment stated in the Biosafety SOP and the Biohazard sign were utilized.

- The occupational health requirements for laboratory personnel involved in the research.
  - Not applicable.

- Any medical surveillance provided or recommended after the incident
  - None were recommended or provided.

- Any injury or illness associated with the incident
  - No.

- Equipment failures
  - No.

DESCRIPTION OF INCIDENT:

On March 4, 2020, the IBC was informed that HGT research occurred in renovated facilities at The Angeles Clinic and Research Institute. Preparation of recombinant agent occurred in a renovated Pharmacy and dosing of this agent occurred in renovated exam rooms. Pharmacy renovations were completed on January 9, 2019, study agent was prepared and a subject was dosed on March 25, 2019, and 6 additional subjects have been dosed to date. The institution failed to obtain IBC approval prior to using these renovated areas for HGT research activities. An IBC meeting is scheduled for March 27, 2020 to review active HGT research and the renovations to the Pharmacy and exam rooms where recombinant agent is handled.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☐YES ☒ NO
Please describe the root cause of this incident:	Failure of the Institution to notify the IBC of facility changes.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

In the future, the Institutional Representative of the Institution will inform the IBC of any relocations or renovations to existing areas at least one month prior to the move.

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Friday, April 17, 2020 3:09 PM
To: Kara Drolet; NIH guidelines
Cc: Sarah Byers; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report of incident from OHSU

Dear Dr. Kara Manning Drolet,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kara Drolet <manningk@ohsu.edu>
Sent: Friday, March 27, 2020 7:02 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Cc: Sarah Byers <byerssa@ohsu.edu>
Subject: Report of incident from OHSU

Dear Dr. Harris,
Please find the attached incident report from OHSU and let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kara Drolet <manningk@ohsu.edu>
Sent: Friday, March 27, 2020 7:02 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Sarah Byers
Subject: Report of incident from OHSU
Attachments: OHSU Report of Centrifuge Spill 02282020.pdf

Dear Dr. Harris,
Please find the attached incident report from OHSU and let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
3181 SW Sam Jackson Park Rd. MC: L106RI
Portland, OR 97239
:manningk@ohsu.edu | ☎: 503.494.6727
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

OHSU

March 27, 2020

Kathryn Harris, Ph.D., RBP
Senior Outreach and Education Specialist
NIH OSP

Institutional Biosafety Committee
Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
ibc@ohsu.edu

Kara M. Drolet, Ph.D.
Associate Vice President
Research Integrity
tel 503 494-6727
manningk@ohsu.edu

Ashlee Moses, Ph.D.
IBC Chair
tel 503 418-2712
mosesa@ohsu.edu

Harjinder Sardar, Ph.D.
OHSU Biosafety Officer
tel 503-346-5028
sardar@ohsu.edu

Sarah Byers, Ph.D.
IBC Program Manager
tel 503 494-9763
byerssa@ohsu.edu

Dear Dr. Harris,

This letter serves as the detailed summary of follow up for a reportable incident that occurred at Oregon Health & Science University (OHSU).

Date of incident	2/28/2020
OHSU IBC registration number	IBC-11-45
OHSU project title	Cloning and production of adeno-associated viral vectors (AAV vectors) by the Molecular Virology Support Core (MVSC)
Nature of the material	Replication defective AAV1 expressing REV-GFP or REV-Gfi1-FLAG
Risk Group	I
Containment level	BSL-1
Nature of the incident	Spill in centrifuge
PPE in use	Gloves, lab coat

Description of incident:

The researcher was preparing viral stocks of replication defective AAV1 expressing non-hazardous inserts and was centrifuging 250 ml bottles containing supernatant. When the researcher opened the centrifuge they found that the bottles had leaked into the buckets in the centrifuge.

Appropriate spill response, as detailed in the lab specific biosafety manual, was followed. When the researchers observed the leak they closed the centrifuge and let it sit for 30 minutes to allow potential aerosols to dissipate. During this time the researchers consulted with the biosafety officer on spill clean up procedures. The centrifuge and all of its contents were sprayed down with Lysol for a 30 minute contact time. All materials used to clean the spill and all PPE worn during the clean up were disposed of as biohazard waste. The researcher thoroughly washed their hands and face after cleaning up the spill.

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Actions taken:

The root cause of the centrifuge spill was determined to be usage of an incorrect bottle adaptor in the bucket. To prevent a future centrifugation error, laboratory procedures have been revised to specifically identify the correct adaptors that are to be used in the centrifuge buckets.

The IBC has determined that this incident has now been resolved with the submission of this report to OSP.

Sincerely,

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

cc: Debra Brickey, PhD, Research Safety Manager; Dana Director, PhD, OHSU Institutional Official

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, June 1, 2020 8:56 AM
To: Kapsalis, Ellen; NIH guidelines
Cc: Bixby, John L; Tsoulfas, Pantelis; Gillooly, Shane David; Laine, Jennifer; IBC Support; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Final incident reports

Dear Dr. Ellen Kapsalis,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to these incidents appear appropriate.

No further information about these incidents are required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kapsalis, Ellen <EKapsali@med.miami.edu>
Sent: Tuesday, May 12, 2020 9:54 AM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Cc: Bixby, John L <jbixby@med.miami.edu>; Tsoulfas, Pantelis <PTsoulfa@med.miami.edu>; Gillooly, Shane David <sxg1519@med.miami.edu>; Laine, Jennifer <jxl2377@med.miami.edu>; IBC Support <ibcsupport@miami.edu>
Subject: Final incident reports

Dear Kathryn,

I hope that you are well. Attached please see the final reports for incidents reports that we discussed in April (see below). Both incidents were discussed at our IBC meeting last week.

Please do not hesitate to contact me if you have any questions.

Eleni

Ellen Kapsalis, Ph.D., CHRC, CPIA
Director of Compliance, IACUC /IBC /ESCRO
University of Miami

Obtained via FOIA by Judicial Watch Inc.

From: Kapsalis, Ellen <EKapsali@med.miami.edu>
Sent: Wednesday, April 1, 2020 3:28 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Bixby, John L <jbixby@med.miami.edu>; Tsoulfas, Pantelis <PTsoulfa@med.miami.edu>; Gillooly, Shane David <sxg1519@med.miami.edu>; IBC Support <ibcsupport@miami.edu>
Subject: preliminary incident report for two rodent bites

Dear Kathryn,

As we discussed on the telephone, the University of Miami has taken prudent measures in response to the pandemic crisis; ramping up biosafety measures while shutting down all but critical research at the University. Most IBC members and the IBC staff are working from home. These concomitant events prevented the IBC office from finalizing the reportable incidents that have taken place in the last month.

Here, we provide you a preliminary report for two events, with a final report to be sent within a month after the University of Miami employees are physically present at the University.

Investigator Sabita Roy, IBC protocol 17-090 IIID/BL2 and BL2-N:

Incident Summary: On February 27th, a female research associate was bitten by a mouse infected with Eco HIV. In Eco HIV, the coding region of gp120 in HIV-1/NL4-3 was replaced with that of gp80 from ecotropic murine leukemia virus. This chimeric retrovirus infects only rodents.
Incident Response: After the bite, the researcher immediately washed the bite for 15 minutes, and cleaned the site with a disinfectant sponge. The researcher reported the incident to her PI and was instructed to contact EHS and visit Employee Health Clinic. The researcher then sought professional medical treatment at the Employee Health Clinic

Investigator Jaime Merchan, IBC protocol 18-030 IIID/BL2 and BL2-N:

Incident Summary: On March 2nd, a female postdoctoral candidate was holding a transgenic mouse who had been treated with a recombinant vaccine strain of measles virus. This modified strain of the virus has a tropism only for mouse tissues, because has been engineered to bind only the mouse uPA receptor.
Incident Response: After the bite, the researcher immediately washed the bite with soap and water for 15 minutes. She reported the incident to the DVR Supervisor, her PI, and the Employee Health Clinic. After washing the bite, the researcher sought professional medical treatment at the Employee Health Clinic, where antibiotics were recommended and applied.

Thanks for your guidance.

Eleni

Ellen Kapsalis, Ph.D., CHRC, CPIA
Director of Compliance, IACUC /IBC /ESCRO

Obtained via FOIA by Judicial Watch Inc.

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	Yes
Institution Name:	University of Miami
Date of Report:	4/24/20
Reporter name and position:	Ellen Kapsalis, PhD. Director of Compliance IACUC/IBC/ESCRO
Telephone number:	305-243-2311
Email address:	ekapsali@med.miami.edu
Reporter mailing address:	University of Miami 1400 NW 10th Ave. Miami, FL 33136
Date of incident:	February 27, 2020
Name of Principal Investigator:	Dr. Sabita Roy
Is this an NIH-funded project?	Yes

What was the nature of the incident?	Personnel exposure

Obtained via FOIA by Judicial Watch Inc.

Did the Institutional Biosafety Committee (IBC) approve this research?	Yes Date of approval: August 7, 2017
What was the approved biosafety level of the research?	BL2
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-4-b
Has a report of this incident been made to other agencies? If so, please indicate	No
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	No recombinant or synthetic material was involved in incident itself. However, the study was reviewed and approved by the IBC in August 2017 due to the use of EcoHIV and HIV-1 ADA in animal models. The incident involved a non-transgenic mouse model (C57BL) previously injected with EcoHIV.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On February 27, 2020 at approximately 1:00pm, a female research associate was bitten by a mouse she was handling at the time. The incident occurred inside the assigned BL-2N animal holding room approved for this project. She was working alone and wearing the required PPE (gloves, disposable lab coat covering, N95 respirator) at the time of the incident. The mouse that the research associate was handling at the time of the incident was a non-transgenic model (WT C57BL strain) that had previously been injected with EcoHIV as approved in both the IBC and IACUC protocols. She was preparing to perform a daily weight check of the animal before the administration of either microbiome or probiotics (as approved in associated animal protocol) when she

Obtained via FOIA by Judicial Watch Inc.

was bitten. She was holding the animal by the tail and pulled back the skin of the neck to read the animal's tag. Upon release of the skin, the animal bit her.

The research associate immediately began first aid and washed the affected area for 15 minutes using the disinfectant sponge placed in all animal holding rooms. After washing the affected area, she contacted her direct supervisor (lab manager) and PI to report the incident. She was instructed to contact the Office of Environmental Health and Safety (EHS) for medical evaluation and treatment. She sought medical treatment/evaluation the same day of the incident.

The research associate arrived at EHS shortly after 1:00pm and was evaluated by the medical team, which included an infectious disease doctor and registered nurse. While the protocol in question involves both HIV-1 and EcoHIV, a final determination was made by the medical staff conducting the evaluation that no anti-viral or anti-integration drugs would be administered or provided to the research associate as the mouse that bit her had been injected with EcoHIV and not HIV-1. EcoHIV is a chimeric HIV and is not known to infect human lymphocytes.

On the same day of the incident (February 27th) the IBC Office and University's Biosafety Officer were notified of the incident. The Biosafety Officer (BSO) contacted the PI to discuss the incident. An incident investigation was launched by the BSO on March 3rd. During this investigation, it was noted that the research associate was current with all required trainings:

- Biosafety Training on May 9, 2018
- Lab Safety Training July 26, 2017
- OSHA BBP Training on September 24, 2019

Based on his incident investigation, the BSO is requiring the research associate complete a Biosafety Training refresher (via EHS) and recommended an Animal Handling Training refresher (via the Division of Veterinary Care).

Due to the ongoing pandemic, retraining of animal handling procedures and revision of those SOPs by DVR have not been discussed between the BSO and DVR Director.

Obtained via FOIA by Judicial Watch Inc.

These items will be discussed and addressed once operations at the University resume normal operations.

Has the IBC reviewed this incident?	Yes The investigation of the incident was completed as the University began conducting operations remotely due to the coronavirus pandemic. This incident was discussed at the May 6th, 2020 IBC meeting.
Please describe the root cause of this incident:	Once normal operations at the University of Miami, animal handling procedures will be reevaluated by DVR and BSO to determine if safer SOPs need to be implemented.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kapsalis, Ellen <EKapsali@med.miami.edu>
Sent: Tuesday, May 12, 2020 9:54 AM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Bixby, John L; Tsoulfas, Pantelis; Gillooly, Shane David; Laine, Jennifer; IBC Support
Subject: Final incident reports
Attachments: Roy Incident Report - Feb 2020.docx; Merchan Incident report March 2020.docx

Dear Kathryn,

I hope that you are well. Attached please see the final reports for incidents reports that we discussed in April (see below). Both incidents were discussed at our IBC meeting last week.

Please do not hesitate to contact me if you have any questions.

Eleni

Ellen Kapsalis, Ph.D., CHRC, CPIA
Director of Compliance, IACUC /IBC /ESCRO
University of Miami

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Incident Summary: On February 27th, a female research associate was bitten by a mouse infected with Eco HIV. In Eco HIV, the coding region of gp120 in HIV-1/NL4-3 was replaced with that of gp80 from ecotropic murine leukemia virus. This chimeric retrovirus infects only rodents.

Obtained via FOIA by Judicial Watch Inc.

Incident Response: After the bite, the researcher immediately washed the bite for 15 minutes, and cleaned the site with a disinfectant sponge. The researcher reported the incident to her PI and was instructed to contact EHS and visit Employee Health Clinic. The researcher then sought professional medical treatment at the Employee Health Clinic

Investigator Jaime Merchan, IBC protocol 18-030 IIID/BL2 and BL2-N:

Incident Summary: On March 2nd, a female postdoctoral candidate was holding a transgenic mouse who had been treated with a recombinant vaccine strain of measles virus. This modified strain of the virus has a tropism only for mouse tissues, because has been engineered to bind only the mouse uPA receptor.
Incident Response: After the bite, the researcher immediately washed the bite with soap and water for 15 minutes. She reported the incident to the DVR Supervisor, her PI, and the Employee Health Clinic. After washing the bite, the researcher sought professional medical treatment at the Employee Health Clinic, where antibiotics were recommended and applied.

Thanks for your guidance.

Eleni

Ellen Kapsalis, Ph.D., CHRC, CPIA
Director of Compliance, IACUC /IBC /ESCRO

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kapsalis, Ellen <EKapsali@med.miami.edu>
Sent: Wednesday, April 1, 2020 3:28 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Bixby, John L; Tsoulfas, Pantelis; Gillooly, Shane David; IBC Support
Subject: preliminary incident report for two rodent bites

Dear Kathryn,

As we discussed on the telephone, the University of Miami has taken prudent measures in response to the pandemic crisis; ramping up biosafety measures while shutting down all but critical research at the University. Most IBC members and the IBC staff are working from home. These concomitant events prevented the IBC office from finalizing the reportable incidents that have taken place in the last month.

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Director of Compliance, IACUC /IBC /ESCRO

Obtained via FOIA by Judicial Watch Inc.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, June 1, 2020 8:56 AM
To: Kapsalis, Ellen; NIH guidelines
Cc: Bixby, John L; Tsoulfas, Pantelis; Gillooly, Shane David; Laine, Jennifer; IBC Support; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Final incident reports

Dear Dr. Ellen Kapsalis,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to these incidents appear appropriate.

No further information about these incidents are required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kapsalis, Ellen <EKapsali@med.miami.edu>
Sent: Tuesday, May 12, 2020 9:54 AM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Cc: Bixby, John L <jbixby@med.miami.edu>; Tsoulfas, Pantelis <PTsoulfa@med.miami.edu>; Gillooly, Shane David <sxg1519@med.miami.edu>; Laine, Jennifer <jxl2377@med.miami.edu>; IBC Support <ibcsupport@miami.edu>
Subject: Final incident reports

Dear Kathryn,

I hope that you are well. Attached please see the final reports for incidents reports that we discussed in April (see below). Both incidents were discussed at our IBC meeting last week.

Please do not hesitate to contact me if you have any questions.

Eleni

Ellen Kapsalis, Ph.D., CHRC, CPIA
Director of Compliance, IACUC /IBC /ESCRO
University of Miami

Obtained via FOIA by Judicial Watch Inc.

From: Kapsalis, Ellen <EKapsali@med.miami.edu>
Sent: Wednesday, April 1, 2020 3:28 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Bixby, John L <jbixby@med.miami.edu>; Tsoulfas, Pantelis <PTsoulfa@med.miami.edu>; Gillooly, Shane David <sxg1519@med.miami.edu>; IBC Support <ibcsupport@miami.edu>
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Incident Summary: On March 2nd, a female postdoctoral candidate was holding a transgenic mouse who had been treated with a recombinant vaccine strain of measles virus. This modified strain of the virus has a tropism only for mouse tissues, because has been engineered to bind only the mouse uPA receptor.
Incident Response: After the bite, the researcher immediately washed the bite with soap and water for 15 minutes. She reported the incident to the DVR Supervisor, her PI, and the Employee Health Clinic. After washing the bite, the researcher sought professional medical treatment at the Employee Health Clinic, where antibiotics were recommended and applied.

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Director of Compliance, IACUC /IBC /ESCRO

Obtained via FOIA by Judicial Watch Inc.

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Does this incident involve research subject to the *NIH Guidelines*?	Yes
Institution Name:	University of Miami
Date of Report:	4/24/20
Reporter name and position:	Ellen Kapsalis, PhD. Director of Compliance IACUC/IBC/ESCRO
Telephone number:	305-243-2311
Email address:	ekapsali@med.miami.edu
Reporter mailing address:	University of Miami 1400 NW 10th Ave. Miami, FL 33136
Date of incident:	March 2, 2020
Name of Principal Investigator:	Dr. Jaime Merchan
Is this an NIH-funded project?	No

What was the nature of the incident?	Personnel exposure

Obtained via FOIA by Judicial Watch Inc.

Did the Institutional Biosafety Committee (IBC) approve this research?	Yes Date of approval: March 16, 2018
What was the approved biosafety level of the research?	BL2
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-4-a
Has a report of this incident been made to other agencies? If so, please indicate	No
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Administration of (attenuated) Recombinant Edmonstron vaccine strain of measles virus in tumor bearing mice

DESCRIPTION OF INCIDENT:

On March 2, 2020, approximately 11:30am, a female post-doctorate was bitten by a mouse she was handling at the time. She was working alone and was wearing the required PPE (gloves, disposable lab coat covering and surgical mask) at the time of the incident. The post-doc was bitten by a nude mouse that had previously been injected with the recombinant measles virus [(attenuated) Recombinant Edmonstron vaccine strain] approved in the study. The administration of the virus was done approximately 3 months prior to the incident. The post-doc was in the process of taking tumor measurements when the animal bit her left finger.

The post-doc immediately began first aid and washed the affected area for 15 minutes using the disinfectant sponge placed in all animal holding rooms. After washing the affected area, she contacted the veterinary tech supervisor and her PI to report the

Obtained via FOIA by Judicial Watch Inc.

incident before seeking medical evaluation and treatment from the Office of Environmental Health and Safety (EHS).

The post-doc arrived at EHS shortly after 11:30am and was evaluated by the medical team, which included the infectious disease doctor and registered nurse. The medical staff recommended and provided her with antibiotics at the time. No further treatment was recommended as the virus previously injected into the mouse was retargeted to the mouse UPA receptor (species specificity of the recombinant virus to the mouse UPA receptor is not known to infect humans, only mouse tissues).

Later that day (March 2nd) the IBC Office and University's Biosafety Officer were notified of the incident. The Biosafety Officer (BSO) contacted the PI to discuss the incident. An incident investigation was launched by the BSO on March 3rd. During this investigation, it was noted that the post-doc was current with all required trainings. The University's required training for laboratory staff is as follows:

- Biosafety Training on January 10, 2020,
- Lab Safety Training on March 4, 2020
- OSHA BBP Training on March 4, 2020

Based on his incident investigation, the BSO is requiring the research associate complete a Biosafety Training refresher (via EHS) and recommends the Division of Veterinary Care (DVR) review recent animal bite incidents and devise safer animal handling standard operating procedures.

Due to the ongoing pandemic, retraining of animal handling procedures and revision of those SOPs by DVR have not been discussed between the BSO and DVR Director. These items will be discussed and addressed once operations at the University resume normal operations.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	Yes The investigation of the incident was completed as the University began conducting operations remotely due to the corona virus pandemic. This incident was discussed at the May 6, 2020 IBC meeting.
Please describe the root cause of this incident:	Once normal operations resume at the University of Miami, animal handling procedures will be reevaluated by DVR and BSO to determine if safer SOPs need to be implemented.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

Obtained via FOIA by Judicial Watch Inc.

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kapsalis, Ellen <EKapsali@med.miami.edu>
Sent: Tuesday, May 12, 2020 9:54 AM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Bixby, John L; Tsoulfas, Pantelis; Gillooly, Shane David; Laine, Jennifer; IBC Support
Subject: Final incident reports
Attachments: Roy Incident Report - Feb 2020.docx; Merchan Incident report March 2020.docx

Dear Kathryn,

I hope that you are well. Attached please see the final reports for incidents reports that we discussed in April (see below). Both incidents were discussed at our IBC meeting last week.

Please do not hesitate to contact me if you have any questions.

Eleni

Ellen Kapsalis, Ph.D., CHRC, CPIA
Director of Compliance, IACUC /IBC /ESCRO
University of Miami

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Sent: Wednesday, April 1, 2020 3:28 PM
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Director of Compliance, IACUC /IBC /ESCRO

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Director of Compliance, IACUC /IBC /ESCRO

Obtained via FOIA by Judicial Watch Inc.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, May 11, 2020 2:43 PM
To: Eric D. Stefansson; NIH guidelines
Cc: Zara Llewellyn; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Involving Recombinant Virus at University of Washington

Dear Eric Stefansson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Eric D. Stefansson <estefans@uw.edu>
Sent: Monday, April 27, 2020 1:34 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Zara Llewellyn <zaral@uw.edu>
Subject: RE: Incident Involving Recombinant Virus at University of Washington

Dear NIH,

Please see attached incident report that was originally reported by email on April 1st. Please let me know if there are any questions.

Best,

Eric

ERIC STEFANSSON, MS, RBP
Senior Biosafety Officer, Alternate Responsible Official
Environmental Health and Safety

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 / Seattle, WA 98195-7165
Direct: 206.543.4969 / Main: 206.221.7770 / Fax 206.221.3068

Obtained via FOIA by Judicial Watch Inc.

estefans@uw.edu / http://www.ehs.washington.edu

UNIVERSITY of WASHINGTON

This information is intended for the individual named above. If you are not the intended recipient, any disclosure, copying, distribution, or use of the contents of this information is prohibited. Please notify the sender by reply email and then destroy all copies of the message and any attachments.

From: Eric D. Stefansson
Sent: Wednesday, April 1, 2020 9:59 AM
To: NIHGuidelines@od.nih.gov
Cc: Zara Llewellyn <zaral@uw.edu>
Subject: Incident Involving Recombinant Virus at University of Washington

Dear NIH,

This message is to inform you that a veterinarian experienced an injury from an animal infected with a recombinant virus on March 26, 2020.

We will be investigating the incident and submitting a formal report to the NIH.

Please let me know if you have any questions before then.

Thank you,

Eric

ERIC STEFANSSON, MS, RBP
Senior Biosafety Officer, Alternate Responsible Official
Environmental Health and Safety

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 / Seattle, WA 98195-7165
Direct: 206.543.4969 / Main: 206.221.7770 / Fax 206.221.3068
estefans@uw.edu / http://www.ehs.washington.edu

UNIVERSITY of WASHINGTON

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Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Washington
Date of Report:	April 26, 2020 (original notification April 1, 2020)
Reporter name and position:	Eric Stefansson, Senior Biosafety Officer
Telephone number:	(206) 543-4969
Email address:	estefans@uw.edu
Reporter mailing address:	University of Washington Environmental Health and Safety Department Research and Occupational Safety Section 1705 NE Pacific Street Box 357165 Seattle, WA 98195-7165
Date of incident:	3/26/2020
Name of Principal Investigator:	Dr. Hans-Peter Kiem
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known)

Obtained via FOIA by Judicial Watch Inc.

	NIH grant of contract number: U19 AI117941 *NIH funding institute or center:* NIAID *NIH program officer (name, email address):* Brigitte Sanders, brigitte.sanders@nih.gov

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: June 19,2019
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☒BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-4-b
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☒OSHA (OSHA 300 log)

Obtained via FOIA by Judicial Watch Inc.

Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Chimeric primate lentivirus (SHIV-1157ipd3N4) and Autologous Chimeric Antigen Receptor (CAR) T cells

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident

Obtained via FOIA by Judicial Watch Inc.

- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

This incident occurred in an animal procedure space connected to a housing room in the Washington National Primate Center ARCF facility. A veterinary specialist was working with a sedated macaque to weigh the animal and obtain an accurate blood pressure. An accurate blood pressure was needed in case additional sedation was required which would affect the blood pressure. The individual was assisted by another veterinary specialist. During the transfer the animal turned his head and bit the affected individual on the right forearm resulting in an open puncture wound. The animal appeared sedated enough for the transfer according to the individuals performing the transfer.

The animal was experimentally infected with SHIV-1157ipd3N4 on 8/5/2019. Suppressive antiretroviral therapy (ART) was initiated on 11/18/19. In addition Autologous Chimeric Antigen Receptor (CAR) T cells were infused on 3/23/20. The SHIV plasma viral load on the day of exposure, 3/26/20, was undetectable.

The employee went to the Emergency Room for medical attention and was also seen the next day by the University employee health clinic.

The employee was wearing the appropriate personal protective equipment (PPE) that included scrubs, Tyvek, hair bonnet, gown, face shield and double gloves.

This individual has been employed in the Primate Center since 2016. The following trainings have been completed:

- Biosafety training
- Bloodborne pathogens
- Biosafety orientation - Primate Center Occupational Health

Obtained via FOIA by Judicial Watch Inc.

- Applicable Annual Primate Center SOP trainings:

  -Blood Draws (0804), Weighing monkeys (1018), IV injection-catheter (0814), IM/Subcutaneous injection (0812), Clinical monitoring and reporting (0919)

Has the IBC reviewed this incident?	☒YES ☐NO This injury was reported at the April 15 IBC meeting.
Please describe the root cause of this incident:	This animal appears to be ketamine resistant. The animal appeared to be adequately sedated and then suddenly bit the individual.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

In the future this animal will receive alternate sedation in addition to ketamine. This will be effective immediately.

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Hunter, Renee (NIH/OD) [C]

From: Eric D. Stefansson <estefans@uw.edu>
Sent: Monday, April 27, 2020 1:34 PM
To: NIH guidelines
Cc: Zara Llewellyn
Subject: RE: Incident Involving Recombinant Virus at University of Washington
Attachments: NIH_Kiem_March_2020_Final.pdf

Dear NIH,

Please see attached incident report that was originally reported by email on April 1st. Please let me know if there are any questions.

Best,

Eric

ERIC STEFANSSON, MS, RBP
Senior Biosafety Officer, Alternate Responsible Official
Environmental Health and Safety

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UNIVERSITY of WASHINGTON

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Sent: Wednesday, April 1, 2020 9:59 AM
To: NIHGuidelines@od.nih.gov
Cc: Zara Llewellyn <zaral@uw.edu>
Subject: Incident Involving Recombinant Virus at University of Washington

Dear NIH,

This message is to inform you that a veterinarian experienced an injury from an animal infected with a recombinant virus on March 26, 2020.

We will be investigating the incident and submitting a formal report to the NIH.

Please let me know if you have any questions before then.

Obtained via FOIA by Judicial Watch Inc.

Thank you,

Eric

ERIC STEFANSSON, MS, RBP
Senior Biosafety Officer, Alternate Responsible Official
Environmental Health and Safety

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 / Seattle, WA 98195-7165
Direct: 206.543.4969 / Main: 206.221.7770 / Fax 206.221.3068
estefans@uw.edu / http://www.ehs.washington.edu

UNIVERSITY of WASHINGTON

This information is intended for the individual named above. If you are not the intended recipient, any disclosure, copying, distribution, or use of the contents of this information is prohibited. Please notify the sender by reply email and then destroy all copies of the message and any attachments.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Eric D. Stefansson <estefans@uw.edu>
Sent: Wednesday, April 1, 2020 12:59 PM
To: NIH guidelines
Cc: Zara Llewellyn
Subject: Incident Involving Recombinant Virus at University of Washington

Dear NIH,

This message is to inform you that a veterinarian experienced an injury from an animal infected with a recombinant virus on March 26, 2020.

We will be investigating the incident and submitting a formal report to the NIH.

Please let me know if you have any questions before then.

Thank you,

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Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Preston, Francine [JRDUS]; NIH guidelines
Cc: Link, David [JRDUS]; Hammonds, Elizabeth [JRDUS]; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report
Date: Friday, April 17, 2020 3:15:12 PM
Attachments: image001.jpg

Dear Francine Preston,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Preston, Francine [JRDUS] <FPreston@its.jnj.com>
Sent: Friday, April 3, 2020 12:49 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Link, David [JRDUS] <DLink@its.jnj.com>; Hammonds, Elizabeth [JRDUS] <EHammond@its.jnj.com>
Subject: Incident Report

Hello Dr. Harris –

There was a reportable incident at Janssen Pharmaceuticals on 2 March 2020. The incident occurred in the BSL2 large scale laboratory.
I've attached the report along with the rDNA risk assessment for this process. Additional physical containment (overwrapping) of welded sample tubing will be performed immediately to reduce the risk of tubing failure. The Janssen IBC will review this report at the next meeting.

Please let me know if you have any questions or concerns.
Kind regards,
Francine

Obtained via FOIA by Judicial Watch Inc.

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Obtained via FOIA by Judicial Watch Inc.

Francine Preston, CBSP, RBP, CSP
Principal Biosafety Specialist
Environment Health Safety & Sustainability
Janssen Pharmaceuticals, Inc.
1400 McKean Road
Spring House, PA 19477

Janssen_Hor_RGB



Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Related to Research Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids* to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA)

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. This template is also available on the NIH OBA Web pages as a Word document (http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting) in which the fields will expand according to the amount of text entered. Use of this template is not required and other formats for submitting reports may be acceptable.

A separate template for reporting Human Gene Transfer Adverse Events is available at:
http://osp.od.nih.gov/sites/default/files/resources/Adverse_Event_Template_.docx

Please note that submitting this completed template to NIH OBA does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

Attention: Incident Reports
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(For all non-USPS deliveries use Zip Code 20817)
Telephone 301-496-9838
Fax 301-496-9839
E-mail: oba-osp@od.nih.gov

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NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://osp.od.nih.gov/sites/default/files/resources/Adverse_Event_Template_.docx

Does this incident involve research subject to the *NIH Guidelines*?	× YES ☐ NO If no, this incident does not have to be reported to OBA
Institution name:	Janssen Pharmaceuticals, LLC
Date of report:	April 3, 2020
Reporter name and position:	Francine Preston, Principal Biosafety Specialist (IBC Chair)
Reporter telephone:	610-574-9556
Reporter email:	fpreston@its.jnj.com
Reporter mailing address:	1400 McKean Road Spring House, PA 19477
Date of incident:	2Mar2020
Name of principal investigator:	Hsu Feng Ko (Paul)
Is this an NIH funded project?	☐ YES ×NO
If yes, please provide:	NIH grant or contract number:
	NIH funding institute or center:
	NIH program officer contact information (name, email etc):
What was the **nature** of incident?	×Personnel exposure ☐ Spill ☐ Loss of containment ☐ Loss of transgenic animal ☐ Failure to obtain IBC approval ☐ Failure to follow approved containment conditions ☐ Other - please describe:

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Did the Institutional Biosafety Committee (IBC) approve this research	x YES ☐ NO If yes, on what date? 4 February 2019
If yes, please provide:	Approval date: 4 February 2019
	Approved biosafety level(s) for the research: BSL2 plus (Large Scale)
	Additional approval requirements: Directional air flow, Single Pass BIBO HEPA filtered room ventilation, Room Emergency Power shut off located near lab exit and second Room Emergency Power shut off in anteroom. Medical Surveillance, Respirator Training, local vacuum, disposable gowns, double nitrile gloves, safety glasses, shoe covers
What section(s) of the *NIH Guidelines* is the research subject to?	Section III: D-1, D-3, and D-6
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	☐ CDC ☐ USDA ☐ FDA ☐ EPA ☐ OSHA ☐ Research Funding Agency/Sponsor: (name)_____ ☐ State/Local Public Health ☐ Federal/State/Local Law Enforcement ☐ Other –

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Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc. as relevant.)	**Ad26.RSV.preF – Ad26.RSV.preF is a replication-incompetent Adenovirus (human Adenovirus group D type 26) based vector encoding the Respiratory Syncytial Virus (RSV) Fusion (F) protein stabilized in a prefusion conformation.** The Ad26.RSV.preF vector has been made replication -incompetent by removing the E1 region of the Ad26 genome, which is require for replication. A large portion of the E3 region, which promotes persistence within the host cell as also been removed to create sufficient space in the vial genome for the insertion of foreign antigens. E1 defect is supplemented by engineered E1(from Ad5) complementing cell lines (PER.C6).

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:
The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space).

- The incident occurred in BSL2 LS process development lab.

Who was involved in the incident/violation, including others present at the incident location? **Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)**.

- Female Scientist, Male Senior Associate Scientist, Female Senior Associate Scientist and Female Contractor.

Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.

- Female contractor stopped work immediately.
- Teared tubing was disinfected immediately with disinfectant (Virkon S.)
- Female contractor evacuated the lab to meet the onsite nurse.

The training received by the individual(s) involved and the date(s) the training was conducted.

Title	Female Scientist	Female Senior Associate	Male Senior Associate	Female Contractor
Biosafety Training	20 Aug 2018	27 Nov2019	30 Aug 2018	6Feb2020
Bloodborne pathogen	29 Jan2020	29 Jan2020	29 Jan2020	6 Feb 2020
Respirator training	20 Aug 2018	7 Nov2019	30 Aug 2018	Not trained
BSL2 plus viral vector biosafety training	15 Jul 2019	15 Jul 2019		23 Jul 2018
Biosafety Risk Assessment Review (BAR and RAC)	12 Nov 2019	12 Nov 2019	12 Nov 2019	12 Nov 2019

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The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.

- SOPs for lab access – no deviation
- SOP for virus handling – no deviation
- Exposure Control Plan – emergency response procedure was followed

Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.

- No deviation

The personal protective equipment in use at the time of the incident/violation.

- Disposable polypropylene gown, double nitrile gloves, safety glasses, shoe covers, hairnet.

The occupational health requirements for laboratory personnel involved in the research.

- Hepatitis B vaccine offer/declination
- Annual biosafety medical surveillance
- Respirator medical clearance

Any medical advice/treatment/surveillance provided or recommended after the incident.

- None

Any injury or illness associated with the incident.

- None

Medical surveillance results (if not available at the time of initial report please indicate when results will be available).

- N/A

Equipment failures.

- Teared tubing

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

Scientists were finishing the Lysis and Precipitation step of the downstream process while other scientists were in the room preparing the chromatography step for the next day. During the Lysis and Precipitation step, female contractor was preparing to connect the tubing (C-flex size 16) from the 1000L bioreactor to the sample bottle by welding with a SCD IIB Sterile tubing welder. While trying to weld the tubing to the sample bottle, one of the old welds from the bioreactor tubing line ripped apart and splashed (<5mL) on the face of the female contractor. The female contractor immediately left the workspace and evacuated the lab. The female senior scientist immediately disinfected the ripped tubing with Virkon S and clamped the end to contain it.

This step in the development process has been performed >20 times successfully in a facility approved for this activity by appropriately trained staff wearing the required PPE. The tubing is appropriately rated for used in the process step. The tear in the tubing was unexpected and was likely related to the previous poor welding and handling of the tubing.

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Has the IBC reviewed this incident?	☐ YES x NO If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed. Next meet April 6, 2020
Has a root cause for this incident been identified?	x YES ☐ NO If yes please describe: Process was sampled several times prior. Sterile weld in tubing from previous sampling failed and tubing ripped
Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary Tubing for sampling will be wrapped in parafilm as to contain any future tears. Effective: Immediately	

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

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BAR:376
RAC: 252

JANSSEN PHARMA
- REGISTRATION DOCUMENT -
Recombinant or Synthetic Nucleic Acid Molecules Research Proposal
PI Must Receive IBC Approval Before Beginning Work
Renewel is required every two years

(Please print or type)

INSTRUCTIONS: To register experiments imvolving Recombinant or Synthetic Nucleic Acid Molecules with the Institutional Biosafety Committee (IBC) complete this form using the most current "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules." Submit a registration form for each project involving recombinant or synthetic nucleic acid molecules. Principal Investigators are obligated to review the latest version of the NIH Guidelines (April 2016) in preparation for conducting Recombinant or Synthetic Nucleic Acid Molecules research and submitting this application. The NIH Guidelines can be accessed at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

Return the completed form to EHS. Incomplete forms will be returned.

Principal Investigator (PI): [redacted]

Alternate Contact Person: [redacted] Ext.: [redacted]

Department IBC Representative: [redacted] Ext. [redacted]

Department: [redacted] Facility: Spring House, PA

Laboratory (Bldg#Rm#) [redacted]

Project Title: RSV DS Late Stage Development

Research Description: (specifically address the use of Recombinant or Synthetic Nucleic Acid Molecules and describe work in the lab directly related to the biological hazard agents)

PER.C6 cells (immortalized human fetal retinal cells containing a plasmid) from a cell bank will be thawed into a chemically defined growth medium and cultured in Wave Bioreactors at the 10L scale (or samller). Once the cells reach sufficient density, they will be transferred to 50L Wave Bioreactors systesm. The cells are then used to inoculate a 250L Single Use Bioreactor (SUB) system that contains a disposable plastic container that holds the cell cuture. Cell densitities can reach as high as 100x10^6 cells/mL. The PER.C6 May then be transferred into a 50L or 1000L scale SUB. Each of the SUB systems is connected to a single use alternating tangential flow perfusion devices. At either 10L, 50L, 250L or 1000L scale (depending on the scale of the process development study), the PER.C6 cell culture will be infected with the respiratory syncytial virus (RSV) vector, Ad26.RSV, that contains the F protein gene of the RSV as the pre-fusion (pre-F) form of the fusion F protein. The culture will remain infected for 3 days and then will be harvested. Harvesting involves lysing the cells and adding flocculant to cause the DNA to precipitate. The lysed cell material is transferred to another single use vessel where it sits undisturbed overnight allowing gravity to cause sedimentation. Further clarification is then performed by depth filtration and membrane filtration. Further purification is achieved with anion exchange chromatography using a single use tubing set and single use chromatographic membrane absorbers. The final process step is tangential flow filtration to retain the viral particles while allowing small contaminates and buffer components to pass through. The process intermediates are analyzed using various analytical techniques such as turbidity, viral titer and qPCR. Samples are also frozen and shipped offsite for analysis. All process steps are closed and connections are made using sterile tubing welders or aseptic connection devices. If a connection is needed that can not be done in sterile manner, the connection is made before the introduction of viral material to the system, and the connection is only opened after decontamination is completed. Samples are taken from the equipment using sample bottles that are connected via sterile welds and have viral retentive hydrophobic filters. All open sampling tasks of virus-containing cultures will be done in a Class II Type A2 Biological Safety Cabinet.

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Non-Technical Summary of Recombinant or Synthetic Nucleic Acid Molecules use for this registration: (This should be written so that someone who is not an expert in your particular field can understand your use of Recombinant or Synthetic Nucleic Acid Molecules)

Human cells containing recombinant DNA will be grown in bioreactors at 10L, 50L, 250L, and 1000L scales. The cultures at each of these scales may be infected by adding Adenovirus (Ad26.RSV.preF) to the culture and incubated for 3 days. Once infection is complete the cells will be opened up releasing virus into the solution. The virus is separated from cell debris first by gravity settling then filtration. Contaminates are then removed with ion exchange chromatography then lastly via tangential flow filtration. All process steps are closed and utilize single use materials. PAPR respirators will be used during spill clean up for any spill under pressure and all spills >50 ml as instructed by the work instruction attached to the BAR form. Staff with acute / active respiratory infection (viral type) should avoid the lab until recovered from illness.

EXEMPTIONS FROM THE NIH GUIDELINES:

The following categories of experiments are exempt from IBC review and approval. (*See Guidelines Section III-F 1 through 8*). If your research is exempt, please mark which categories are the basis for your answer. Exempt experiments include:

- ☐ Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.
- ☐ Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
- ☐ Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
- ☐ Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.
- ☐ Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- ☐ Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. See Appendices A-I through A-VI, *Exemptions under Section III-F-6--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*.
- ☐ Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.
- ☐ Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), *Major Actions*), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III-F-8* for other classes of experiments which are exempt from the *NIH Guidelines*.

- If your research is exempt, go to "Section 6" and obtain the appropriate departmental signatures. There is no need to complete the remainder of this form. Please forward this form to EHS and retain a copy for your records.

- If your research is not exempt, please provide the required information shown below.

CHECK THE APPROPRIATE REGISTRATION CATEGORY FOR THE EXPERIMENT COVERED BY THE NIH GUIDELINES:

A. Experiments that require IBC approval, Research Advisory Committee (RAC) review, and NIH Director Approval before initiation.

Major actions under the NIH guidelines cannot be initiated without submission of relevant information on the proposed **experiment to the Office of /Science Policy (OSP), NIH.** (See Section IV-C-1-b-(1), Major Actions).

- ☐ Deliberate transfer of drug resistance trait to microorganisms that are unknown to acquire the trait naturally (*see* Section V-B, *Footnotes and References of Sections I-IV*) if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, agriculture, will be reviewed by RAC.

B. Experiments that require NIH/OSP and Institutional Biosafety Committee Approval before initiation.

- ☐ Experiments involving the cloning of toxin molecules with LD_{50} of less than 100 nanograms per kilogram body weight.

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☐ Experiments that have been Approved (under Section III-A-1-a) as Major Actions under the NIH Guidelines.

C. Experiments that require Institutional Biosafety Committee and Institutional Review Board Approvals plus RAC review before participant enrollment.

☐ Experiments involving the deliberate transfer of recombinant or Synthetic Nucleic Acid Molecules, or DNA, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into one or more Human Research Participants (human gene transfer).

D. Experiments that require only Institutional Biosafety Committee Approval before initiation.

☒ Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems *e.g.., Adenovirus, Lentivirus Retrovirus, etc. (*See Section II-A, Risk Assessment)

☐ Experiments in which DNA from Risk Group 2, 3, 4 or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.

☒ Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.

☐ Experiments involving whole animals. *(The RAC must be submitted to the IBC prior to submitting the ACUC application.)*

☐ Experiments to genetically engineer plants by recombinant or synthetic nucleic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid .

☒ Experiments involving more than 10 liters of culture.

☐ Experiments involving Influenza Viruses.

E. Experiments that require Institutional Biosafety Committee notice simultaneous with initiation.

☐ Experiments involving the formation of Recombinant or Synthetic Nucleic Acid Molecules containing no more than two-thirds of the genome of any eukaryotic virus.

☐ Experiments involving nucleic acid molecule-modified whole plants and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants, except those associated with Section D above .

☐ Experiments involving transgenic rodents.

1. RECOMBINANT INSERT:

(Add page(s) if needed)

a. Source(s) of DNA/RNA(siRNA)/cDNA sequences (*include genus, species, gene name*): The gene inserted was synthesized to create pre fusion F protein from Human orthopneumovirus, also know as respiratory scyncytial virus (RSV). The synthetic form contains three stabilizing mutations and two mutations to improve antigenic match with the A2 strain of RSV.

b. What is the biological activity/function of the siRNA, gene product or inserted DNA sequences?

The biological activity of the inserted gene is to code for RSV proteins (preF). Prefusion F is a form of the RSV fusion protein. The RSV fusion protein is responsible for fusing the virus and host cell membrane and is not involved in the replication of RSV. Pre fusion F is a stabilized form of the fusion protein that does not refold, therefore it is not able to function as fusion protein. [redacted]

2. VECTOR

(*Add page(s) if needed*)

a. Identify specific vector(s): Adenovirus serotype 26.

b. Describe the Host (will Recombinant or Synthetic Nucleic Acid Molecules be grown in tissue culture, animals, etc.)? Cell culture

c. Host strain for propagation of the recombinant: PER.C6 (human)

d. What percentage of the original (viral vector) genome is present in the recombinant vector? 90%

e. Is the vector replication competent? ☐ YES ☒ NO

If no, what has been done to make it replication incompetent?

E1 and E3 have been deleted. E1 is essential for the replication of the adenovirus. An E1 gene from Adenovirus 5 is present in the PER.C6 cell line for replication of the vector. There is absence of sequence overlap between the Ad26 and the PER.C6 cells that ensures that no replication competent particles are produced. E3 is involved in making the Ad26 more robust. See also attachment 1. This vector and insert

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combination were well tolerated in clinical trials.

3. GENE DRIVE SYSTEM

(*Add page(s) if needed*)

a. Does your research involve CRISPR or other gene editing technologies? ☐ YES ☒ NO
If yes, please indicate which technology (CRISPR-Cas9, zinc finger nucleases, TALENS, meganucleases, other [specify])

b. Will the technology target embryos or germ line cells? ☐ YES ☐ NO

c. How is the gene editing technology being delivered (i.e. nanoparticles, plasmid, Lentivirus, Adeno-Associate virus etc.)

d. For CRISPR systems, is the guide RNA and nuclease on the same plasmid, vector, or delivery vehicle ? ☐ YES ☐ NO

e. For CRISPR-CAS9, can this plasmid, vector, or delivery vehicle transfect or infect a human cell? ☐ YES ☐ NO

f. For CRISPR research involving viral vectors, has a genome target scan (or similar scan) for off-target effects by the guide RNA been completed? ☐ YES ☐ NO
This is necessary to determine if there is homology to human DNA and for assessing the risk of potential exposure in the event of an unanticipated incident. Off -target databases are available at the following:
- http://www.deepcrispr.net/about
- https://sourceforge.net/projects/crispr-offinder-v1-2/
- http://www.bioconductor.org/packages/release/bioc/html/GUIDEseq.html

g. Describe the potential effects due to accidental worker exposure and the different effects via inhalation, percutaneous and oral exposure (as appropriate to the work). If unknown, state 'unknown'. What are the gene product effects? *(Specifically, it's toxicity, biological function or physiological activity, allergenicity, oncogenic potential or ability to alter cell cycle).*

3. GENE (Recombinant DNA or Synthetic Nucleic Acid Molecule) EXPRESSION, FUNCTION & SOURCE

(*Add page(s) if needed*)

h. Will you be expressing gene products from the Recombinant or Synthetic Nucleic Acid Molecule gene insert)?
☐ YES ☒ NO
If yes, what are the gene product effects? *(Specifically, it's toxicity, biological function or physiological activity, allergenicity, oncogenic potential or ability to alter cell cycle).*

i. Will the recombinant genes(s) be intentionally mutated? ☐ YES ☐ NO
If yes, please explain the effect on the biological function of the resulting expressed protein.

4. FOR ANIMAL EXPERIMENTS ONLY

a. Has an IACUC protocol been submitted? ☐ YES ☐ NO
If yes, what is the IACUC protocol # _____ and approval date? _____

b. For *in vivo* vector administration discuss the safety concerns for the host (name species) and target organs or systems.

c. Is the host a potential carrier of helper viruses that could lead to replication-competency of the recombinant viral vector construct? ☐ YES ☐ NO
If yes, what are these?

d. If gene drives are used, will the experiment make transgenic or sexually reproducing organisms? ☐ YES ☐ NO

e. If gene drives are used, please describe containment strategies (molecular, ecological, reproductive and barrier) used to prevent animal release._____

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f. If gene drives are used is there a means of abrogating the gene drive change should an animal escape? ☐ YES ☐ NO
If yes, please describe._____
_____

g. Describe the potential off-target effects

h. Does the approach to this study have biohazard implications or consequences? ☐ YES ☐ NO
Is there potential for exposure to staff and animal colonies? ☐ YES ☐ NO
If yes, please explain how the recombinant viral vector might be transmitted (by shedding or aerosol, etc.) from the animal host?_____
_____

i. Do you require special animal containment facilities? ☐ YES ☐ NO

5. RISK ASSESSMENT:

(*Add page(s) if needed*)

Classification of AGENT should be based on the Agent and how it is manipulated. Factors to consider are: Virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment and gene product effects such as toxicity, physiological activity and allergenicity.

- Any strain known to be more hazardous than the parent strain should be considered for handling at a higher containment level.
- Certain attenuated strains or strains that have been demonstrated to irreversible loss of known virulence factors may qualify for reduction of containment level compared to the Risk Group Assigned to the parent strains.
- *Note Well: **Although Adeno Associated virus** (AAV) **has been considered a non-pathogenic virus,** AAV vectors have been associated with some forms of cancer. **Therefore, the Janssen IBC recommends BSL-2 containment for AAV research activities.**

a. What is the NIH Assigned Risk Group for Parent Strain? ☐ RSG-1 ☒ RSG-2 ☐ RSG-3
b. What Containment level do you propose for this experiment? ☐ BSL-1 ☒ BSL-2 plus ☐ BSL-3
c. Will the study be performed in Large Scale (greater than 10 liters)? ☒ YES ☐ NO
d. Will Recombinant or Synthetic Nucleic Acids (r/sNA) be introduced into experimental animals or plants that fall under NIH Guidelines? ☐ YES ☒ NO
e. Will Recombinant or Synthetic Nucleic Acid Molecules be introduced into Gene therapy human trials? ☐ YES ☒ NO
f. Has a corresponding BAR form been completed for this study? ☒ YES ☐ NO

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6. **LABORATORY BIOSAFETY LEVEL CRITERIA –** Standard laboratory practices (BSL1) requires lab coat, safety glasses and disposable gloves. Biosafety Level 2 requires standard laboratory practices and additional controls (engineering, procedure/administrative, PPE) to preve mucous membrane, aerosol and skin exposures.

Will you work with biological agents in any of the following aerosol-producing devices/procedures (underline or circle as appropriate): centrifuges, vortexers, shakers, blenders, tissue homogenizers, sonicators, cell sorters, flow cytometry, infected animal necropsy, intranasal inoculation of animals, pressurized vessels (besides autoclaves)? Note all aerosol-producing steps must be performed within a BSC or other aerosol-containing device unless prior approval from the IBC is obtained.

a. **Identify additional Personal Protective Equipment (PPE) controls recommended for this task.**

☒Double (nitrile) gloves ☐Double gloves (other)_____ ☐Tyvek disposable sleeve covers	☒Standard (front closing) disposable lab coat ☐Solid front disposable lab coat	☐Respiratory protection ☐Goggles ☐Face shield	☒Shoe covers ☒Hair cover ☐Hearing Protection	☐Other-(list below) _____ _____ _____

b. **Identify Engineering / Equipment Controls recommended for this procedure/ task**

☒Biosafety Cabinet Vented Outside ☐Ventilated Enclosure ☐Chemical Fume Hood	☐Splash Shield ☒Controlled Access ☒Anteroom ☐Local Vacuum Pump	☒Centrifuge Safety Cups ☐Double Sealed Centrifuge Rotor ☐O-Ring fitted tubes	☒Equipment Control Systems(list) high pressure automatic shut off on bioreactors and chromatography system_____ _____ _____	☒Other-list _pressure_____ _____ _monitoring while pumping____

7. **List personnel assigned to project (Add page, if needed)** The undersigned individual(s) will be involved in the experimentation described above. They are familiar with and agree to abide by the current biosafety guidelines.

[redacted]

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I acknowledge my responsibility as principal investigator for conducting this research in compliance with the latest NIH Guidelines use of Recombinant or Synthetic Nucleic Acid Molecules and to have completed full risk assessment and controlled unacceptable risks. I will inform all personnel of the hazards associated with this work and the level of containment required to perform this research safely. I will ensure all personnel conducting this work have had appropriate background safety training

Principal Investigator(s): [redacted] Ext.: _____

Department Director: _____ Ext.: _____

Date of presentation to IBC: 26-Feb-2019

Recommendation of Institutional Biosafety Committee:

Approved: ☒
Disapproved: ☐
Exempt: ☐
Other: ☐

COMMENTS: NIH requires reporting of incidents involving breach of containment, exposure, etc. to the NIH within 30 days.

Recommendations: _____

_____ _____ _____
Manager, Biosafety Date Ext.

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[redacted]

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OF Johnson & Johnson

[redacted]

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Obtained via FOIA by Judicial Watch Inc.

[redacted]

Obtained via FOIA by Judicial Watch Inc.

[redacted]

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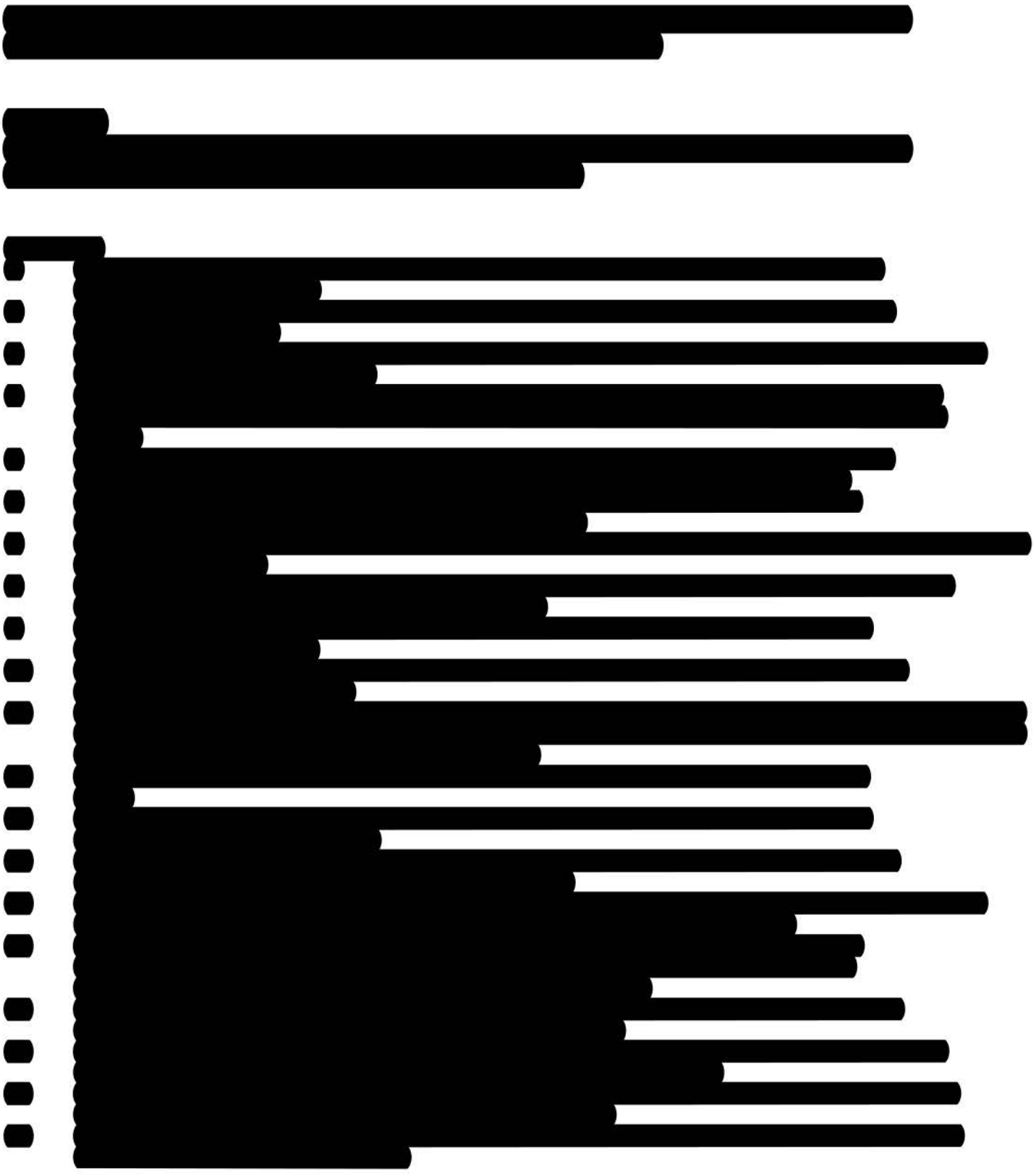

Obtained via FOIA by Judicial Watch Inc.

From: Preston, Francine [JRDUS]
To: NIH guidelines
Cc: Link, David [JRDUS]; Hammonds, Elizabeth [JRDUS]
Subject: Incident Report
Date: Friday, April 3, 2020 12:49:16 PM
Attachments: image001.jpg
Janssen Incident Reporting 2 March 2020.pdf
Redacted RAC252 Submission signed.pdf

Hello Dr. Harris –

There was a reportable incident at Janssen Pharmaceuticals on 2 March 2020. The incident occurred in the BSL2 large scale laboratory.
I've attached the report along with the rDNA risk assessment for this process. Additional physical containment (overwrapping) of welded sample tubing will be performed immediately to reduce the risk of tubing failure. The Janssen IBC will review this report at the next meeting.

Please let me know if you have any questions or concerns.
Kind regards,
Francine

Francine Preston, CBSP, RBP, CSP
Principal Biosafety Specialist
Environment Health Safety & Sustainability
Janssen Pharmaceuticals, Inc.
1400 McKean Road
Spring House, PA 19477

Janssen_Hor_RGB

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Template for Reporting Incidents Related to Research Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids* to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA)

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. This template is also available on the NIH OBA Web pages as a Word document (http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting) in which the fields will expand according to the amount of text entered. Use of this template is not required and other formats for submitting reports may be acceptable.

A separate template for reporting Human Gene Transfer Adverse Events is available at:
http://osp.od.nih.gov/sites/default/files/resources/Adverse_Event_Template_.docx

Please note that submitting this completed template to NIH OBA does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

Attention: Incident Reports
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(For all non-USPS deliveries use Zip Code 20817)
Telephone 301-496-9838
Fax 301-496-9839
E-mail: oba-osp@od.nih.gov

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NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://osp.od.nih.gov/sites/default/files/resources/Adverse_Event_Template_.docx

Does this incident involve research subject to the *NIH Guidelines*?	× YES ☐ NO If no, this incident does not have to be reported to OBA
Institution name:	Janssen Pharmaceuticals, LLC
Date of report:	April 3, 2020
Reporter name and position:	Francine Preston, Principal Biosafety Specialist (IBC Chair)
Reporter telephone:	610-574-9556
Reporter email:	fpreston@its.jnj.com
Reporter mailing address:	1400 McKean Road Spring House, PA 19477
Date of incident:	2Mar2020
Name of principal investigator:	Hsu Feng Ko (Paul)
Is this an NIH funded project?	☐ YES ×NO
If yes, please provide:	NIH grant or contract number:
	NIH funding institute or center:
	NIH program officer contact information (name, email etc):
What was the **nature** of incident?	×Personnel exposure ☐ Spill ☐ Loss of containment ☐ Loss of transgenic animal ☐ Failure to obtain IBC approval ☐ Failure to follow approved containment conditions ☐ Other - please describe:

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Did the Institutional Biosafety Committee (IBC) approve this research	x YES ☐ NO If yes, on what date? 4 February 2019
If yes, please provide:	Approval date: 4 February 2019
	Approved biosafety level(s) for the research: BSL2 plus (Large Scale)
	Additional approval requirements: Directional air flow, Single Pass BIBO HEPA filtered room ventilation, Room Emergency Power shut off located near lab exit and second Room Emergency Power shut off in anteroom. Medical Surveillance, Respirator Training, local vacuum, disposable gowns, double nitrile gloves, safety glasses, shoe covers
What section(s) of the *NIH Guidelines* is the research subject to?	Section III: D-1, D-3, and D-6
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	☐ CDC ☐ USDA ☐ FDA ☐ EPA ☐ OSHA ☐ Research Funding Agency/Sponsor: (name)_____ ☐ State/Local Public Health ☐ Federal/State/Local Law Enforcement ☐ Other –

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Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc. as relevant.)	**Ad26.RSV.preF – Ad26.RSV.preF is a replication-incompetent Adenovirus (human Adenovirus group D type 26) based vector encoding the Respiratory Syncytial Virus (RSV) Fusion (F) protein stabilized in a prefusion conformation.** The Ad26.RSV.preF vector has been made replication -incompetent by removing the E1 region of the Ad26 genome, which is require for replication. A large portion of the E3 region, which promotes persistence within the host cell as also been removed to create sufficient space in the vial genome for the insertion of foreign antigens. E1 defect is supplemented by engineered E1(from Ad5) complementing cell lines (PER.C6).

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:
The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space).

- The incident occurred in BSL2 LS process development lab.

Who was involved in the incident/violation, including others present at the incident location? **Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)**.

- Female Scientist, Male Senior Associate Scientist, Female Senior Associate Scientist and Female Contractor.

Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.

- Female contractor stopped work immediately.
- Teared tubing was disinfected immediately with disinfectant (Virkon S.)
- Female contractor evacuated the lab to meet the onsite nurse.

The training received by the individual(s) involved and the date(s) the training was conducted.

Title	Female Scientist	Female Senior Associate	Male Senior Associate	Female Contractor
Biosafety Training	20 Aug 2018	27 Nov2019	30 Aug 2018	6Feb2020
Bloodborne pathogen	29 Jan2020	29 Jan2020	29 Jan2020	6 Feb 2020
Respirator training	20 Aug 2018	7 Nov2019	30 Aug 2018	Not trained
BSL2 plus viral vector biosafety training	15 Jul 2019	15 Jul 2019		23 Jul 2018
Biosafety Risk Assessment Review (BAR and RAC)	12 Nov 2019	12 Nov 2019	12 Nov 2019	12 Nov 2019

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The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.

- SOPs for lab access – no deviation
- SOP for virus handling – no deviation
- Exposure Control Plan – emergency response procedure was followed

Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.

- No deviation

The personal protective equipment in use at the time of the incident/violation.

- Disposable polypropylene gown, double nitrile gloves, safety glasses, shoe covers, hairnet.

The occupational health requirements for laboratory personnel involved in the research.

- Hepatitis B vaccine offer/declination
- Annual biosafety medical surveillance
- Respirator medical clearance

Any medical advice/treatment/surveillance provided or recommended after the incident.

- None

Any injury or illness associated with the incident.

- None

Medical surveillance results (if not available at the time of initial report please indicate when results will be available).

- N/A

Equipment failures.

- Teared tubing

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

Scientists were finishing the Lysis and Precipitation step of the downstream process while other scientists were in the room preparing the chromatography step for the next day. During the Lysis and Precipitation step, female contractor was preparing to connect the tubing (C-flex size 16) from the 1000L bioreactor to the sample bottle by welding with a SCD IIB Sterile tubing welder. While trying to weld the tubing to the sample bottle, one of the old welds from the bioreactor tubing line ripped apart and splashed (<5mL) on the face of the female contractor. The female contractor immediately left the workspace and evacuated the lab. The female senior scientist immediately disinfected the ripped tubing with Virkon S and clamped the end to contain it.

This step in the development process has been performed >20 times successfully in a facility approved for this activity by appropriately trained staff wearing the required PPE. The tubing is appropriately rated for used in the process step. The tear in the tubing was unexpected and was likely related to the previous poor welding and handling of the tubing.

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Has the IBC reviewed this incident?	☐ YES x NO If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed. Next meet April 6, 2020
Has a root cause for this incident been identified?	x YES ☐ NO If yes please describe: Process was sampled several times prior. Sterile weld in tubing from previous sampling failed and tubing ripped
Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary Tubing for sampling will be wrapped in parafilm as to contain any future tears. Effective: Immediately	

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

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BAR:376
RAC: 252

JANSSEN PHARMA
- REGISTRATION DOCUMENT -
Recombinant or Synthetic Nucleic Acid Molecules Research Proposal
PI Must Receive IBC Approval Before Beginning Work
Renewel is required every two years

(Please print or type)

INSTRUCTIONS: To register experiments imvolving Recombinant or Synthetic Nucleic Acid Molecules with the Institutional Biosafety Committee (IBC) complete this form using the most current "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules." Submit a registration form for each project involving recombinant or synthetic nucleic acid molecules. Principal Investigators are obligated to review the latest version of the NIH Guidelines (April 2016) in preparation for conducting Recombinant or Synthetic Nucleic Acid Molecules research and submitting this application. The NIH Guidelines can be accessed at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

Return the completed form to EHS. Incomplete forms will be returned.

Principal Investigator (PI): [redacted]

Alternate Contact Person: [redacted] Ext.: [redacted]

Department IBC Representative: [redacted] Ext. [redacted]

Department: [redacted] Facility: Spring House, PA

Laboratory (Bldg#Rm#) [redacted]

Project Title: RSV DS Late Stage Development

Research Description: (specifically address the use of Recombinant or Synthetic Nucleic Acid Molecules and describe work in the lab directly related to the biological hazard agents)

PER.C6 cells (immortalized human fetal retinal cells containing a plasmid) from a cell bank will be thawed into a chemically defined growth medium and cultured in Wave Bioreactors at the 10L scale (or samller). Once the cells reach sufficient density, they will be transferred to 50L Wave Bioreactors systesm. The cells are then used to inoculate a 250L Single Use Bioreactor (SUB) system that contains a disposable plastic container that holds the cell cuture. Cell densitities can reach as high as 100x10^6 cells/mL. The PER.C6 May then be transferred into a 50L or 1000L scale SUB. Each of the SUB systems is connected to a single use alternating tangential flow perfusion devices. At either 10L, 50L, 250L or 1000L scale (depending on the scale of the process development study), the PER.C6 cell culture will be infected with the respiratory syncytial virus (RSV) vector, Ad26.RSV, that contains the F protein gene of the RSV as the pre-fusion (pre-F) form of the fusion F protein. The culture will remain infected for 3 days and then will be harvested. Harvesting involves lysing the cells and adding flocculant to cause the DNA to precipitate. The lysed cell material is transferred to another single use vessel where it sits undisturbed overnight allowing gravity to cause sedimentation. Further clarification is then performed by depth filtration and membrane filtration. Further purification is achieved with anion exchange chromatography using a single use tubing set and single use chromatographic membrane absorbers. The final process step is tangential flow filtration to retain the viral particles while allowing small contaminates and buffer components to pass through. The process intermediates are analyzed using various analytical techniques such as turbidity, viral titer and qPCR. Samples are also frozen and shipped offsite for analysis. All process steps are closed and connections are made using sterile tubing welders or aseptic connection devices. If a connection is needed that can not be done in sterile manner, the connection is made before the introduction of viral material to the system, and the connection is only opened after decontamination is completed. Samples are taken from the equipment using sample bottles that are connected via sterile welds and have viral retentive hydrophobic filters. All open sampling tasks of virus-containing cultures will be done in a Class II Type A2 Biological Safety Cabinet.

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Non-Technical Summary of Recombinant or Synthetic Nucleic Acid Molecules use for this registration: (This should be written so that someone who is not an expert in your particular field can understand your use of Recombinant or Synthetic Nucleic Acid Molecules)

Human cells containing recombinant DNA will be grown in bioreactors at 10L, 50L, 250L, and 1000L scales. The cultures at each of these scales may be infected by adding Adenovirus (Ad26.RSV.preF) to the culture and incubated for 3 days. Once infection is complete the cells will be opened up releasing virus into the solution. The virus is separated from cell debris first by gravity settling then filtration. Contaminates are then removed with ion exchange chromatography then lastly via tangential flow filtration. All process steps are closed and utilize single use materials. PAPR respirators will be used during spill clean up for any spill under pressure and all spills >50 ml as instructed by the work instruction attached to the BAR form. Staff with acute / active respiratory infection (viral type) should avoid the lab until recovered from illness.

EXEMPTIONS FROM THE NIH GUIDELINES:

The following categories of experiments are exempt from IBC review and approval. (*See Guidelines Section III-F 1 through 8*). If your research is exempt, please mark which categories are the basis for your answer. Exempt experiments include:

- ☐ Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.
- ☐ Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
- ☐ Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
- ☐ Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.
- ☐ Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- ☐ Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. See Appendices A-I through A-VI, *Exemptions under Section III-F-6--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*.
- ☐ Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.
- ☐ Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), *Major Actions*), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III-F-8* for other classes of experiments which are exempt from the *NIH Guidelines*.

- If your research is exempt, go to "Section 6" and obtain the appropriate departmental signatures. There is no need to complete the remainder of this form. Please forward this form to EHS and retain a copy for your records.

- If your research is not exempt, please provide the required information shown below.

CHECK THE APPROPRIATE REGISTRATION CATEGORY FOR THE EXPERIMENT COVERED BY THE NIH GUIDELINES:

A. Experiments that require IBC approval, Research Advisory Committee (RAC) review, and NIH Director Approval before initiation.

Major actions under the NIH guidelines cannot be initiated without submission of relevant information on the proposed **experiment to the Office of /Science Policy (OSP), NIH.** (See Section IV-C-1-b-(1), Major Actions).

- ☐ Deliberate transfer of drug resistance trait to microorganisms that are unknown to acquire the trait naturally (*see* Section V-B, *Footnotes and References of Sections I-IV*) if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, agriculture, will be reviewed by RAC.

B. Experiments that require NIH/OSP and Institutional Biosafety Committee Approval before initiation.

- ☐ Experiments involving the cloning of toxin molecules with LD_{50} of less than 100 nanograms per kilogram body weight.

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☐ Experiments that have been Approved (under Section III-A-1-a) as Major Actions under the NIH Guidelines.

C. Experiments that require Institutional Biosafety Committee and Institutional Review Board Approvals plus RAC review before participant enrollment.

☐ Experiments involving the deliberate transfer of recombinant or Synthetic Nucleic Acid Molecules, or DNA, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into one or more Human Research Participants (human gene transfer).

D. Experiments that require only Institutional Biosafety Committee Approval before initiation.

☒ Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems *e.g.., Adenovirus, Lentivirus Retrovirus, etc. (*See Section II-A, Risk Assessment)

☐ Experiments in which DNA from Risk Group 2, 3, 4 or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.

☒ Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.

☐ Experiments involving whole animals. *(The RAC must be submitted to the IBC prior to submitting the ACUC application.)*

☐ Experiments to genetically engineer plants by recombinant or synthetic nucleic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid .

☒ Experiments involving more than 10 liters of culture.

☐ Experiments involving Influenza Viruses.

E. Experiments that require Institutional Biosafety Committee notice simultaneous with initiation.

☐ Experiments involving the formation of Recombinant or Synthetic Nucleic Acid Molecules containing no more than two-thirds of the genome of any eukaryotic virus.

☐ Experiments involving nucleic acid molecule-modified whole plants and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants, except those associated with Section D above .

☐ Experiments involving transgenic rodents.

1. RECOMBINANT INSERT:

(Add page(s) if needed)

a. Source(s) of DNA/RNA(siRNA)/cDNA sequences (*include genus, species, gene name*): The gene inserted was synthesized to create pre fusion F protein from Human orthopneumovirus, also know as respiratory scyncytial virus (RSV). The synthetic form contains three stabilizing mutations and two mutations to improve antigenic match with the A2 strain of RSV.

b. What is the biological activity/function of the siRNA, gene product or inserted DNA sequences?

The biological activity of the inserted gene is to code for RSV proteins (preF). Prefusion F is a form of the RSV fusion protein. The RSV fusion protein is responsible for fusing the virus and host cell membrane and is not involved in the replication of RSV. Pre fusion F is a stabilized form of the fusion protein that does not refold, therefore it is not able to function as fusion protein. [redacted]

2. VECTOR

(*Add page(s) if needed*)

a. Identify specific vector(s): Adenovirus serotype 26.

b. Describe the Host (will Recombinant or Synthetic Nucleic Acid Molecules be grown in tissue culture, animals, etc.)? Cell culture

c. Host strain for propagation of the recombinant: PER.C6 (human)

d. What percentage of the original (viral vector) genome is present in the recombinant vector? 90%

e. Is the vector replication competent? ☐ YES ☒ NO

If no, what has been done to make it replication incompetent?

E1 and E3 have been deleted. E1 is essential for the replication of the adenovirus. An E1 gene from Adenovirus 5 is present in the PER.C6 cell line for replication of the vector. There is absence of sequence overlap between the Ad26 and the PER.C6 cells that ensures that no replication competent particles are produced. E3 is involved in making the Ad26 more robust. See also attachment 1. This vector and insert

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combination were well tolerated in clinical trials.

3. GENE DRIVE SYSTEM

(*Add page(s) if needed*)

a. Does your research involve CRISPR or other gene editing technologies? ☐ YES ☒ NO
If yes, please indicate which technology (CRISPR-Cas9, zinc finger nucleases, TALENS, meganucleases, other [specify])

b. Will the technology target embryos or germ line cells? ☐ YES ☐ NO

c. How is the gene editing technology being delivered (i.e. nanoparticles, plasmid, Lentivirus, Adeno-Associate virus etc.)

d. For CRISPR systems, is the guide RNA and nuclease on the same plasmid, vector, or delivery vehicle ? ☐ YES ☐ NO

e. For CRISPR-CAS9, can this plasmid, vector, or delivery vehicle transfect or infect a human cell? ☐ YES ☐ NO

f. For CRISPR research involving viral vectors, has a genome target scan (or similar scan) for off-target effects by the guide RNA been completed? ☐ YES ☐ NO
This is necessary to determine if there is homology to human DNA and for assessing the risk of potential exposure in the event of an unanticipated incident. Off -target databases are available at the following:
- http://www.deepcrispr.net/about
- https://sourceforge.net/projects/crispr-offinder-v1-2/
- http://www.bioconductor.org/packages/release/bioc/html/GUIDEseq.html

g. Describe the potential effects due to accidental worker exposure and the different effects via inhalation, percutaneous and oral exposure (as appropriate to the work). If unknown, state 'unknown'. What are the gene product effects? *(Specifically, it's toxicity, biological function or physiological activity, allergenicity, oncogenic potential or ability to alter cell cycle).*

3. GENE (Recombinant DNA or Synthetic Nucleic Acid Molecule) EXPRESSION, FUNCTION & SOURCE

(*Add page(s) if needed*)

h. Will you be expressing gene products from the Recombinant or Synthetic Nucleic Acid Molecule gene insert)?
☐ YES ☒ NO
If yes, what are the gene product effects? *(Specifically, it's toxicity, biological function or physiological activity, allergenicity, oncogenic potential or ability to alter cell cycle).*

i. Will the recombinant genes(s) be intentionally mutated? ☐ YES ☐ NO
If yes, please explain the effect on the biological function of the resulting expressed protein.

4. FOR ANIMAL EXPERIMENTS ONLY

a. Has an IACUC protocol been submitted? ☐ YES ☐ NO
If yes, what is the IACUC protocol # _____ and approval date? _____

b. For *in vivo* vector administration discuss the safety concerns for the host (name species) and target organs or systems.

c. Is the host a potential carrier of helper viruses that could lead to replication-competency of the recombinant viral vector construct? ☐ YES ☐ NO
If yes, what are these?

d. If gene drives are used, will the experiment make transgenic or sexually reproducing organisms? ☐ YES ☐ NO

e. If gene drives are used, please describe containment strategies (molecular, ecological, reproductive and barrier) used to prevent animal release._____

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f. If gene drives are used is there a means of abrogating the gene drive change should an animal escape? ☐ YES ☐ NO
If yes, please describe._____
_____

g. Describe the potential off-target effects

h. Does the approach to this study have biohazard implications or consequences? ☐ YES ☐ NO
Is there potential for exposure to staff and animal colonies? ☐ YES ☐ NO
If yes, please explain how the recombinant viral vector might be transmitted (by shedding or aerosol, etc.) from the animal host?_____
_____

i. Do you require special animal containment facilities? ☐ YES ☐ NO

5. RISK ASSESSMENT:

(*Add page(s) if needed*)

Classification of AGENT should be based on the Agent and how it is manipulated. Factors to consider are: Virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment and gene product effects such as toxicity, physiological activity and allergenicity.

- Any strain known to be more hazardous than the parent strain should be considered for handling at a higher containment level.
- Certain attenuated strains or strains that have been demonstrated to irreversible loss of known virulence factors may qualify for reduction of containment level compared to the Risk Group Assigned to the parent strains.
- *Note Well: **Although Adeno Associated virus** (AAV) **has been considered a non-pathogenic virus,** AAV vectors have been associated with some forms of cancer. **Therefore, the Janssen IBC recommends BSL-2 containment for AAV research activities.**

a. What is the NIH Assigned Risk Group for Parent Strain? ☐ RSG-1 ☒ RSG-2 ☐ RSG-3
b. What Containment level do you propose for this experiment? ☐ BSL-1 ☒ BSL-2 plus ☐ BSL-3
c. Will the study be performed in Large Scale (greater than 10 liters)? ☒ YES ☐ NO
d. Will Recombinant or Synthetic Nucleic Acids (r/sNA) be introduced into experimental animals or plants that fall under NIH Guidelines? ☐ YES ☒ NO
e. Will Recombinant or Synthetic Nucleic Acid Molecules be introduced into Gene therapy human trials? ☐ YES ☒ NO
f. Has a corresponding BAR form been completed for this study? ☒ YES ☐ NO

Obtained via FOIA by Judicial Watch Inc.

6. **LABORATORY BIOSAFETY LEVEL CRITERIA –** Standard laboratory practices (BSL1) requires lab coat, safety glasses and disposable gloves. Biosafety Level 2 requires standard laboratory practices and additional controls (engineering, procedure/administrative, PPE) to preve mucous membrane, aerosol and skin exposures.

Will you work with biological agents in any of the following aerosol-producing devices/procedures (underline or circle as appropriate): centrifuges, vortexers, shakers, blenders, tissue homogenizers, sonicators, cell sorters, flow cytometry, infected animal necropsy, intranasal inoculation of animals, pressurized vessels (besides autoclaves)? Note all aerosol-producing steps must be performed within a BSC or other aerosol-containing device unless prior approval from the IBC is obtained.

a. **Identify additional Personal Protective Equipment (PPE) controls recommended for this task.**

☒Double (nitrile) gloves ☐Double gloves (other)_____ ☐Tyvek disposable sleeve covers	☒Standard (front closing) disposable lab coat ☐Solid front disposable lab coat	☐Respiratory protection ☐Goggles ☐Face shield	☒Shoe covers ☒Hair cover ☐Hearing Protection	☐Other-(list below) _____ _____ _____

b. **Identify Engineering / Equipment Controls recommended for this procedure/ task**

☒Biosafety Cabinet Vented Outside ☐Ventilated Enclosure ☐Chemical Fume Hood	☐Splash Shield ☒Controlled Access ☒Anteroom ☐Local Vacuum Pump	☒Centrifuge Safety Cups ☐Double Sealed Centrifuge Rotor ☐O-Ring fitted tubes	☒Equipment Control Systems(list) high pressure automatic shut off on bioreactors and chromatography system_____ _____ _____	☒Other-list _pressure_____ _____ _monitoring while pumping____

7. **List personnel assigned to project (Add page, if needed)** The undersigned individual(s) will be involved in the experimentation described above. They are familiar with and agree to abide by the current biosafety guidelines.

[redacted]

Obtained via FOIA by Judicial Watch Inc.

BAR:376
RAC: 252

I acknowledge my responsibility as principal investigator for conducting this research in compliance with the latest NIH Guidelines use of Recombinant or Synthetic Nucleic Acid Molecules and to have completed full risk assessment and controlled unacceptable risks. I will inform all personnel of the hazards associated with this work and the level of containment required to perform this research safely. I will ensure all personnel conducting this work have had appropriate background safety training

Principal Investigator(s): [redacted] Ext.: _____

Department Director: _____ Ext.: _____

Date of presentation to IBC: 26-Feb-2019

Recommendation of Institutional Biosafety Committee:

Approved: ☒
Disapproved: ☐
Exempt: ☐
Other: ☐

COMMENTS: NIH requires reporting of incidents involving breach of containment, exposure, etc. to the NIH within 30 days.

Recommendations: _____

Francine Preston

Digitally signed by Francine Preston
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1064612, cn=Francine Preston
Reason: I attest to the accuracy and integrity of this document.
Date: 2019.10.21 16:35:35 -04'00'
Adobe Acrobat version: 11.0.20

Manager, Biosafety Date Ext.

Obtained via FOIA by Judicial Watch Inc.

[redacted]

janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

[redacted]

Obtained via FOIA by Judicial Watch Inc.

[redacted]

[redacted]

[redacted]

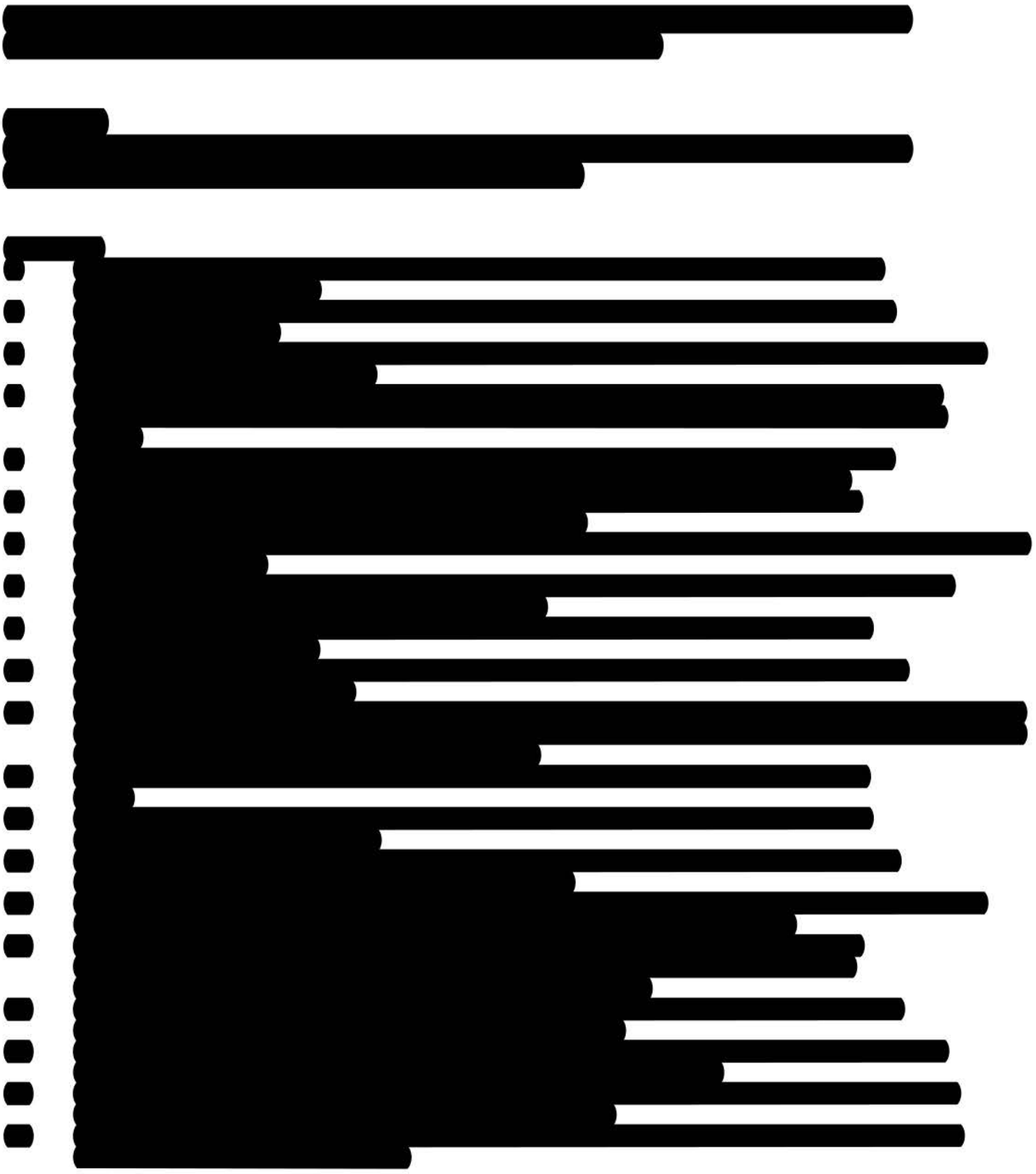
Obtained via FOIA by Judicial Watch Inc.

[redacted]

Obtained via FOIA by Judicial Watch Inc.

[redacted]

Obtained via FOIA by Judicial Watch Inc.



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Tuesday, May 12, 2020 12:22 PM
To: IBC; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report of Non-Compliance

Dear Dr. Daniel Kirienko,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: IBC <ibc@rice.edu>
Sent: Thursday, April 23, 2020 5:37 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Report of Non-Compliance

To Whom it May Concern,

The William Marsh Rice University ("Rice") Institutional Biosafety Committee (IBC) has recently concluded an inquiry that has determined that a primary investigator at Rice has performed research out of compliance with NIH Guidelines. Please find attached our official report and our response.

If you have any additional questions, please do not hesitate to contact me.

Daniel R. Kirienko, Ph.D.
Preferred pronouns: he, him, his
Compliance Administrator I (IBC and SCRO)
Office of Sponsored Projects and Research Compliance (SPARC)
Rice University| 350 Allen Center | 6100 Main Street, MS 16 | Houston, TX 77005
Tel: 713.348.7349
dk32@rice.edu

Obtained via FOIA by Judicial Watch Inc.

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	William Marsh Rice University
Date of Report:	April 12 2020
Reporter name and position:	Daniel Kirienko, IBC Compliance Administrator
Telephone number:	713-348-7349
Email address:	ibc@rice.edu
Reporter mailing address:	Office of Research Compliance Allen Center 350 6100 Main St, MS16 Rice University Houston TX 77005
Date of incident:	July 25th, 2019 (original date of incident reported by the PI per completion of an inquiry April 2, 2020)
Name of Principal Investigator:	Xue Sherry Gao, PhD
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:*

Obtained via FOIA by Judicial Watch Inc.

	NIH funding institute or center: *NIH program officer (name, email address):*

What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: August 27 2019
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☒BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-a and III-D-3-a
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in	The material involved was a second-generation lentivirus strain that was being used to generate a cell line that would mimic Cystic Fibrosis by integrating an ~200 bp

Obtained via FOIA by Judicial Watch Inc.

incident (strain, attenuation, etc.)	fragment into the genome of HEK293T cells. Appropriate safety measures were used for the experiments.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Incident/Violation Location: Rice University, laboratory, BSL2+

Description of Incident: In accordance with Section I-D of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2019. William Marsh Rice University ("Rice") provides this incident report involving a Principal Investigator's (PI's) use of a second-generation lentivirus strain, prior to obtaining IBC approval. The PI confirmed reports of the incident to the Office of Research on April 2, 2020.

The event took place on July 25, 2019. The research involved a second-generation lentivirus strain that was used to generate a cell line to mimic Cystic Fibrosis by integrating an ~200 bp fragment into the genome of HEK293T cells. The PI reported instructing Male Graduate Student #1 ("MGS1") to carry out the experiment despite the lack of IBC approval. The experiment was performed by MGS1 on July 25th, 2019. The work was performed under BSL2+ conditions, which were the conditions required by the IBC protocol later approved for this work. After infection of the cells, work continued with the selection and expansion of a transformed cell line with the desired traits. This work continued for at least 2 weeks, and integration was verified by extracting DNA from the cells and performing PCR. The first experiments using this new cell line as a resource were not performed until after the PI's IBC Protocol was approved.

MGS1 performed this work under the supervision of Male Graduate Student #2. A laboratory SOP was created for lentivirus work and was observed. Both MGS1 and MGS2 had received general and biological safety training from Rice Environmental Health & Safety.

The PI submitted an amendment to her IBC registration to include the proposed work on July 15, 2019. On August 27th, 2019, the amendment to the IBC protocol was approved by Rice's IBC.

To the best of our knowledge, there was no exposure to the lentivirus by the personnel in the lab.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	The PI, knowing that there was no approval, directed a graduate student to perform unapproved research. The PI was feeling pressure about the possibility of being "scooped" at the time.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

> Rice policy is clear that *all research involving rDNA molecules conducted by Rice University faculty, research staff, post docs and students, regardless of sponsorship or source of funding, shall be undertaken only with the approval and under the cognizance of the Rice University Institutional Biosafety Committee (IBC).*

As a corrective action, the IBC has required the following:

1) The PI and her entire lab will be required to have a one (1) hour Zoom meeting with the Biological Safety Officer for Rice University. At that meeting, the areas of laboratory safety and protocol adherence will be covered.
2) The PI is further required to submit a report summarizing the recombinant and synthetic nucleic acid activities, including the personnel involved, to the IBC administrator every 6 months for the next 3 years.
3) The Biological Safety Officer for Rice University may perform additional unannounced visits to confirm that research activities are being performed safely, at his/her discretion.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: IBC <ibc@rice.edu>
Sent: Thursday, April 23, 2020 5:37 PM
To: NIH guidelines
Subject: Report of Non-Compliance
Attachments: Non Compliance Report April 2020 Final.pdf

To Whom it May Concern,

The William Marsh Rice University ("Rice") Institutional Biosafety Committee (IBC) has recently concluded an inquiry that has determined that a primary investigator at Rice has performed research out of compliance with NIH Guidelines. Please find attached our official report and our response.

If you have any additional questions, please do not hesitate to contact me.

Daniel R. Kirienko, Ph.D.
Preferred pronouns: he, him, his
Compliance Administrator I (IBC and SCRO)
Office of Sponsored Projects and Research Compliance (SPARC)
Rice University| 350 Allen Center | 6100 Main Street, MS 16 | Houston, TX 77005
Tel: 713.348.7349
dk32@rice.edu

Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Tamara Casebolt PhD; NIH guidelines
Cc: John Zaia; Alyse DiStefano; Bernard Tegtmeier; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report for Needlestick with recombinant virus
Date: Tuesday, May 12, 2020 12:36:34 PM
Attachments: image001.png

Dear Dr. Tamara Casebolt,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. However, we note that the incident was not immediately reported and medical evaluation was not sought until several days after the incident. We recommend reminding staff they should report incidents promptly and consult with or be evaluated by a medical care provider as soon as possible after an exposure incident in case treatment is warranted. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Tamara Casebolt PhD <tcasebolt@coh.org>
Sent: Monday, May 4, 2020 8:11 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: John Zaia <JZaia@coh.org>; Alyse DiStefano <adistefano@coh.org>; Bernard Tegtmeier <btegtmei@coh.org>
Subject: Incident Report for Needlestick with recombinant virus

Please see attached for the finalized report regarding a needle stick exposure to a genetically modified oncolytic vaccinia virus as I reported last week by phone.

Dr. John Zaia, our Institutional Official, is copied on this email and should be included on any correspondence.
Address:
City of Hope National Medical Center

Obtained via FOIA by Judicial Watch Inc.





Obtained via FOIA by Judicial Watch Inc.

Center for Gene Therapy-BRI
Familian Science, C201H
1500 E. Duarte Road
Duarte, CA 91010

phone 626 218-1817
email: jzaia@coh.org

Thank you,
Tamara

Tamara Casebolt, PhD
Biosafety Officer | Occupational Safety & Health
Senior Manager | Biological & Laboratory Safety Division
City of Hope |1500 E. Duarte Road, Duarte, CA 91010
Tel: 626-218-8079 |Cell: Redacted by agreement Internal: 88079 | Email: tcasebolt@coh.org
Follow City of Hope: Facebook | Twitter | Instagram | LinkedIn | YouTube | Blog

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Obtained via FOIA by Judicial Watch Inc.

Report to NIH OSP- Needle stick with potential exposure to attenuated oncolytic vaccinia virus

To: NIHGuidelines@od.nih.gov

Reported by:

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	City of Hope Beckman Research Institute
Date of Report:	5/4/2020
Reporter name and position:	Dr. John Zaia, City of Hope Institutional Official
Telephone number:	626-218-1817
Email address:	jzaia@coh.org
Reporter mailing address:	City of Hope Center for Gene Therapy- BRI Familian Science C201H 1500 E. Duarte Road Duarte, CA 91010 Attn: Institutional Official
Date of incident:	4/24/2020
Name of Principal Investigator(s):	Stephen Forman, M.D. Yuman Fong, M.D.
Is this an NIH-funded project?	☐YES ☒NO
What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure (potential) ☐Spill ☒Other (please describe): Needlestick

Obtained via FOIA by Judicial Watch Inc.

Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: a) Yuman Fong: IBC protocol 14022:approval until 11/16/2020 b) Stephen Forman: IBC protocol 05040: approval until 10/16/2020
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☒State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	CF33 Chimeric oncolytic virus with thymidine kinase knocked out (CF33 control) The CF33 chimeric parental strain: Chimerization of orthopox viruses was achieved by co-infecting CV-1 cells with Cowpox virus strain Brighton, raccoon pox virus strain Herman, rabbit pox virus strain Utrecht, vaccinia virus strains, Western Reserve (WR), International Health Department (IHD), Elstree, CL, Lederle-Chorioallantoic (LC) and AS (MOI of 0.01 per virus). Following the co-infection, one hundred individual plaques were picked and subjected to a total of three rounds of plaque purification in CV-1 cells to obtain 100 clonally purified chimeric orthopoxviruses. High-throughput screening was used to compare the cytotoxic efficacy of these chimeric clones and the parental strains against the NCI-60 panel. CF33 was selected as the chimeric isolate that demonstrated superior cancerous cell killing in the NCI-60 panel when compared to all parental viruses and other plaque-purified isolates. From this isolate, the TK gene was deleted.

Obtained via FOIA by Judicial Watch Inc.

Description of incident:

1. On Friday, April 24, 2020, a needlestick was sustained in the COH ABSL2 animal facility (Parvin 1020 A) at approximately 5:30- 6PM by a graduate student who had been injecting C57BL6 mice implanted with mouse MC38 colorectal tumor cells. A research associate was assisting with the work and was anesthetizing the mice prior to injection, and removing the mice into cages after injection. The research associate was unaffected.
2. After completing an intratumoral injection with a recombinant oncolytic vaccinia virus (attenuated strain, thymidine kinase knockout), the graduate student was stuck in the right index finger by a used insulin syringe that was sticking out of the sharps container when he tried to place the next syringe into the sharps bin.
3. After he felt the stick, the individual removed his double gloves, examined the area, saw no bleeding, but washed for 10 minutes and disinfected with ethanol. The individual re-gloved and completed the rest of the injections.
4. Over the weekend (approximately 2AM, Sunday morning), the individual noticed a raised lesion had formed at the needle stick site. He did not seek medical assistance at that time, but treated the area with Neosporin and covered the area with a bandage.
5. On Monday, April 27, 2020, the individual came in to Employee Health for medical evaluation.

Medical Surveillance and Follow-up after incident:

The graduate student was evaluated by a Nurse Practitioner at Employee Health Services (EHS) and found to have a small (3mm) lesion on his right index finger. The employee was advised to monitor the wound, keep the lesion covered, and provided education and supplies for wound care management as recommended by the CDC for small pox vaccine (vaccinia) inoculation site management and wound care. He was given an infectious disease physician referral for further follow-up. In addition, both LA County and Orange County Communicable Diseases were consulted and the needles stick was reported to the LA County Public Health Department.

Training:

Employee training:

All researchers are required to have lab safety training, and lab specific training at hiring. In addition, lab specific and agent specific training for orthopox oncolytic virus use is provided (see list below):

1. Vaccinia virus and other BSL-2 poxviruses, SOP training
2. Lab Specific training (Yuman Fong laboratory)
3. Lab Specific training (Stephen Forman laboratory)
4. General lab safety and blood borne pathogens training

In addition to the training above, both individuals received refresher training, BBP and biosafety, on 1/31/2020. Included in this training was a case report on vaccinia needle stick exposure that was recently published in October 2019.

Occupational Health Requirements:

All laboratory personnel receive pre-employment screening, and free Hepatitis B vaccination or check.

Obtained via FOIA by Judicial Watch Inc.

COH policy on vaccination for work with chimeric orthopox virus CF33-TK knockout: not recommended for this type (highly attenuated) vaccinia strain; Individuals must be medically screened prior to initiating work with this virus and every three years thereafter while work continues.

Personnel working with this virus received refresher training (see above) for vaccinia virus and bloodborne pathogens training for research and needlestick safety.

Deviation from the IBC approvals/ containment: The Principal investigator(s) are approved for work under NIH guideline III-D and work was conducted at the approved ABSL2 containment level.

PPE/engineering controls in use: The PPE required for this work was worn at the time of the incident and included face mask, head cover, double gloves, gown, and shoe covers. All work was conducted within the biological safety cabinet.

Has the IBC reviewed this incident?	☐YES ☒NO (scheduled for review- IBC chair has reviewed)
Please describe the root cause of this incident:	The graduate student disposed a sharp where the previous sharp had not completely dropped into the container. This resulted in a needlestick injury (human error).

Recommended measures for mitigation or follow-up:

1. Retraining for all staff utilizing sharps in biocontainment (ABSL-2) (on or before 6/5/2020) to include:
    a) Consideration of transitioning to safety engineered sharps for use in biocontainment
    b) Appropriate operation and ergonomics of sharps containers

2. Biosafety to meet with Animal Care Manager to identify process improvements for ABSL2 biocontainment in order to prevent future incidents (on or before 5-30-2020)

3. Any additional recommendations to be determined after Institutional Biosafety Committee (IBC) review (on May, 18, 2020)

Obtained via FOIA by Judicial Watch Inc.

From: Tamara Casebolt PhD
To: NIH guidelines
Cc: John Zaia; Alyse DiStefano; Bernard Tegtmeier
Subject: Incident Report for Needlestick with recombinant virus
Date: Monday, May 4, 2020 8:11:37 PM
Attachments: image002.png
NIH OSP Report 5-4--2020 (final).pdf

Please see attached for the finalized report regarding a needle stick exposure to a genetically modified oncolytic vaccinia virus as I reported last week by phone.

Dr. John Zaia, our Institutional Official, is copied on this email and should be included on any correspondence.

Address:
City of Hope National Medical Center
Center for Gene Therapy-BRI
Familian Science, C201H
1500 E. Duarte Road
Duarte, CA 91010

phone 626 218-1817
email: jzaia@coh.org

Thank you,
Tamara

Tamara Casebolt, PhD
Biosafety Officer | Occupational Safety & Health
Senior Manager | Biological & Laboratory Safety Division
City of Hope |1500 E. Duarte Road, Duarte, CA 91010
Tel: 626-218-8079 |Cell: Redacted by agreement Internal: 88079 | Email: tcasebolt@coh.org
Follow City of Hope: Facebook | Twitter | Instagram | LinkedIn | YouTube | Blog



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Obtained via FOIA by Judicial Watch Inc.





Obtained via FOIA by Judicial Watch Inc.

Report to NIH OSP- Needle stick with potential exposure to attenuated oncolytic vaccinia virus

To: NIHGuidelines@od.nih.gov

Reported by:

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	City of Hope Beckman Research Institute
Date of Report:	5/4/2020
Reporter name and position:	Dr. John Zaia, City of Hope Institutional Official
Telephone number:	626-218-1817
Email address:	jzaia@coh.org
Reporter mailing address:	City of Hope Center for Gene Therapy- BRI Familian Science C201H 1500 E. Duarte Road Duarte, CA 91010 Attn: Institutional Official
Date of incident:	4/24/2020
Name of Principal Investigator(s):	Stephen Forman, M.D. Yuman Fong, M.D.
Is this an NIH-funded project?	☐YES ☒NO
What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure (potential) ☐Spill ☒Other (please describe): Needlestick

Obtained via FOIA by Judicial Watch Inc.

Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: a) Yuman Fong: IBC protocol 14022:approval until 11/16/2020 b) Stephen Forman: IBC protocol 05040: approval until 10/16/2020
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☒State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	CF33 Chimeric oncolytic virus with thymidine kinase knocked out (CF33 control) The CF33 chimeric parental strain: Chimerization of orthopox viruses was achieved by co-infecting CV-1 cells with Cowpox virus strain Brighton, raccoon pox virus strain Herman, rabbit pox virus strain Utrecht, vaccinia virus strains, Western Reserve (WR), International Health Department (IHD), Elstree, CL, Lederle-Chorioallantoic (LC) and AS (MOI of 0.01 per virus). Following the co-infection, one hundred individual plaques were picked and subjected to a total of three rounds of plaque purification in CV-1 cells to obtain 100 clonally purified chimeric orthopoxviruses. High-throughput screening was used to compare the cytotoxic efficacy of these chimeric clones and the parental strains against the NCI-60 panel. CF33 was selected as the chimeric isolate that demonstrated superior cancerous cell killing in the NCI-60 panel when compared to all parental viruses and other plaque-purified isolates. From this isolate, the TK gene was deleted.

Obtained via FOIA by Judicial Watch Inc.

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2. After completing an intratumoral injection with a recombinant oncolytic vaccinia virus (attenuated strain, thymidine kinase knockout), the graduate student was stuck in the right index finger by a used insulin syringe that was sticking out of the sharps container when he tried to place the next syringe into the sharps bin.
3. After he felt the stick, the individual removed his double gloves, examined the area, saw no bleeding, but washed for 10 minutes and disinfected with ethanol. The individual re-gloved and completed the rest of the injections.
4. Over the weekend (approximately 2AM, Sunday morning), the individual noticed a raised lesion had formed at the needle stick site. He did not seek medical assistance at that time, but treated the area with Neosporin and covered the area with a bandage.
5. On Monday, April 27, 2020, the individual came in to Employee Health for medical evaluation.

Medical Surveillance and Follow-up after incident:

The graduate student was evaluated by a Nurse Practitioner at Employee Health Services (EHS) and found to have a small (3mm) lesion on his right index finger. The employee was advised to monitor the wound, keep the lesion covered, and provided education and supplies for wound care management as recommended by the CDC for small pox vaccine (vaccinia) inoculation site management and wound care. He was given an infectious disease physician referral for further follow-up. In addition, both LA County and Orange County Communicable Diseases were consulted and the needles stick was reported to the LA County Public Health Department.

Training:

Employee training:

All researchers are required to have lab safety training, and lab specific training at hiring. In addition, lab specific and agent specific training for orthopox oncolytic virus use is provided (see list below):

1. Vaccinia virus and other BSL-2 poxviruses, SOP training
2. Lab Specific training (Yuman Fong laboratory)
3. Lab Specific training (Stephen Forman laboratory)
4. General lab safety and blood borne pathogens training

In addition to the training above, both individuals received refresher training, BBP and biosafety, on 1/31/2020. Included in this training was a case report on vaccinia needle stick exposure that was recently published in October 2019.

Occupational Health Requirements:

All laboratory personnel receive pre-employment screening, and free Hepatitis B vaccination or check.

Obtained via FOIA by Judicial Watch Inc.

COH policy on vaccination for work with chimeric orthopox virus CF33-TK knockout: not recommended for this type (highly attenuated) vaccinia strain; Individuals must be medically screened prior to initiating work with this virus and every three years thereafter while work continues.

Personnel working with this virus received refresher training (see above) for vaccinia virus and bloodborne pathogens training for research and needlestick safety.

Deviation from the IBC approvals/ containment: The Principal investigator(s) are approved for work under NIH guideline III-D and work was conducted at the approved ABSL2 containment level.

PPE/engineering controls in use: The PPE required for this work was worn at the time of the incident and included face mask, head cover, double gloves, gown, and shoe covers. All work was conducted within the biological safety cabinet.

Has the IBC reviewed this incident?	☐YES ☒NO (scheduled for review- IBC chair has reviewed)
Please describe the root cause of this incident:	The graduate student disposed a sharp where the previous sharp had not completely dropped into the container. This resulted in a needlestick injury (human error).

Recommended measures for mitigation or follow-up:

1. Retraining for all staff utilizing sharps in biocontainment (ABSL-2) (on or before 6/5/2020) to include:
    a) Consideration of transitioning to safety engineered sharps for use in biocontainment
    b) Appropriate operation and ergonomics of sharps containers

2. Biosafety to meet with Animal Care Manager to identify process improvements for ABSL2 biocontainment in order to prevent future incidents (on or before 5-30-2020)

3. Any additional recommendations to be determined after Institutional Biosafety Committee (IBC) review (on May, 18, 2020)

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Obtained via FOIA by Judicial Watch Inc.

From: Tamara Casebolt PhD
To: NIH guidelines; Harris, Kathryn (NIH/OD) [C]
Cc: Tamara Casebolt PhD
Subject: NIH guidelines incident- needlestick
Date: Monday, April 27, 2020 5:37:24 PM
Attachments: image002.png

This email is to report a needle stick that occurred on Friday, April 24, 2020, with a recombinant vaccinia oncolytic virus during a procedure at the City of Hope, National Medical Center within the Parvin animal facility. The researcher, a graduate student, was injecting animals with a recombinant attenuated oncolytic virus, when he received a superficial needle stick on his right index finger from a sharp as he disposed a used syringe/needle into a sharps container. The container had a previously disposed syringe/needle that had not dropped in.

I am preparing a full report for the incident, but wanted to provide an immediate notification of the injury/exposure to this BSL2 agent, as required by the NIH guidelines.

Should you have any questions, I can be reached by phone or email as per contacts listed below.
Thank you,
Tamara

Tamara Casebolt, PhD
Biosafety Officer | Occupational Safety & Health
Senior Manager | Biological & Laboratory Safety Division
City of Hope |1500 E. Duarte Road, Duarte, CA 91010
Tel: 626-218-8079 |Cell: Redacted by agreement Internal: 88079 | Email: tcasebolt@coh.org
Follow City of Hope: Facebook | Twitter | Instagram | LinkedIn | YouTube | Blog



-SECURITY/CONFIDENTIALITY WARNING-

This message and any attachments are intended solely for the individual or entity to which they are addressed. This communication may contain information that is privileged, confidential, or exempt from disclosure under applicable law (e.g., personal health information, research data, financial information). Because this e-mail has been sent without encryption, individuals other than the intended recipient may be able to view the information, forward it to others or tamper with the information without the knowledge or consent of the sender. If you are not the intended recipient, or the employee or person responsible for delivering the message to the intended recipient, any dissemination, distribution or copying of the communication is strictly prohibited. If you received the communication in error, please notify the sender immediately by replying to this message and deleting the message and any accompanying files from your system. If, due to the security risks, you do not wish to receive

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further communications via e-mail, please reply to this message and inform the sender that you do not wish to receive further e-mail from the sender. (LCP301)

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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Tuesday, May 12, 2020 1:11 PM
To: Hubert Olipares; NIH guidelines
Cc: Norman Magno; Ako, Eric; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: University of Incident Report: Transgenic Cassava

Dear Hubert Olipares,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Hubert Olipares <olipares@hawaii.edu>
Sent: Tuesday, April 28, 2020 5:06 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Norman Magno <nmagno@hawaii.edu>; Ako, Eric <akoe002@hawaii.rr.com>
Subject: University of Incident Report: Transgenic Cassava

NIH OSP staff

Attach find an incident report from the University of Hawaii regarding shipment of transgenic cassava plants without notification to IBC.

-

Hubert B. Olipares
Biosafety Officer, Inspections and Audits Specialist
Biosafety Program, Office of Research Compliance
2425 Campus Road, Sinclair 10 University of Hawaii Honolulu HI 96822-2427
Office: 956-3197 **Voice/Text**: 285-7619
https://researchcompliance.hawaii.edu/programs/biological-safety//

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Hawaii
Date of Report:	Wednesday 29 April 2020
Reporter name and position:	Hubert Olipares., Biosafety Officer
Telephone number:	(808) 956-3197
Email address:	olipares@hawaii.edu
Reporter mailing address:	Biosafety Program, Office of Research Compliance 2425 Campus Road, Sinclair 10 University of Hawaii Honolulu HI 96822-2427
Date of incident:	20 March 2020
Name of Principal Investigator:	Dr. Sharon Wages (Motomura)
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	YES X NO If yes, date of approval: Wednesday 29 April 2020
What was the approved biosafety level of the research?	☒BL1 ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-E3
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☒State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The recombinant DNA is present in the form of a stably integrated T-DNA (19.2 kb, or approximately 0.0025%, assuming single insertion) flanked by left and right borders. Our risk assessment of these elements is low. The T-DNA consists of the following elements: Selectable Marker (expressed): Promoter - 35S Cauliflower mosaic caulimovirus, Gene - Hygromycin B, Terminator -35S Cauliflower mosaic caulimovirus Gene of Interest

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	(expressed): Promoter - Ubiquitin10 from Arabidopsis thaliana, Gene -dCas9, Terminator - NOS Genes of Interest (expressed together): Promoter: Ubiquitin10, Gene - DRM2 catalytic domain from Nicotiana tabacum Gene - GFP,Terminator - OCS from Agrobacterium tumefaciens Element (expressed): Promoter - 35S,Element - Guide RNAs (cloned into plasmid referenced below) Ref.: Papikian, A., Liu, W., Gallego-Bartolomé, J., and Jacobsen,S.E. (2019). Site-specific manipulation of Arabidopsis loci using CRISPR-Cas9 SunTag systems. Nat. Comm. 10:

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- **The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)**

  Not notifying IBC of transgenic project (reporting of recombinant activity) and importing recombinant plants into the State without University approval.

- **Who was involved in the incident/violation, including others present at the incident location?**

  Assistant Extension Agent and Project Manager.

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- **Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event**

  Once an email of notification of shipment of transgenic plants was being shipped, I notified PI of potential violation of state import requirements as well as University policy of registration of recombinant activity.

- **The training received by the individual(s) involved and the date(s) the training was conducted**

  Initial biosafety training and Transportation of Biological Substances was completed on 21 April 2020 and Recombinant Plant Biosafety training done on 27 April 2020.

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- **The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation**

  Yes, registration was not given for recombinant activity. University's Office of Research Services did not notify researcher of recombinant activity, thus bypassing IBC. Once researcher was notified researcher moved transgenic material to a USDA approved biosecured and USDA approved recombinant plant storage site.

- **Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation**

  N/A. Since recombinant plant were moved prior to storage. Site inspection of lab, greenhouse was completed on 6 April 2020. There were no issues relating to the facilities. Laboratory, Greenhouse, and field site inspected by Environmental Health and Safety Office at our counterpart at the University of Hawaii at Hilo.

- **The personal protective equipment in use at the time of the incident/violation**

  N/A

- **The occupational health requirements for laboratory personnel involved in the research**

` N/A

- **Any medical surveillance provided or recommended after the incident**

  N/A

- **Any injury or illness associated with the incident**

  N/A

- **Equipment failures**

  N/A

DESCRIPTION OF INCIDENT: (use additional space as necessary)

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Has the IBC reviewed this	☒YES ☐NO

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incident?	
Please describe the root cause of this incident:	Not trained.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Once PI had notified Biosafety Program on 27 March 2020 that they were in possession of transgenic plants. Information was advised to register the project with IBC and to secure the plants. Transgenic plant was received on 20 March 2020. Facilities was inspected on 6 April and met the minimum requirements. However, since the project was not approved by the IBC, transgenic plants items were transported to the USDA sites for storage and security.

Draft IBC registration was received on 5 April 2020 and was revised several times. IBC will meet on 29 April to review this proposal.

Due to interisland travel restriction on travel due to pandemic, State inspection and UH biosafety inspection is halted.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

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- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Hubert Olipares <olipares@hawaii.edu>
Sent: Tuesday, April 28, 2020 5:06 PM
To: NIH guidelines
Cc: Norman Magno; Ako, Eric
Subject: University of Incident Report: Transgenic Cassava
Attachments: NIH Incident Report Wages Cassava Apr 2020.docx

NIH OSP staff

Attach find an incident report from the University of Hawaii regarding shipment of transgenic cassava plants without notification to IBC.

-

Hubert B. Olipares
Biosafety Officer, Inspections and Audits Specialist
Biosafety Program, Office of Research Compliance
2425 Campus Road, Sinclair 10 University of Hawaii Honolulu HI 96822-2427
Office: 956-3197 **Voice/Text**: 285-7619
https://researchcompliance.hawaii.edu/programs/biological-safety//

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, May 11, 2020 2:56 PM
To: Peeples, Mark; NIH guidelines
Cc: Ghosh, Sumit; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report

Dear Dr. Mark Peeples,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Peeples, Mark <Mark.Peeples@nationwidechildrens.org>
Sent: Wednesday, May 6, 2020 8:29 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Ghosh, Sumit <Sumit.Ghosh@nationwidechildrens.org>
Subject: Incident Report

Please accept this report of a spill that was cleaned up without incident.

Mark E. Peeples, Ph.D.
Professor, Department of Pediatrics
The Ohio State University College of Medicine
Center for Vaccines and Immunity, WA4012
Abigail Wexner Research Institute at Nationwide Children's Hospital
700 Children's Drive
Columbus, Ohio 43205
Office: 614-722-3696
Fax: 614-722-3680

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	X YES If no, this incident does not require reporting to OSP
Institution Name:	Abigail Wexner Research Institute at Nationwide Children's Hospital
Date of Report:	04/18/2020
Reporter name and position:	Dr. Mark Peeples – Chair, Institutional Biosafety Committee
Telephone number:	614-722-3696
Email address:	Mark.Peeples@nationwidechildrens.org
Reporter mailing address:	Dr. Mark Peeples
Date of incident:	04/07/2020
Name of Principal Investigator:	Wade Macedone
Is this an NIH-funded project?	**NO** If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure **X Spill** ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	**X YES** ☐ NO If yes, date of approval: **04/27/2018**
What was the approved biosafety level of the research?	☐ BL1 **X BL2** ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-E and Appendix G-II-A and Appendix G-II-B
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA **X Other (please describe): NIH** ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The harvest bag had rAAV-145b, which is an adeno-associated viral (AAV) vector that contains sequences encoding a chimeric antigen receptor (CAR) flanked by AAV inverted terminal repeats (ITRs). The AAV ITRs, consisting of only 6% of the wild type AAV genome, are the only AAV specific sequences packaged into the rAAV-145b particles. The removal of the viral structural genes renders the vector replication-defective and dependent on adenovirus helper functions provided in trans. rAAV-145b is generated in the presence of a helper plasmid, not a helper virus. The vector is generated by transient transfection of HEK293 cells using three plasmids (the cis ITR-containing plasmid, the trans plasmid encoding AAV2 replicase and AAV6 capsid genes and the adenoviral helper plasmid) which result in the pseudotyping of vector genomes with AAV6 serotype capsid proteins. All AAV vectors are based on AAV viruses which are non-pathogenic in humans and the vectors themselves are not known to cause any diseases in humans or animals.

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

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DESCRIPTION OF INCIDENT:

SITUATION: At approximately 9:30 am on April 7th, 2020, there was a spill in Production Room 1 (WB3342, Research Building III) of the Clinical Manufacturing Facility (CMF) at the Abigail Wexner Research Institute at Nationwide Children's Hospital. The team working in Production Room 1 was harvesting a batch of recombinant AAV vector from adherent cell culture vessels. The spill was caused by leakage from the harvest bag containing recombinant AAV. The harvest bag at the time of leakage held around 90 L of recombinant AAV, and approximately 17 L of the harvested viral vector was released in the production room. The spill was contained within the room in the facility. The production room has appropriate engineering controls in place, which include lower pressure relative to the hallway to contain aerosol resulting from a spill. Each room in the CMF has seamless floors and walls with coatings to hold liquid and withstand harsh cleaners. Additionally, the cleanroom utilizes a recirculation air handler with a HEPA filtration unit to maintain product integrity.

At the time of the incident, 6 Staff **[Title: Scientists 1 (4), Scientist 2 (2)]** were present in the production room. Three members were of the production team, and the other three members were present to perform the next downstream process. The procedure being performed at the time of the release involved pooling media from cell culture vessels used in the production of the viral vectors. The media is first harvested from cell culture vessels into 20 L bioprocessing bags. From there, the media is pooled into a single 200 L 3-D bag. During the process of pooling media into the 200 L 3-D bag, it was discovered that the bag had shifted in its holder (drum). The production team adjusted the bag to free a length of tubing connected to a port at the base of the bag that had become pinched. The tubing itself is medical-grade silicone, made by Cole-Parmer. The tubing is affixed to the base (bottom) of the bag via a hard plastic (polypropylene) hose barb. The tubing is attached via a zip-tie onto the hose barb. This tubing encounters pressure if the bag shifts as it fills and moves from protruding out the base of the drum. This prevents the tubing from being trapped under the bag and against the hard bottom of the drum.

After this tubing attached by a zip-tie was adjusted, it became detached from the hose barb holding it to the bag. This allowed the crude harvest media to flow freely from the base of the bag. The production team and the additional staff attempted to stem the flow. The team also radioed the supervisor **(Title: Operations Supervisor)** that they had a leak in the production room so that they could get additional help for the clean-up process. The team was unable to reconnect the tubing to the hose barb at this time. After transferring some of the bulk media from the 200L 3-D bag back to a 20L bioprocess bag, the 200L 3-D bag and its holder were tilted on its side, allowing the team to reattach the tubing and halt the flow from the bag. All staff were wearing the appropriate PPE for the work, and there was no exposure (splash or mucosal exposure) to any of the staff.

At this time, the staff in the production room initiated the spill response plan of the GMP facility. The team wearing the cleanroom PPE donned disposable Tyvek suits over their cleanroom PPE and exited the facility through the emergency exit and disposed of their Tyvek suits and cleanroom PPE into a biohazard bag. The room was left idle. Approximately two hours later, three other team members **(Title: Scientist 1 (1), Scientist 2 (1), Operations Supervisor (1))** entered the facility to clean the floors of the common areas. Three additional team members **(Title: Scientist 1 (2), Senior Scientist (1)) entered the facility** wearing waterproof Tyvek suits helped to clean the production room. Spill pads soaked with Bleach-Rite ready to use 1:10 dilution bleach were used for spill clean-up. Sporeklenze and Vesphene were then used to complete the clean-up process.

The staff used a contact time of 10 minutes for each reagent and collected all the materials used in the spill response in multiple Biohazard bags. All the biohazard bags were removed from the

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cleanroom and placed inside Stericycle bins for disposal through a vendor contracted with NCH. The spill clean-up was completed in approximately 4 hours. There were no issues reported while the clean-up was performed by the staff following the SOP of the facility.

PPE STAFF WAS WEARING IN CLEAN ROOM AT THE TIME OF INCIDENT: Dedicated scrubs, dedicated shoes and disposable shoe covers, surgical mask, hair net, beard cover (where applicable), safety glasses and nitrile gloves. Over this PPE, the staff wore polyester cleanroom jumpsuits, boot covers (reusable after laundering), hair nets, and sterile nitrile gloves.

VECTOR INFORMATION: The harvest bag held rAAV-145b, an adeno-associated viral (AAV) vector that contains sequences encoding a chimeric antigen receptor (CAR) flanked by AAV inverted terminal repeats (ITRs). The AAV ITRs, consisting of only 6% of the wild type AAV genome, are the only AAV specific sequences packaged into the rAAV-145b particles. The removal of the viral structural genes renders the vector replication-defective, and dependent on adenovirus helper functions provided in trans. rAAV-145b is generated in the presence of a helper plasmid, not a helper virus. The vector is generated by transiently transfecting HEK293 cells with three plasmids (the cis ITR-flanked CAR gene plasmid, the trans plasmid encoding AAV2 replicase and AAV6 capsid genes and the adenoviral helper plasmid), which results in vector genomes pseudotyped with AAV6 serotype capsid proteins. All AAV vectors are based on AAV viruses which are non-pathogenic in humans, and the vectors themselves are not known to cause any disease in humans or animals.

BACKGROUND: The vector production process involves the culturing of adherent eukaryotic cells in cell culture vessels. The cells are transiently transfected, and the vector is released into the media over time. The media is then collected, and the vector purified from this media.

TRAINING REQUIREMENTS OF STAFF: Operations team members training consists of in-person research safety orientation, reading the applicable standard operating procedures (SOPs), observation of the process, and hands-on training in the execution of the process. There is a dedicated SOP addressing spill response that all members are required to read. An SOP exists for the practice of spill management and clean-up. All the Operations staff are also required to read this SOP.

ASSESSMENT: ***The spill in the GMP facility was not a result of a deviation from a current standard operating procedure.*** It is possible that the tubing attached by a zip-tie to the hose barb holding it to the harvest bag became detached due to a faulty part or quality issue. The team working in the production room recently found that several bags had loose zip-ties that hold the tubing to the hose barb connected to the 200 L bag.

Another reason might be the smaller diameter of the drum opening at the bottom. This small opening in the drum holding the harvest bag might have restricted the ability of the staff to align the tubing if the harvest bag had moved in the container when it was being filled with media. Additionally, it may have prevented the tubing from protruding from the base of the drum, which may have resulted in the zip-tie being detached when the staff was trying to realign the tubing in the drum (containing the 200L Bag).

Has the IBC reviewed this incident?	**X YES** ☐NO

Obtained via FOIA by Judicial Watch Inc.

Please describe the root cause of this incident:	**Quality Issue/Equipment Failure – Tube Failure of the Harvest Bag**

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

RECOMMENDATION: The following incident investigation recommendations were made to the facility:

- **Administrative Controls**
  - Check the tubing for damage, quality of materials and properly attachment to the bottom of the harvest bag before initiating filling.
  - Contact the vendor if a quality issue is noted.
  - Add a liquid collection container below the drum containing the 200 L 3-D bag.
  - Practice and document spill response drills annually.
  - Develop a flow chart for a spill response in these areas.

  Timeline for Implementation:
  - ✓ Checking for damage to tubing before filling with Harvest Media – Immediately
  - ✓ Spill Response Drills – December 2020
  - ✓ Insert a liquid collection container below the drum containing the 200 L 3-D harvest bag. – December 2020
  - ✓ Flow Chart of Spill Response in these areas – December 2020

- **Engineering Controls**
  - Increasing the diameter of the opening at the bottom of the harvest container so that the tubing can be aligned into the drum more readily.

  Timeline for Implementation:
  - ✓ Changing the diameter of Harvest Containers - August 2021

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Peeples, Mark <Mark.Peeples@nationwidechildrens.org>
Sent: Wednesday, May 6, 2020 8:29 PM
To: NIH guidelines
Cc: Ghosh, Sumit
Subject: Incident Report
Attachments: Incident-Reporting-GMP Spill (IBC) May 6 2020.pdf

Please accept this report of a spill that was cleaned up without incident.

Mark E. Peeples, Ph.D.
Professor, Department of Pediatrics
The Ohio State University College of Medicine
Center for Vaccines and Immunity, WA4012
Abigail Wexner Research Institute at Nationwide Children's Hospital
700 Children's Drive
Columbus, Ohio 43205
Office: 614-722-3696
Fax: 614-722-3680

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, June 1, 2020 9:00 AM
To: Trundy, Robin L; NIH guidelines
Cc: McClain, Mark S; Warren, Kevin; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Exposure incident involving recombinant DNA materials: Vanderbilt University Medical Center

Dear Robin Trundy,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Trundy, Robin L <robin.trundy@vumc.org>
Sent: Thursday, May 14, 2020 3:14 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
Cc: McClain, Mark S <mark.s.mcclain@vumc.org>; Warren, Kevin <kevin.warren@vumc.org>
Subject: RE: Exposure incident involving recombinant DNA materials: Vanderbilt University Medical Center
Importance: High

Dr. Harris:

The full report related to this exposure event is attached for your review.

Please contact me via email or the numbers provided if further information is needed.

Thank You,

Robin Trundy

Obtained via FOIA by Judicial Watch Inc.

From: Trundy, Robin L
Sent: Tuesday, May 12, 2020 11:05 AM
To: HarrisKath@od.nih.gov
Cc: McClain, Mark S <mark.s.mcclain@vumc.org>; Warren, Kevin <kevin.warren@vumc.org>
Subject: Exposure incident involving recombinant DNA materials: Vanderbilt University Medical Center
Importance: High

Dr. Harris:

I hope you are safe and well during this challenging time. I am writing to let you know that we were recently made aware of an exposure incident that occurred on April 17, 2020. A laboratorian was attempting to remove an ultracentrifuge tube from a rotor as part of a plasmid DNA purification (maxi prep) procedure involving a mutant R9 full-length HIV-1 molecular clone. The tube had become wedged in the rotor and the individual was using a metal tool (forceps with flattened, curved tips presumably intended for use with these tubes) to attempt to dislodge the tube. The person was holding the rotor with their non-dominant hand while attempting to dislodge the tube with the tool. After repeated attempts, the tool slipped and punctured the laboratorian's glove and skin at the base of their thumb. The individual immediately and thoroughly flushed the exposure site, attempted to notify her Principal Investigator and reported to Occupational Health for post-exposure follow-up.

At the time of this incident, a number of extenuating circumstances associated with institutional pandemic response prevented me and my team from receiving this information in a timely manner from the individual or Occupational Health and therefore incident follow-up and reporting was delayed. We are in the process of conducting an incident analysis and plan to have a full report to you before the close of business on Friday, May 15th, 2020.

Thanks in advance for your understanding,

Robin

Robin Trundy, M.S., RBP, CBSP
Assistant Director & Institutional Biosafety Officer
Biological Safety Section
Vanderbilt Environmental Health & Safety
1161 21st Ave. S., A-0201 MCN
Nashville, TN 37232

Office: 615-322-0927
Cell: Redacted by agreement
Robin.trundy@vumc.org



Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Vanderbilt University Medical Center
Date of Report:	5/15/2020
Reporter name and position:	Robin Trundy Assistant Director & Institutional Biosafety Officer
Telephone number:	615-322-0927
Email address:	Robin.trundy@vumc.org
Reporter mailing address:	VEHS 1161 21st Avenue South (A-0201 MCN) Nashville, TN 37232
Date of incident:	4/17/2020
Name of Principal Investigator:	Christopher Aiken
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* NIH R56 AI076121-10A1 *NIH funding institute or center:* NIAID *NIH program officer (name, email address):* Refsland, Eric (NIH/NIAID) [E] <eric.refsland@nih.gov>

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):

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Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 8/22/2017
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	IIII-D-2-a (production of mutant HIV-1 plasmid DNA using *E. coli* K-12)
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA No other reports have been made.
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The plasmid was an R9 full-length HIV-1 molecular clone encoding two amino acid substitutions in the capsid protein that markedly reduce HIV-1 infectivity. (This plasmid was being propagated in *E.coli*.) The R9 parental provirus is a laboratory adapted strain of HIV-1 that is replication competent.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On Friday, April 17, 2020 at approximately 1:30 p.m., a female laboratorian was attempting to remove an ultracentrifuge tube from a rotor as part of a plasmid DNA purification (maxi prep) procedure involving a mutant R9 HIV-1 molecular clone. The individual was working alone in the main BSL-2 laboratory of Dr. Christopher Aiken located at A-5216 Medical Center North at the time of the event. She was wearing standard BSL-2 PPE including a lab coat and fluid-resistant disposable gloves. The tube had become wedged in the rotor after the centrifuge run, and the individual was using a metal tool (forceps with flattened, curved tips presumably intended for use with these tubes) to attempt to dislodge the tube. The person was holding the rotor with their non-dominant hand while attempting to dislodge the tube with the tool. After repeated attempts, the tool slipped and punctured the laboratorian's glove and skin at the base of their thumb. The individual immediately and thoroughly flushed the exposure site, attempted to notify her Principal Investigator and then immediately reported to Occupational Health for post-exposure follow up.

This individual is a senior laboratorian who has worked in this lab for ~10 years. Her bloodborne pathogens and biosafety training status was current at the time of the incident. She initially completed BSL-2 and bloodborne pathogen trainings on 12/6/2010. She completed

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subsequent lab-specific trainings addressing procedural aspects associated with HIV-related activities carried out by this lab and was appointed as the designated oversight person for HIV-related activities requiring BSL-2 with enhanced containment practices in 2017 and remains in that role.

The procedure that resulted in the exposure is one that this laboratorian has carried out routinely for years, usually several times a month. Based on her report, tubes getting stuck occurs about 5% of the time. When this condition has arisen in the past, she would seek assistance from other lab members who generally have stronger hands to assist with the removal. On the date of the incident, she was working alone in the lab. After working for an extended time to pry out the tube, the tube top became quite deteriorated. This condition, in combination with the force applied, resulted in slippage of the tool and the puncture wound was sustained.

The PI did not notify the Biosafety Officer or VEHS Biosafety of the exposure event as he believed the injured laboratorian had reported the event to this group. Although the laboratorian attempted to contact the BSO by stopping by the VEHS Office, she was unable to be directed to the BSO due to a miscommunication at the VEHS Office.

Has the IBC reviewed this incident?	☒YES ☐NO This incident will be reviewed at the 5/26/2020 IBC meeting.
Please describe the root cause of this incident:	The use of excessive force to remove a sample tube from a centrifuge rotor. While there was no deviation from the SOP, it should be updated to include safety precautions which will address this problem should it occur.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The PI discussed the accident at his lab's next group meeting (4/24/2020) and reminded them to never use strong force when performing any lab procedure and to notify the PI of stuck tube scenarios before attempting removal. The lab is exploring blunted alternatives to the tube removal tool that was used in the procedure.

VEHS Biosafety is collaborating with the PI and other laboratorians who perform the same procedure to identify any preventable causes of tube failure and best (and safest) methods for tube removal under failure conditions. All corrective measures will be incorporated into a written standard operating procedure for this activity, and all personnel will undergo requalification to perform this activity in accordance with that procedure. *(Implementation target: July 15, 2020)*

The communication breakdowns that occurred with the timely reporting of this incident are only partially attributable to current pandemic response actions that have disrupted research. The PI will be attending the 5/26/2020 VUMC IBC Meeting to participate in the review of this incident. The current IBC policy for responding to personnel spills and exposures involving biological materials (see attached) will be reviewed as part of that discussion. This will both reinforce the PI's knowledge and allow the IBC to determine if any policy revisions are needed at this time. *(Implementation target: July 15, 2020 if applicable)*

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Additionally, the VUMC IBC is already taking action to promote and sustain greater awareness of institutional biosafety policies among lab leaders. At the 4/28/2020 IBC meeting, the committee endorsed a plan to require all IBC-registered PI's to complete the most recent version of the Biosafety101: Standard Microbiological Practices course as a condition of their IBC approval. This course, which is offered online through the Vanderbilt Learning Management Systems, was revised and expanded in late 2019 to include more detailed information about institutional policies and biomaterial exposure/injury prevention, response and reporting actions. VEHS Biosafety is currently taking action to support this retraining effort and will also enroll incoming faculty who have self-identified as using biological materials in research going forward. *(Implementation target: July 15, 2020)*

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Institutional Biosafety Committee Policy: Responding to Personnel Exposures & Spills Involving Biological Materials

Applies to:

☒ Vanderbilt University (VU)

☒ Vanderbilt University Medical Center (MC)

Biological materials used in research include microorganisms, viruses, body fluids and tissues, cells, recombinant or synthetic nucleic acid molecules, biological toxins and other biological materials that may be contaminated or otherwise capable of causing contamination or disease. All biological materials present a risk for cross-contamination in lab operations, and most can be an exposure risk for the personnel handling them. Therefore, it is essential that all lab personnel understand and are proficient and consistent in performing biosafety practices in accordance with applicable biosafety standards. In doing so, the potential for exposure incidents and spills of biological materials will be minimized.

Exposure Incident Response

A "***biological materials exposure incident***" occurs when biological materials enter the body through:

- a puncture, cut or abrasion of the skin involving a biologically-contaminated object (including animal bites/scratches);
- contact of biological contamination with compromised skin;
- contact of biological contamination with mucus membranes of eyes, nose or mouth.

It is important to note that most laboratory-acquired infections documented in the literature have no specific exposure incident associated with the infection. Incidental contact with contaminants followed by handling a personal item that comes in contact with your eyes, nose, mouth or broken skin can lead to an undetected exposure that could lead to infection. It is essential that you know the medical features of the biological agents that you work with in the lab. If you experience any symptoms that may be attributable to an agent you have been handling in the lab, notify your PI and the Occupational Health Clinic.

In the event that a ***biological materials exposure incident*** occurs, the exposed person should take the following actions immediately:

1. Proceed to the closest sink/eyewash. Remove impacted PPE and flush the exposure site.
2. If the exposure involved broken or compromised skin, use soap and water to thoroughly cleanse the wound. (Do not use bleach or other harsh chemicals that can degrade tissues.)
3. Flush/cleanse the exposure site for 15 minutes.
4. Cover the wound with a bandage (if applicable).
5. Report to the Occupational Health Clinic (or Adult Emergency if outside routine business hours).
    - Occupational Health Clinic hours are 7:00 am – 6:00 pm, Monday – Friday; 640 Medical Arts Building; 615-936-0955;
    - Take any information about the source material that you have readily available along with you.
6. Notify the LAB SUPERVISOR and Biosafety Officer (BSO) at 615-322-0927 as soon as possible once medical follow-up actions have been initiated.

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Biological Spill Response

A spill is an unintended release of materials from a container. Biological material spills (aside from those involving materials requiring BSL-3 containment) present the greatest risk for personnel exposure when they involve:

- broken glass,
- large quantities (in excess of 50 mls per vessel), or
- occur in public or common use areas.

Labs that carry out operations that could generate these types of spills will need designated supplies and an established procedure for responding to such spills in a manner that ensures safety for all. This can be achieved by assembling a spill kit and training personnel on the response procedure.

VEHS Biosafety has prepared a spill response procedure appropriate for the spills previously described and this is available on Page 5 of this document. The necessary contents for a kit to be used in conjunction with that procedure includes:

- A supply of fluid-resistant disposable gloves
- A lab coat or disposable smock
- Safety glasses
- Shoe or boot covers
- Absorbent paper towels
- Autoclavable biohazard bags
- Appropriate disinfectant solution
- Expendable broom and dustpan
- Small brush with handle
- Laminated clean-up procedure card



Here is an example of an assembled kit using a bucket to store the kit contents. The bucket can be lined with the biohazard bag for collection of spill waste.

Small-scale spills

When working with small containers of biological materials at the bench or in the biosafety cabinet, disinfectant, paper towels, and a biohazardous waste receptacle should be readily available in order to clean and disinfect the area at the end of the procedure. In most cases, you should have everything you need to clean up a spill. The basic steps for cleaning up this kind of spill safely include:

1. Stop your procedure and assess the scene. Determine what was spilled and where the contamination went. (If the spill ended up on the floor, outside the BSC, or involved broken glass, use the procedure on Page 5.)
2. Assess your gloves and lab coat for contamination. If these items became contaminated, replace them before proceeding with cleanup.
3. Wet a paper towel with disinfectant and then carefully blot up the visible contamination. Discard towel as biohazardous waste.
4. Discard contaminated items that cannot be effectively surface-disinfected as biohazardous waste.
5. Apply disinfectant to all surfaces impacted by the spill; wait the prescribed contact time before removing disinfectant residues and resuming procedure.
6. If the spill enters the grille of the BSC, this will require cleaning and disinfection of the containment pan underneath the work surface. This procedure does not need to be done immediately but generally requires 2 people and some amount of cabinet disassembly. Contact VEHS Biosafety for guidance and assistance in performing this cleanup.

All biological spills, regardless of scale or exposure potential need to be reported to the Lab Supervisor or Principal Investigator (PI). Any biological spill that occurs outside the lab or a biological spill resulting in a

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personnel exposure needs to be reported to the BSO at 615-322-0927 as soon as possible once medical follow-up actions have been initiated.

Spills Occurring Inside Processing Equipment (Shakers & Centrifuges)
To reduce spill potential associated with processing equipment, inspect all components (including vessels) for signs of degradation that could lead to equipment malfunction. The processing equipment should be used only in accordance with the manufacturer's equipment manual. If during the processing operation, there is any visible or audible sign of equipment malfunction (i.e., knocking, rattling, visibly damaged components, etc.), immediately de-energize the device and notify your lab supervisor or PI and the Biosafety Officer (615-322-0927). Do not open the device for 30 minutes to allow sufficient time for aerosols to settle. If the device is leaking, close off the lab area. The BSO will provide assistance in managing the spill and will assess the event for potential biological exposure.

Toxin, Select Agent and BSL-3 Spills
Laboratories using these materials have specific spill response plans that address the unique requirements for managing these spills safely. However, the reporting requirements related to potential exposure are the same as described in this document.

Spill Response Considerations
The following considerations will aid in assuring that spill response is effectively completed:

- Assure that disinfectant is not expired and is properly prepared. A ready-to-use, EPA-rated tuberculocidal product is a good choice for a broad spectrum of spills. These products tend to have a longer shelf-life, shorter contact time, and are generally safer to handle because there is no preparation required. **NOTE: If you use bleach, and your spill wastes are heavily saturated with bleach, do NOT autoclave the waste as this can be hazardous to both personnel and equipment. Contact VEHS Biosafety for assistance with disposal.**
- Place the spill kit in a well-identified and accessible location and assure that it is routinely checked to make sure components have not degraded or been removed.
- Labs should identify their most likely spill scenario and perform a mock response/cleanup exercise to reinforce the procedure to be followed as it relates to that scenario.
- Contact the BSO for assistance with assembling lab-specific kits, procedures and spill drills.

Spill Prevention Considerations
Biological material spill cleanup procedures present a greater exposure risk than most standard bench procedures, because they put the responder in direct contact with contamination. It is important to note that consistent adherence to spill prevention measures as outlined below can reduce the frequency of spills occurring and further drive down the exposure potential for all:

- Select primary containers constructed of non-breakable materials whenever possible.
- Store primary containers in an upright position, preferably in a rack.
- Where possible, eliminate the use of wet ice. Wet items are difficult to handle and melting ice contributes to the size of a spill.
- Assure that lids of containers are properly installed. Avoid picking up or carrying primary containers by lids.
- When transporting primary containers outside of the lab, place containers in a secondary container with the following features necessary to effectively contain a spill:
    - rigid, non-breakable & leak-proof

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- constructed of material capable of being disinfected
- has a lid that can be securely closed

NOTE: Secondary containers for transporting materials requiring BSL-2 containment need to be marked with the biohazard symbol and lab contact information.

- When transporting materials out of the lab, use elevators instead of stairs to reduce the potential for a trip hazard and resulting spill.
- When transporting multiple items, use a cart and avoid stacking materials to prevent a "tip over" event.
- Assure that waste bags (including bagged tissues and carcasses) are always stored in a leak-proof container to capture any leakage if the bag gets punctured.
- Sharps containers do not have leak-proof lids. Do not store sharps containers on their sides.

Reporting Other "Releases" of Biological Materials Containing Recombinant or Synthetic Nucleic Acid Molecules

Because genetically-modified materials present an environmental release risk, the following events must also be reported to the Biosafety Officer (615-322-0927) in order to meet reporting requirements under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules:

- **Loss or release of transgenic animal (dead or alive) outside the institution**
- **Loss or release of viable materials containing recombinant or synthetic nucleic acid molecules outside the institution**

Policy adopted by the MC IBC on 7/26/16; policy reviewed and minor edits adopted on 4/23/19.

Policy adopted by the VU IBC on 7/26/16; policy reviewed and minor edits adopted on 4/23/19.

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Cleanup Procedure for Bio-Spills outside a BSC

Personal protective equipment for spill cleanup should include:
2 pairs fluid-resistant disposable gloves, safety glasses, shoe covers and a lab coat!

1. Step back from the spill zone at least 2 steps, then examine your feet. If your shoes are visibly contaminated, or there is visible spill contamination where you are standing, your shoes need to be considered part of the "spill" and decontaminate or discard as appropriate.
2. Notify others in the lab of the event and have someone post the lab as "do not enter".
3. When spills occur in the open lab, the best response is carried out by a small team, not an individual. Have one person perform cleanup-others should retrieve supplies & review procedure.
4. When treating the spill area, go at least 3 feet beyond the visible contamination area; don't forget walls and anything that was within the "splash zone".

If a spill occurs in a public area, the following basics apply:

1. Stay with the spill and keep others away from it. Send someone to the lab to retrieve spill response supplies and LAB SUPERVISOR or PI if feasible.
2. Contact VEHS Biosafety (2-2057) for assistance with spill and scene management.

Spills & exposure incidents must be reported!

- Report all spills to LAB SUPERVISOR. (NOTE: Biological material spills that occur outside the lab or a biological spill resulting in a personnel exposure needs to be reported to the Biosafety Officer (BSO) at 2-0927 as soon as possible.)
- If any biological material from the lab enters your body through:
  - A break in the skin or
  - Contact with your eyes, nose or mouth
    YOU MUST FLUSH, FLUSH, FLUSH!... get to the sink and flush the exposure site for 15 minutes with water! Soap and water should be used if the exposure involved broken skin.

After flushing the exposure site, you must report to Occupational Health (or Adult Emergency if outside routine business hours and exposure involved human or non-human primate derived materials) for post-exposure follow-up. Then, notify the LAB SUPERVISOR/PI and BSO.

The 1-2-3 for Spill Cleanup

1. **Remove the breached container.** If breached container was glass, use tongs or disposable broom/dust pan. Place glass in sharps container for disposal. If container was not glass, place it in a biohazard bag for disposal or appropriate secondary container.
2. **Treat, absorb and remove the spill contamination.** Cover spill with disinfectant saturated towel and allow to treat spill for several minutes. Absorb and remove spill contamination. Place absorbed spill materials and associated wastes in biohazard bag. Repeat this process if any evidence of contamination is still remaining.
3. **Disinfect all impacted surfaces.** Apply disinfectant to all surfaces impacted by the spill (including those in the "splash zone"); wait the prescribed contact time before removing disinfectant residues. **Use care to limit contact with contaminated surfaces when removing PPE! Place all used spill response materials (including mechanical tools and disposable PPE) in the biohazard bag for treatment as biohazardous waste.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Trundy, Robin L <robin.trundy@vumc.org>
Sent: Thursday, May 14, 2020 3:14 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: McClain, Mark S; Warren, Kevin
Subject: RE: Exposure incident involving recombinant DNA materials: Vanderbilt University Medical Center
Attachments: 4.17.2020 VUMC (AIKEN) - NIH REPORT.pdf

Importance: High

Dr. Harris:

The full report related to this exposure event is attached for your review.

Please contact me via email or the numbers provided if further information is needed.

Thank You,

Robin Trundy

From: Trundy, Robin L
Sent: Tuesday, May 12, 2020 11:05 AM
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Cc: McClain, Mark S <mark.s.mcclain@vumc.org>; Warren, Kevin <kevin.warren@vumc.org>
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Dr. Harris:

I hope you are safe and well during this challenging time. I am writing to let you know that we were recently made aware of an exposure incident that occurred on April 17, 2020. A laboratorian was attempting to remove an ultracentrifuge tube from a rotor as part of a plasmid DNA purification (maxi prep) procedure involving a mutant R9 full-length HIV-1 molecular clone. The tube had become wedged in the rotor and the individual was using a metal tool (forceps with flattened, curved tips presumably intended for use with these tubes) to attempt to dislodge the tube. The person was holding the rotor with their non-dominant hand while attempting to dislodge the tube with the tool. After repeated attempts, the tool slipped and punctured the laboratorian's glove and skin at the base of their thumb. The individual immediately and thoroughly flushed the exposure site, attempted to notify her Principal Investigator and reported to Occupational Health for post-exposure follow-up.

At the time of this incident, a number of extenuating circumstances associated with institutional pandemic response prevented me and my team from receiving this information in a timely manner from the individual or Occupational Health and therefore incident follow-up and reporting was delayed. We are in the process of conducting an incident analysis and plan to have a full report to you before the close of business on Friday, May 15th, 2020.

Thanks in advance for your understanding,

Obtained via FOIA by Judicial Watch Inc.

Robin

Robin Trundy, M.S., RBP, CBSP
Assistant Director & Institutional Biosafety Officer
Biological Safety Section
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1161 21st Ave. S., A-0201 MCN
Nashville, TN 37232

Office: 615-322-0927
Cell: Redacted by agreement
Robin.trundy@vumc.org



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

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Sent: Tuesday, May 12, 2020 12:05 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: McClain, Mark S; Warren, Kevin
Subject: Exposure incident involving recombinant DNA materials: Vanderbilt University Medical Center

Importance: High

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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, June 22, 2020 1:23 PM
To: Major, Sheryl; NIH guidelines
Cc: McMahill, Angela; Scott, Lance; Komiyama, Takaki; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: UCSD Report to the NIH

Dear Sheryl Major,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Major, Sheryl <smajor@ucsd.edu>
Sent: Wednesday, June 3, 2020 11:57 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: McMahill, Angela <amcmahill@ucsd.edu>; Scott, Lance <lscott@ucsd.edu>; Komiyama, Takaki <tkomiyama@ucsd.edu>
Subject: UCSD Report to the NIH

Dear NIH Office of Science Policy,

Please find attached an incident report subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids. This report describes the IBC's failure to obtain NIH approval prior to authorizing the downgrade of animal housing from ABSL-2 to ABSl-1 for a viral vector in an animal model.

Mouse models previously administered at ABSL-2 with a G-protein deleted and EnVa-pseudotyped rabies viral vector were housed at ABSL-1 rather than ABSL-2. This does not represent a Principal Investigator failure to adhere to the IBC approved containment level, but rather an institutional failure on the part of the UC San Diego IBC to obtain prior OSP permission for an animal biosafety level downgrade from ABSL-2 to ABSL-1. This downgrade request was submitted by the Principal Investigator to the UC San Diego Institutional Biosafety Committee (IBC) and reviewed and approved at the August 11, 2017 IBC meeting, but IBC guidance to the PI was incorrect, and the OSP request was never carried forward.

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This incident was uncovered during the renewal of the PI's protocol. The renewal protocol was reviewed by the University of California, San Diego (UCSD) Institutional Biosafety Committee (IBC) on March 13th, 2020. The research with the vector in question is not currently being carried out, the downgrade request has been submitted to OSP, and the amendment requesting the downgrade from ABSL-2 to ABSL-1 is pending IBC approval at this time. Training has been provided to the IBC regarding this incident.

Due to the campus COVID-19 response, the IBC was delayed in providing this report to the NIH.

Please let me know if you have any questions regarding this report.

Best,

Sheryl Major
Biosafety Officer (BSO)
High Containment Officer (HCO)
UC San Diego
Environment, Health and Safety
CRSF 241
Ph: 858-822-2493
Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

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Does this incident involve research subject to the *NIH Guidelines*?	xYES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of California, San Diego
Date of Report:	05/07/2020
Reporter name and position:	Sheryl Major, Biosafety Officer
Telephone number:	(858) 220-9669
Email address:	smajor@uscd.edu
Reporter mailing address:	9500 Gilman Drive, MC 0090 La Jolla, California, 92093-0090
Date of incident:	03/13/2020
Name of Principal Investigator:	Dr. Takaki Komiyama
Is this an NIH-funded project?	☐YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill X Other (please describe): Failure to obtain OSP approval prior to IBC approval
Did the Institutional Biosafety Committee (IBC) approve this research?	xYES ☐NO If yes, date of approval: August 11, 2017
What was the approved biosafety level of the research?	X BL1 ☐ BL2 ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-4
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	SAD19 rabies viral vector pseudotyped with avian sarcoma leucosis virus glycoprotein EnvA (EnvA-dGRabV rabies virus).

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

In August 2017, the University of California, San Diego (UCSD) Institutional Biosafety Committee (IBC) approved a downgrade from ABSL-2 to ABSl-1 for a viral vector in an animal model without OSP approval. Mouse models previously administered at ABSL-2 with a G-protein deleted and EnVa-pseudotyped rabies viral vector were approved to be housed at ABSL-1. The committee's risk assessment determined the downgrade to be appropriate for housing of mouse models, however, the committee did not follow the appropriate procedures and did not request approval through OSP.

The Principal Investigator (PI) reached out to the biosafety program to discuss downgrading the housing post administration in July 2017. At that time, the biosafety officer and IBC was not aware that this determination required OSP approval and instructed the PI to amend the protocol for review by the IBC. This does not represent a Principal Investigator failure to adhere to the IBC approved containment level, but rather a misstep on the part of the IBC to obtain prior OSP permission.

This incident was uncovered during the renewal of the PI's protocol. The renewal protocol was reviewed by the IBC on March 13th, 2020. The research with the vector in question is not currently being carried out pending OSP review. The downgrade request has been submitted to OSP, and the amendment requesting the downgrade from ABSL-2 to ABSL-1 is pending IBC approval at this time. Training has been provided to the IBC regarding this incident.

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Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	Insufficient IBC training

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

IBC members have received training regarding recombinant or synthetic nucleic acid in animal models using the NIH Guidelines FAQs for Research on Genetically Modified (Transgenic) Animals – May 2019.

The UCSD Recombinant or Synthetic Nucleic Acid Training for researchers and Principal Investigators was updated to include additional details regarding work with genetically modified animals and the appropriate process set forth by the NIH Guidelines.

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Hunter, Renee (NIH/OD) [C]

From: Major, Sheryl <smajor@ucsd.edu>
Sent: Wednesday, June 3, 2020 11:57 AM
To: NIH guidelines
Cc: McMahill, Angela; Scott, Lance; Komiyama, Takaki
Subject: UCSD Report to the NIH
Attachments: Incident-Reporting-Form_Komiyama.pdf

Dear NIH Office of Science Policy,

Please find attached an incident report subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids. This report describes the IBC's failure to obtain NIH approval prior to authorizing the downgrade of animal housing from ABSL-2 to ABSl-1 for a viral vector in an animal model.

Mouse models previously administered at ABSL-2 with a G-protein deleted and EnVa-pseudotyped rabies viral vector were housed at ABSL-1 rather than ABSL-2. This does not represent a Principal Investigator failure to adhere to the IBC approved containment level, but rather an institutional failure on the part of the UC San Diego IBC to obtain prior OSP permission for an animal biosafety level downgrade from ABSL-2 to ABSL-1. This downgrade request was submitted by the Principal Investigator to the UC San Diego Institutional Biosafety Committee (IBC) and reviewed and approved at the August 11, 2017 IBC meeting, but IBC guidance to the PI was incorrect, and the OSP request was never carried forward.

This incident was uncovered during the renewal of the PI's protocol. The renewal protocol was reviewed by the University of California, San Diego (UCSD) Institutional Biosafety Committee (IBC) on March 13th, 2020. The research with the vector in question is not currently being carried out, the downgrade request has been submitted to OSP, and the amendment requesting the downgrade from ABSL-2 to ABSL-1 is pending IBC approval at this time. Training has been provided to the IBC regarding this incident.

Due to the campus COVID-19 response, the IBC was delayed in providing this report to the NIH.

Please let me know if you have any questions regarding this report.

Best,

Sheryl Major
Biosafety Officer (BSO)
High Containment Officer (HCO)
UC San Diego
Environment, Health and Safety
CRSF 241
Ph: 858-822-2493
Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Bifano, Ph.D., Abby; NIH guidelines
Cc: McDonald, Christine; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Cleveland Clinic Incident Report
Date: Monday, June 22, 2020 1:27:49 PM
Attachments: image001.jpg

Dear Dr. Abby Bifano,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Bifano, Ph.D., Abby <bifanoa@ccf.org>
Sent: Tuesday, June 9, 2020 10:33 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: McDonald, Christine <mcdonac2@ccf.org>
Subject: Cleveland Clinic Incident Report

Hello,

This email is to submit an incident report for an issue that we identified, in which a lab has utilized rDNA modified cells for experiments subject to the NIH Guidelines without approval by the IBC.

If you need additional information, we will be glad to provide it.

Thank you,
Abby Bifano

Abby Bifano, PhD
Research Regulatory & QA Manager | Lerner Research Institute
Biosafety Officer | Environmental Health and Safety | Enterprise Quality Institute
Cleveland Clinic | 9500 Euclid Ave., ND46 | Cleveland, OH 44195 | (216) 444-4423 |



Cleveland Clinic

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Pager: 83710 | bifanoa@ccf.org

Please consider the environment before printing this e-mail
Cleveland Clinic is currently ranked as one of the nation's top hospitals by *U.S. News & World Report* (2019-2020). Visit us online at http://www.clevelandclinic.org for a complete listing of our services, staff and locations. Confidentiality Note: This message is intended for use only by the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please contact the sender immediately and destroy the material in its entirety, whether electronic or hard copy. Thank you.

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National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Cleveland Clinic
Date of Report:	May 15, 2020
Reporter name and position:	Abby Bifano, PhD Biosafety Officer
Telephone number:	216-444-4423
Email address:	bifanoa@ccf.org
Reporter mailing address:	Cleveland Clinic 9500 Euclid Avenue ND46 Cleveland, Ohio 44195
Date of incident:	Identification of potential issue on May 1, 2020. Confirmation of research experiments by PI on May 19, 2020.
Name of Principal Investigator:	Neetu Gupta, PhD (laboratory PI; Co-I on IRB protocol) Brian Hill, MD (Owner of IRB protocol; Co-I on pending IBC protocol)
Is this an NIH-funded project?	☐ YES ☒ NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions ☒ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES ☒ NO (approval is pending, June 2020) If yes, date of approval:
What was the approved biosafety level of the research?	Once approved, it will be: ☐ BL1 ☒ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-A
Has a report of this incident been made to other agencies? If so, please indicate	Not applicable. ☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	rDNA modified CAR-T cells (FDA approved) are given to patients as part of their standard of care. Extra blood and saliva samples are collected for research purposes at the same time that samples are obtained for standard of care, under an IRB approved protocol. The collected blood and saliva samples for research may contain recombinant modified cells.

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)

  Cleveland Clinic laboratory, BSL2.

- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

  Principle Investigator

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event

  Upon identification, the principle investigator contacted the Biosafety Office and initiated an application to submit to the IBC.

- The training received by the individual(s) involved and the date(s) the training was conducted.

  On the date of the incident, the PI had completed Cleveland Clinic-required biosafety training on 08/05/2018.

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation

  Cleveland Clinic policy requires IBC approval prior to initiating an experiment subject to the NIHG. At the time of the incident, the laboratory Principal Investigator knew that IBC approval was required for these experiments, but was under the assumption that the PI who held the IRB approval for the collection of the cells had obtained approval by the IBC for the subsequent research use of the rDNA modified cells.

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation

  This was not an approved experiment. However, the experiment would have been approved at BSL2, due to the human origin of the cells. Facilities are BSL1/2. Despite

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the laboratory not having IBC approval, the lab was handling the cells using BSL2 practices.

- The personal protective equipment in use at the time of the incident/violation

  Lab coat, nitrile gloves, protective eye wear

- The occupational health requirements for laboratory personnel involved in the research

  None for this experiment.

- Any medical surveillance provided or recommended after the incident

  None for this experiment, since personal injury, illness, or exposure was not reported.

- Any injury or illness associated with the incident

  None reported.

- Equipment failures

  None reported or identified.

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

The administration of recombinant modified CAR-T cells is a potential therapy for some patients. This therapy is given to patients at Cleveland Clinic. The cells are FDA approved for treatment and are provided as standard of care. Some patients also offer consent to provide blood and saliva samples for research purposes as part of an IRB approved study at Cleveland Clinic. Samples are taken at the same time that standard of care samples are obtained and are transferred from the clinical area to a basic research lab at Cleveland Clinic. Research only samples are banked and used for *in vitro* research analysis. Laboratory experiments include flow cytometry analysis, cytokine arrays, and metabolomics. Specimens are not shared with any collaborators, nor are they administered to animals. Residual samples are not taken for research.

It should be mentioned that the PI who has oversight of the IRB study is not the same PI who has oversight of the laboratory. However, the laboratory PI is a Co-Investigator on the IRB approved study and the PI of the IRB study will be a Co-Investigator on the pending IBC protocol.

The PI self-identified that an IBC protocol did not exist for the handling of the recombinant modified T cells that were collected from the Cleveland Clinic patients. She had been under the impression that the PI who owned the IRB protocol also had the necessary IBC approval, but he did not. Also, the PI of IRB approved study was under the impression that IBC approval was not necessary, since the IRB did not flag the protocol at the time of approval as requiring prior IBC approval. This issue was identified when the laboratory PI asked for a copy of the IBC approval letter.

The IBC was notified of the incident at the May 27th, IBC meeting. The laboratory PI will have an IBC protocol reviewed at an IBC meeting in June 2020. The PI will attend the IBC meeting.

The owner of the IRB approved protocols and the supporting coordinators have been educated on the requirement for IBC approval.

The Biosafety Office has contacted the Cleveland Clinic Institutional Review Board to make them aware of this incident and to provide education that this type of study requires approval by the IBC. The Biosafety Office will be working with the IRB to integrate a question within the IRB application to ask investigators if they intend to use rDNA modified cells from human subject research participants for research purposes. The Biosafety Office has asked the IRB whether there are any similar IRB studies that the Biosafety Office should review to determine whether IBC approval was missed.

This topic will also be added to the education that is available for our clinical research teams. The updated presentation and resources will be made available on the IBC website.

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Has the IBC reviewed this incident?	☐ YES ☒ NO The committee was notified of the incident at the May 27th, IBC meeting. An IBC protocol will be reviewed at a June 2020 IBC meeting.
Please describe the root cause of this incident:	Lack of communication and education: The laboratory PI was under the impression that that the PI who owned the IRB protocol had IBC approval. This Staff member, who owned the IRB approved protocol, was aware of the NIHG, as he has other IBC approved protocols for clinical trials only. However, there was a breakdown in communication as to the requirement for IBC approval and who would submit the protocol to the IBC. Also, the PI of IRB approved study was relying on the IRB to flag the protocol at the time of approval as requiring prior IBC approval. The IRB did not.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The laboratory PI will submit an IBC protocol for review at an IBC meeting in June 2020. The PI will attend the IBC meeting.

The owner of the IRB approved protocols and the supporting coordinators have been educated on the requirement for IBC approval.

The Biosafety Office has contacted the Cleveland Clinic Institutional Review Board to make them aware of this incident and to provide education that this type of study requires approval by the IBC. The Biosafety Office will be working with the IRB to integrate a question within the IRB application to ask investigators if they intend to use rDNA modified cells from human subject research participants for research purposes. The Biosafety Office has asked the IRB whether there are any similar IRB studies that the Biosafety Office should review to determine whether IBC approval was missed.

This topic will also be added to the education that is available for our clinical research teams. The updated presentation and resources will be made available on the IBC website.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

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- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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From: Bifano, Ph.D., Abby
To: NIH guidelines
Cc: McDonald, Christine
Subject: Cleveland Clinic Incident Report
Date: Tuesday, June 9, 2020 10:33:55 AM
Attachments: image001.jpg
Cleveland Clinic Incident Report NG, BH 2020.pdf

Hello,

This email is to submit an incident report for an issue that we identified, in which a lab has utilized rDNA modified cells for experiments subject to the NIH Guidelines without approval by the IBC.

If you need additional information, we will be glad to provide it.

Thank you,
Abby Bifano

Redacted by agreement



Abby Bifano, PhD
Research Regulatory & QA Manager | Lerner Research Institute
Biosafety Officer | Environmental Health and Safety | Enterprise Quality Institute
Cleveland Clinic | 9500 Euclid Ave., ND46 | Cleveland, OH 44195 | (216) 444-4423 |
Pager: [redacted] bifanoa@ccf.org

Please consider the environment before printing this e-mail
Cleveland Clinic is currently ranked as one of the nation's top hospitals by *U.S. News & World Report* (2019-2020). Visit us online at http://www.clevelandclinic.org for a complete listing of our services, staff and locations. Confidentiality Note: This message is intended for use only by the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please contact the sender immediately and destroy the material in its entirety, whether electronic or hard copy. Thank you.



Cleveland Clinic

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Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Cleveland Clinic
Date of Report:	May 15, 2020
Reporter name and position:	Abby Bifano, PhD Biosafety Officer
Telephone number:	216-444-4423
Email address:	bifanoa@ccf.org
Reporter mailing address:	Cleveland Clinic 9500 Euclid Avenue ND46 Cleveland, Ohio 44195
Date of incident:	Identification of potential issue on May 1, 2020. Confirmation of research experiments by PI on May 19, 2020.
Name of Principal Investigator:	Neetu Gupta, PhD (laboratory PI; Co-I on IRB protocol) Brian Hill, MD (Owner of IRB protocol; Co-I on pending IBC protocol)
Is this an NIH-funded project?	☐ YES ☒ NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐ Failure to follow approved containment conditions ☒ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES ☒ NO (approval is pending, June 2020) If yes, date of approval:
What was the approved biosafety level of the research?	Once approved, it will be: ☐ BL1 ☒ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-A
Has a report of this incident been made to other agencies? If so, please indicate	Not applicable. ☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	rDNA modified CAR-T cells (FDA approved) are given to patients as part of their standard of care. Extra blood and saliva samples are collected for research purposes at the same time that samples are obtained for standard of care, under an IRB approved protocol. The collected blood and saliva samples for research may contain recombinant modified cells.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)

  Cleveland Clinic laboratory, BSL2.

- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

  Principle Investigator

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event

  Upon identification, the principle investigator contacted the Biosafety Office and initiated an application to submit to the IBC.

- The training received by the individual(s) involved and the date(s) the training was conducted.

  On the date of the incident, the PI had completed Cleveland Clinic-required biosafety training on 08/05/2018.

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation

  Cleveland Clinic policy requires IBC approval prior to initiating an experiment subject to the NIHG. At the time of the incident, the laboratory Principal Investigator knew that IBC approval was required for these experiments, but was under the assumption that the PI who held the IRB approval for the collection of the cells had obtained approval by the IBC for the subsequent research use of the rDNA modified cells.

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation

  This was not an approved experiment. However, the experiment would have been approved at BSL2, due to the human origin of the cells. Facilities are BSL1/2. Despite

Obtained via FOIA by Judicial Watch Inc.

the laboratory not having IBC approval, the lab was handling the cells using BSL2 practices.

- The personal protective equipment in use at the time of the incident/violation

  Lab coat, nitrile gloves, protective eye wear

- The occupational health requirements for laboratory personnel involved in the research

  None for this experiment.

- Any medical surveillance provided or recommended after the incident

  None for this experiment, since personal injury, illness, or exposure was not reported.

- Any injury or illness associated with the incident

  None reported.

- Equipment failures

  None reported or identified.

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

The administration of recombinant modified CAR-T cells is a potential therapy for some patients. This therapy is given to patients at Cleveland Clinic. The cells are FDA approved for treatment and are provided as standard of care. Some patients also offer consent to provide blood and saliva samples for research purposes as part of an IRB approved study at Cleveland Clinic. Samples are taken at the same time that standard of care samples are obtained and are transferred from the clinical area to a basic research lab at Cleveland Clinic. Research only samples are banked and used for *in vitro* research analysis. Laboratory experiments include flow cytometry analysis, cytokine arrays, and metabolomics. Specimens are not shared with any collaborators, nor are they administered to animals. Residual samples are not taken for research.

It should be mentioned that the PI who has oversight of the IRB study is not the same PI who has oversight of the laboratory. However, the laboratory PI is a Co-Investigator on the IRB approved study and the PI of the IRB study will be a Co-Investigator on the pending IBC protocol.

The PI self-identified that an IBC protocol did not exist for the handling of the recombinant modified T cells that were collected from the Cleveland Clinic patients. She had been under the impression that the PI who owned the IRB protocol also had the necessary IBC approval, but he did not. Also, the PI of IRB approved study was under the impression that IBC approval was not necessary, since the IRB did not flag the protocol at the time of approval as requiring prior IBC approval. This issue was identified when the laboratory PI asked for a copy of the IBC approval letter.

The IBC was notified of the incident at the May 27th, IBC meeting. The laboratory PI will have an IBC protocol reviewed at an IBC meeting in June 2020. The PI will attend the IBC meeting.

The owner of the IRB approved protocols and the supporting coordinators have been educated on the requirement for IBC approval.

The Biosafety Office has contacted the Cleveland Clinic Institutional Review Board to make them aware of this incident and to provide education that this type of study requires approval by the IBC. The Biosafety Office will be working with the IRB to integrate a question within the IRB application to ask investigators if they intend to use rDNA modified cells from human subject research participants for research purposes. The Biosafety Office has asked the IRB whether there are any similar IRB studies that the Biosafety Office should review to determine whether IBC approval was missed.

This topic will also be added to the education that is available for our clinical research teams. The updated presentation and resources will be made available on the IBC website.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☐ YES ☒ NO The committee was notified of the incident at the May 27th, IBC meeting. An IBC protocol will be reviewed at a June 2020 IBC meeting.
Please describe the root cause of this incident:	Lack of communication and education: The laboratory PI was under the impression that that the PI who owned the IRB protocol had IBC approval. This Staff member, who owned the IRB approved protocol, was aware of the NIHG, as he has other IBC approved protocols for clinical trials only. However, there was a breakdown in communication as to the requirement for IBC approval and who would submit the protocol to the IBC. Also, the PI of IRB approved study was relying on the IRB to flag the protocol at the time of approval as requiring prior IBC approval. The IRB did not.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The laboratory PI will submit an IBC protocol for review at an IBC meeting in June 2020. The PI will attend the IBC meeting.

The owner of the IRB approved protocols and the supporting coordinators have been educated on the requirement for IBC approval.

The Biosafety Office has contacted the Cleveland Clinic Institutional Review Board to make them aware of this incident and to provide education that this type of study requires approval by the IBC. The Biosafety Office will be working with the IRB to integrate a question within the IRB application to ask investigators if they intend to use rDNA modified cells from human subject research participants for research purposes. The Biosafety Office has asked the IRB whether there are any similar IRB studies that the Biosafety Office should review to determine whether IBC approval was missed.

This topic will also be added to the education that is available for our clinical research teams. The updated presentation and resources will be made available on the IBC website.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

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- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

From: McKinney, Michelle (NIH/OD) [E]
To: Nancy Henderson; NIH guidelines
Cc: Debra Murphy; Hugh Mason; ibc@asu.edu; Jacobs, Bertram; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Arizona State University Incident Report 05.29.2020
Date: Monday, June 22, 2020 1:12:19 PM

Dear Nancy Henderson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Nancy Henderson <Nancy.J.Henderson@asu.edu>
Sent: Monday, June 15, 2020 2:58 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Debra Murphy <Debra.Murphy@asu.edu>; Hugh Mason <Hugh.Mason@asu.edu>; ibc@asu.edu; Jacobs, Bertram <bjacobs@asu.edu>
Subject: Arizona State University Incident Report 05.29.2020
Importance: High

Good Afternoon,

Attached is ASU's report of an incident that occurred on May 29, 2020. If you have any questions regarding this report please don't hesitate to contact me.

Best Regards and please stay safe,
Nancy

Nancy J. Henderson| Assistant Director
Research Operations | Office of Research Integrity & Assurance
Arizona State University | Knowledge Enterprise

Obtained via FOIA by Judicial Watch Inc.

t 480-965-6792| mobile Redacted by agreement
Nancy.J.Henderson@asu.edu|http://researchadmin.asu.edu
How am I doing? Email my supervisor

This message may contain information that is privileged, confidential and exempt from disclosure under applicable law. Please do not copy or forward this message without permission. If you are not the intended recipient, please delete all copies and notify me immediately by reply e-mail or by telephone (480) 965-6792 so we may correct our records

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Arizona State University
Date of Report:	6/15/2020
Reporter name and position:	Nancy Henderson Assistant Director - Office of Research Integrity and Assurance Arizona State University
Telephone number:	480-965-6792
Email address:	Nancy.J.Henderson@asu.edu
Reporter mailing address:	660 S. Mill Ave, Suite 312 PO Box 876011 Tempe, AZ 85287-6111
Date of incident:	5/29/2020
Name of Principal Investigator:	Bertram Jacobs
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 11/8/2018 IBC # 19-856
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1 Risk Group 2 and 3, III-D-2 Risk Group 2, III-D-3 Risk Group 2 and 3, III-D-4 Risk Group 1, III-F-1, III-F-6, and III-F-8 Appendices C-II and C-VIII
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Vaccinia virus strain NYVAC-KC covered under IACUC protocol number 20-1746R (approval period 10/30/2019-10/29/2022)

Please provide a narrative of the incident including a timeline of events.

Obtained via FOIA by Judicial Watch Inc.

On May 29, 2020, a male staff member from the Jacobs Lab was working with mice that were infected with Vaccinia virus strain NYVAC-KC. The staff member was transferring a mouse to a clean cage and was bitten on the thumb. The gloves and skin were both penetrated and a small amount of blood was drawn. The staff member was wearing a gap wrap, face mask, shoe covers, and gloves. Following the bite, the staff member replaced the mouse, removed gloves, and disinfected his hands with virex and isopropanol. He then replaced his gloves, finished transferring the mice and immediately reported the incident to his supervisor, Dr. Bertram Jacobs. The staff member is current on DTAP and Smallpox vaccinations. He did not seek or receive medical attention for the bite and no lasting illness or injury has manifested as a result of the bite. There was no indication of infection and the bite appeared to be completely healed within three days of exposure. Environmental Health and Safety was notified and they followed up with the staff member. The Office of Research Integrity and Assurance and the alternate IBC Chair were both notified.

The staff member is current on all trainings. Completed trainings include the following:

- Biosafety and Bloodborne Pathogens Training: Completed 11/14/2019
- OHSP Clearance: 1/7/2020
- Level I Basic Animal Training: 1/24/2019
- Level II Rodent Training: 1/24/2019

There was no deviation from approved containment level or conditions.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	A staff member was bitten by a transgenic mouse.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The IBC reviewed the incident and confirmed the training and experience of the staff member. No additional measures are required at this time.

The staff member is scheduling additional training for restraining mice.

Obtained via FOIA by Judicial Watch Inc.

From: Nancy Henderson
To: NIH guidelines
Cc: Debra Murphy; Hugh Mason; ibc@asu.edu; Jacobs, Bertram
Subject: Arizona State University Incident Report 05.29.2020
Date: Monday, June 15, 2020 2:58:53 PM
Attachments: Arizona State University Incident Report 05.29.2020.pdf
Importance: High

Good Afternoon,

Attached is ASU's report of an incident that occurred on May 29, 2020. If you have any questions regarding this report please don't hesitate to contact me.

Best Regards and please stay safe,
Nancy

Nancy J. Henderson| Assistant Director
Research Operations | Office of Research Integrity & Assurance
Arizona State University | Knowledge Enterprise
t 480-965-6792| mobile Redacted by agreement
Nancy.J.Henderson@asu.edu|http://researchadmin.asu.edu
How am I doing? Email my supervisor

This message may contain information that is privileged, confidential and exempt from disclosure under applicable law. Please do not copy or forward this message without permission. If you are not the intended recipient, please delete all copies and notify me immediately by reply e-mail or by telephone (480) 965-6792 so we may correct our records

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Arizona State University
Date of Report:	6/15/2020
Reporter name and position:	Nancy Henderson Assistant Director - Office of Research Integrity and Assurance Arizona State University
Telephone number:	480-965-6792
Email address:	Nancy.J.Henderson@asu.edu
Reporter mailing address:	660 S. Mill Ave, Suite 312 PO Box 876011 Tempe, AZ 85287-6111
Date of incident:	5/29/2020
Name of Principal Investigator:	Bertram Jacobs
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 11/8/2018 IBC # 19-856
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1 Risk Group 2 and 3, III-D-2 Risk Group 2, III-D-3 Risk Group 2 and 3, III-D-4 Risk Group 1, III-F-1, III-F-6, and III-F-8 Appendices C-II and C-VIII
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Vaccinia virus strain NYVAC-KC covered under IACUC protocol number 20-1746R (approval period 10/30/2019-10/29/2022)

Please provide a narrative of the incident including a timeline of events.

Obtained via FOIA by Judicial Watch Inc.

On May 29, 2020, a male staff member from the Jacobs Lab was working with mice that were infected with Vaccinia virus strain NYVAC-KC. The staff member was transferring a mouse to a clean cage and was bitten on the thumb. The gloves and skin were both penetrated and a small amount of blood was drawn. The staff member was wearing a gap wrap, face mask, shoe covers, and gloves. Following the bite, the staff member replaced the mouse, removed gloves, and disinfected his hands with virex and isopropanol. He then replaced his gloves, finished transferring the mice and immediately reported the incident to his supervisor, Dr. Bertram Jacobs. The staff member is current on DTAP and Smallpox vaccinations. He did not seek or receive medical attention for the bite and no lasting illness or injury has manifested as a result of the bite. There was no indication of infection and the bite appeared to be completely healed within three days of exposure. Environmental Health and Safety was notified and they followed up with the staff member. The Office of Research Integrity and Assurance and the alternate IBC Chair were both notified.

The staff member is current on all trainings. Completed trainings include the following:

- Biosafety and Bloodborne Pathogens Training: Completed 11/14/2019
- OHSP Clearance: 1/7/2020
- Level I Basic Animal Training: 1/24/2019
- Level II Rodent Training: 1/24/2019

There was no deviation from approved containment level or conditions.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	A staff member was bitten by a transgenic mouse.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The IBC reviewed the incident and confirmed the training and experience of the staff member. No additional measures are required at this time.

The staff member is scheduling additional training for restraining mice.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Monday, June 22, 2020 1:16 PM
To: Kasahara, Noriyuki; NIH guidelines
Cc: Zhu, Peili; Michael McGrath; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: incident report to NIH OBA

Dear Dr. Noriyuki Kasahara,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kasahara, Noriyuki <Noriyuki.Kasahara@ucsf.edu>
Sent: Wednesday, June 17, 2020 6:24 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Zhu, Peili <Peili.Zhu@ucsf.edu>; Michael McGrath <mike.mcgrath@ucsf.edu>
Subject: incident report to NIH OBA

Dear NIH Office of Biotechnology Activities staff:

I am writing to report an incident involving a graduate student researcher, Redacted by agreement who was working in the lab this past Sunday afternoon (June 14, 2020), and who accidentally injured herself with a disposable scalpel while walking toward the sharps container to dispose of it. My lab manager, Dr. Sara Collins, was also present at the time, and fortunately this was a minor stab injury, but after washing the wound, my student called Employee Health and also called me to report the incident, as there was a possible exposure risk to a retroviral vector.

As you will see from the attached incident report, our student was dissecting tumor tissues from animal studies under our approved biosafety and IACUC protocols, and was using disposable scalpels while working in a biosafety cabinet, and she reported that she had just unwrapped the last scalpel but then decided that she had enough tissue, so fortunately she actually did not use the scalpel, and was just going to dispose of it unused, when she stabbed herself going to the sharps container.

Obtained via FOIA by Judicial Watch Inc.

However, she could not recall whether she might have momentarily put down the scalpel in the biosafety cabinet, where it might have contacted a surface that might also have been in contact with tissue infected with retroviral vector. Accordingly, out of an abundance of caution, I discussed with her as well as the Employee Health clinic physician on weekend call, regarding the possible risk vs. benefit of potential genotoxicity risk from potential exposure vs. prophylactic use of anti-retroviral treatment, which of course also has known adverse effects. The physician on call also agreed that this potential exposure incident likely did not warrant anti-retroviral treatment.

In addition, since there was potential exposure to recombinant DNA / viral vectors, even if overall this appears to be a remote possibility, nonetheless we thought it would be advisable to formally report this incident, which we first reported internally to the UCSF Biosafety office and IBC the following day. Also, per guidance from Dr. Peili Zhu (Biosafety Officer, UCSF; also CC:ed on this email), we would like to report this incident to NIH OBA, and I have attached the incident report form to this email.

Of course, please do let me know if I can provide any additional information or clarification.

Many thanks, and kind regards,
Nori

Noriyuki Kasahara, M.D. Ph.D.

Alvera L. Kan Endowed Chair

Professor in Residence

Departments of Neurological Surgery and Radiation Oncology

University of California, San Francisco (UCSF)

UCSF e-mail: Noriyuki.Kasahara@ucsf.edu

Associate Medical Director

HLA Clinical Immunogenetics Laboratory

Eurofins VRL - Los Angeles Operations

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Involving Recombinant DNA to the NIH Office of Biotechnology Activities (OBA)

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. You may download this template as a Word document and the fields will expand according to the amount of text entered. Use of this template is not required and other formats may be acceptable.

A separate template for reporting Human Gene Transfer Adverse Events is available at: http://www4.od.nih.gov/oba/RAC/Adverse_Event_Template.doc)

Please note that submitting this completed template to NIH OBA does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

Attention: Incident Reports
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(For all non-USPS deliveries use Zip Code 20817)
Telephone 301-496-9838
Fax 301-496-9839
E-mail: oba@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://www4.od.nih.gov/oba/RAC/Adverse_Event_Template.doc

Does this incident involve research subject to the *NIH Guidelines*?	☐ **YES** ☐ NO If no, this incident does not have to be reported to OBA
Institution name:	University of California, San Francisco
Date of report:	6/15/2020
Reporter name and position:	Noriyuki Kasahara MD PhD, Professor, Dept of Neurological Surgery, UCSF
Reporter telephone:	(415) 514-0861
Reporter email:	Noriyuki.Kasahara@ucsf.edu
Date of incident:	June 14, 2020
Name of principal investigator:	Noriyuki Kasahara, MD PhD
Is this an NIH funded project?	☐ YES ☐ **NO**
If yes, please provide:	
What was the **nature** of incident?	☐ **Personnel exposure** ☐ Spill ☐ Loss of containment ☐ Loss of transgenic animal ☐ Failure to obtain IBC approval ☐ Failure to follow approved containment conditions ☐ Other - please describe:

Obtained via FOIA by Judicial Watch Inc.

Did the Institutional Biosafety Committee (IBC) approve this research	☐ YES ☐ NO If yes, on what date? 05/06/2020 (BU180688-01B)
If yes, please provide:	Approval date: 05/06/2020 (BU180688-01B)
	Approved biosafety level for the research: BSL-2
	Additional approval requirements:
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	☐ CDC ☐ USDA ☐ FDA ☐ EPA ☐ OSHA ☐ Research Funding Agency/Sponsor: (name)_____ ☐ State/Local Public Health ☐ Federal/State/Local Law Enforcement ☐ Other – please describe:

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident.

The incident occurred while a graduate student researcher was in the process of disposing an unused disposable scalpel into a sharps container. The student researcher had been dissecting mouse brain tumor tissues from a gene therapy experiment, which included tumors infected with a retroviral replicating vector (RRV) expressing a prodrug activator ('suicide') gene, using disposable scalpels. This procedure was being performed inside a biosafety cabinet in a BSL-2 lab under the supervision of the lab manager, a Ph.D. scientist with >15 years experience using viral vectors. The student was wearing a single pair of gloves and a lab coat at the time. While dissecting the last tumor in a biosafety cabinet, the student unwrapped a new disposable scalpel, then apparently decided that she did not need any additional tissue and was going to dispose of the

Obtained via FOIA by Judicial Watch Inc.

scalpel without actually using it, but accidentally stabbed herself in the arm while walking over to the sharps container. The student stated that she definitely did not use the scalpel for dissection, but could not recall whether she might have momentarily put it down on a surface of the biosafety cabinet that might have been in contact with RRV-infected brain tissue specimens. As soon as she injured herself, student disposed of the scalpel in the sharps container, then with the assistance of the lab manager, she removed her lab coat, washed the wound copiously with running water for several minutes and placed a bandage on it to stop bleeding. The student and lab manager contacted the Employee Health clinic, and as this incident occurred during the weekend, she was referred for a telephone consultation with the after-hours physician on call for the Employee Health clinic.

The student then contacted the supervisor (Principal Investigator) of the laboratory in which this work was being conducted. Upon discussion, as the employee had just unwrapped a sterile disposable scalpel and this was actually unused, the likelihood of any biosafety risk from exposure to RRV was considered to be low. The only potential infection risk might have been if she had placed the unused scalpel momentarily on the work surface of the biosafety cabinet, which might have been in contact with infected tumor tissue, but she did not recall doing this, and in any case this would be indirect transfer of an extremely low infectious dose of virus.

RRV, such as Toca 511 (originally developed in the PI's lab, and translated to clinical trials by Tocagen Inc.) have been evaluated in Phase I through Phase III human clinical trials for recurrent high-grade glioma via injection into post-resection tumor cavity walls (clinicaltrials.gov NCT01156584, NCT01470794, NCT02414165), as well as Phase I trials for recurrent high-grade glioma as well as colorectal and pancreatic cancer via systemic intravenous injection (NCT01985256, NCT02576665), and this vector platform has shown a highly favorable safety profile without evidence of replication in normal tissues in all human clinical trials to date.

The employee was counseled regarding the risk vs. benefit of potential genotoxicity from this potential exposure event vs. known adverse effects of prophylactic treatment with antiretroviral drugs, and the Occupational Health physician on call agreed that the risk was small and unlikely to warrant post-exposure prophylaxis. The supervisor contacted the Biosafety Office via email on the day after the incident (June 15, 2020), and also notified the UCSF HR Disability Management Services office via email to file a Supervisor Incident Report documenting this incident. The student researcher is up-to-date on all biosafety trainings, including fundamental lab safety, biological safety, bloodborne pathogen, waste management.

Has the IBC reviewed this incident?	☐ YES ☐ **NO** If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.

Obtained via FOIA by Judicial Watch Inc.

Has a root cause for this incident been identified?	☐ **YES** ☐ NO If yes please describe: **Lack of a sharps container in immediate proximity**

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)

- In lab meeting the following day (June 15, 2020), we discussed the need to conduct lab-specific safety training on a regular basis to keep lab staff as up-to-date as possible in terms of emergency response procedures and incident reporting procedures.
- Lab discussion included refresher education on the exact procedures to follow in the event of a minor penetrating injury caused by sharps, including scalpel and needle stick injuries. These include exposing the skin around the puncture site (i.e., removing gloves or other PPE if the needle stick occurred at another site on the body), expressing the wound (applying pressure to push blood and possible infectious material out of the puncture site), and then flushing the area for at least 5 minutes. This will help to minimize the amount of any agent that might actually enter the bloodstream.
- Also discussed was the incident reporting structure, noting that the UCSF Biosafety Office and NIH will need to be notified within 24 hours of an incident occurring that involves recombinant DNA.
- Further preventative measures will be implemented, including making it a lab policy to place sharps containers in immediate proximity of any work being conducted using sharps (e.g. inside the biosafety cabinet).

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kasahara, Noriyuki <Noriyuki.Kasahara@ucsf.edu>
Sent: Wednesday, June 17, 2020 6:24 AM
To: NIH guidelines
Cc: Zhu, Peili; Michael McGrath
Subject: incident report to NIH OBA
Attachments: Montoya - Kasahara lab_NIH OBA Report.doc

Dear NIH Office of Biotechnology Activities staff:

I am writing to report an incident involving a graduate student researcher, Redacted by agreement who was working in the lab this past Sunday afternoon (June 14, 2020), and who accidentally injured herself with a disposable scalpel while walking toward the sharps container to dispose of it. My lab manager, Dr. Sara Collins, was also present at the time, and fortunately this was a minor stab injury, but after washing the wound, my student called Employee Health and also called me to report the incident, as there was a possible exposure risk to a retroviral vector.

As you will see from the attached incident report, our student was dissecting tumor tissues from animal studies under our approved biosafety and IACUC protocols, and was using disposable scalpels while working in a biosafety cabinet, and she reported that she had just unwrapped the last scalpel but then decided that she had enough tissue, so fortunately she actually did not use the scalpel, and was just going to dispose of it unused, when she stabbed herself going to the sharps container.

However, she could not recall whether she might have momentarily put down the scalpel in the biosafety cabinet, where it might have contacted a surface that might also have been in contact with tissue infected with retroviral vector. Accordingly, out of an abundance of caution, I discussed with her as well as the Employee Health clinic physician on weekend call, regarding the possible risk vs. benefit of potential genotoxicity risk from potential exposure vs. prophylactic use of anti-retroviral treatment, which of course also has known adverse effects. The physician on call also agreed that this potential exposure incident likely did not warrant anti-retroviral treatment.

In addition, since there was potential exposure to recombinant DNA / viral vectors, even if overall this appears to be a remote possibility, nonetheless we thought it would be advisable to formally report this incident, which we first reported internally to the UCSF Biosafety office and IBC the following day. Also, per guidance from Dr. Peili Zhu (Biosafety Officer, UCSF; also CC:ed on this email), we would like to report this incident to NIH OBA, and I have attached the incident report form to this email.

Of course, please do let me know if I can provide any additional information or clarification.

Many thanks, and kind regards,
Nori

Noriyuki Kasahara, M.D. Ph.D.
Alvera L. Kan Endowed Chair
Professor in Residence
Departments of Neurological Surgery and Radiation Oncology

Obtained via FOIA by Judicial Watch Inc.

University of California, San Francisco (UCSF)
UCSF e-mail: Noriyuki.Kasahara@ucsf.edu

Associate Medical Director
HLA Clinical Immunogenetics Laboratory
Eurofins VRL - Los Angeles Operations

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, August 13, 2020 12:55 PM
To: Rausch, Tamara (Tammy); NIH guidelines
Cc: Waggoner, Stephen; Gulick, James; Corsmo, Jeremy; Dowdy, Tabitha; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: July 2, 2020 Incident at CCHMC VPF

Dear Tamara Rausch,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Tuesday, July 21, 2020 4:06 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Waggoner, Stephen <Stephen.Waggoner@cchmc.org>; Gulick, James <James.Gulick@cchmc.org>; Corsmo, Jeremy <Jeremy.Corsmo@cchmc.org>; Dowdy, Tabitha <Tabitha.Dowdy@cchmc.org>
Subject: July 2, 2020 Incident at CCHMC VPF

Good afternoon,

Attached is the final report of the spill that that was reported to you by e-mail on 7/2/2020.

Please feel free to contact me with any questions.

Sincerely,

Tammy

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Obtained via FOIA by Judicial Watch Inc.

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229
Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Tuesday, July 21, 2020 4:06 PM
To: NIH guidelines
Cc: Waggoner, Stephen; Gulick, James; Corsmo, Jeremy; Dowdy, Tabitha
Subject: July 2, 2020 Incident at CCHMC VPF
Attachments: NIH Incident Report July 2_2020.pdf

Good afternoon,

Attached is the final report of the spill that that was reported to you by e-mail on 7/2/2020.

Please feel free to contact me with any questions.

Sincerely,

Tammy

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229
Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	✓YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Cincinnati Children's
Date of Report:	July 21, 2020
Reporter name and position:	Tamara Rausch, Biosafety Officer
Telephone number:	513.636.4843
Email address:	tamara.rausch@cchmc.org
Reporter mailing address:	240 Albert Sabin Way MLC 70 Cincinnati, OH 45229
Date of incident:	July 2, 2020
Name of Principal Investigator:	Carolyn Lutzko, PhD
Is this an NIH-funded project?	☐YES ✓NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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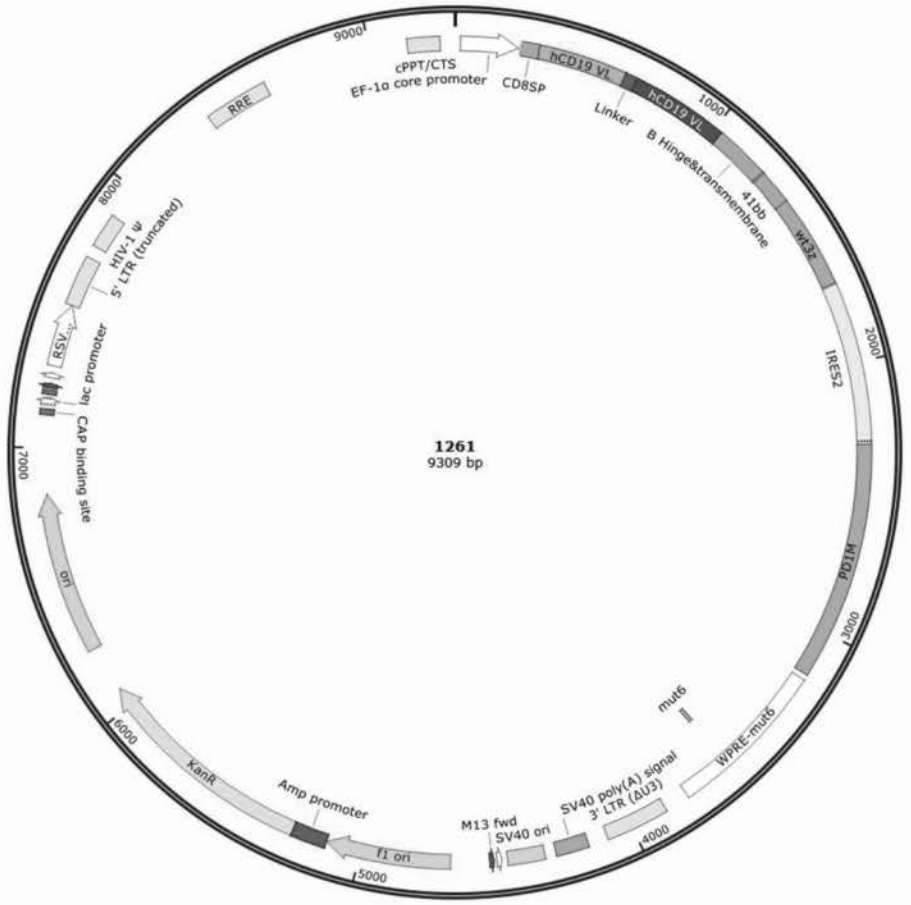
What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ✓ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	✓ YES ☐ NO If yes, date of approval: IBC2017-0046 7/11/2017 IBC2020-0040 7/14/2020
What was the approved biosafety level of the research?	☐ BL1 ✓ BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-2 III-D-3 III-D-6 III-E
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ✓ Other (please describe): ☐ OSHA Sponsor of the clinical research
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The material involved in the incident was a lentiviral vector to be used for a Chimeric antigen receptor immunotherapy to treat cancer. The expression gene is Anti-CD19 CAR bicistronic with a dominant negative PD-1 gene in the second position. The two transgenes are separated by a 2A peptide. The map is included in the report.

Obtained via FOIA by Judicial Watch Inc.



Obtained via FOIA by Judicial Watch Inc.

Figure 3: 1261 (9309 bp) Nucleotide Sequence (FASTA format, 80 bp per line)

CGGCTCCGGTGCCCGTCAGTGGGCAGAGCGCACATCGCCCACAGTCCCCGAGAAGTTGGGGGGAGGGGTCGGCAATTGAA
CCGGTGCCTAGAGAAGGTGGCGCGGGGTAAACTGGGAAAGTGATGTCGTGTACTGGCTCCGCCTTTTTCCCGAGGGTGGG
GGAGAACCGTATATAAGTGCAGTAGTCGCCGTGAACGTTCTTTTTCGCAACGGGTTTGCCGCCAGAACACAGGATCCGCC
ACCATGGCCTTACCAGTGACCGCCTTGCTCCTGCCGCTGGCCTTGCTGCTCCACGCCGCCAGGCCGGATATCCAGATGAC
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GAAGAACTTAGATCATTATATAATACAGTAGCAACCCTCTATTGTGTGCATCAAAGGATAGAGATAAAAGACACCAAGGA
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AATCCACTTTGGCTCGAGAAGCTTGATAT

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space): The incident occurred in an approved BSL 2 ISO 7 cleanroom [Redacted by agreement] in the Vector Production Facility (VPF) on 7/2/2020.

- Who was involved in the incident/violation, including others present at the incident location? The following were present during the incident: VPF Manager, Research Assistant, two GxP Specialists (GxP Specialist #1, GxP Specialist #2).

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event: The pump was immediately stopped, the outlet tubing line clamped just below the filter and the situation assessed. Material was slowly leaking from a weld seam on the labtainer. A picture and short video was taken. GxP Specialist #2 tried to stop the leak by clamping the weld seam adjacent to the tubing, but the hemostat was not large enough. This caused some tearing of the labtainer where the hemostat was clamped. Because the labtainer was so large and lying flat, the leak was not apparent until there was sufficient pressure on the weld seam from the labtainer filling up. At most, 50 mL leaked out of the bag onto the cart and onto the floor. The spill was contained. It was absorbed with dry cleanroom wipes and the floor area under BSC 1578 was cleaned with LpH disinfectant

- The training received by the individual(s) involved and the date(s) the training was conducted:

Personnel	Biosafety Training	SOP AL-04-10. 13Cleanroom Cleaning 'Read & Understand' Training	Cleanroom Cleaning Technical Training	SOP AL-04-02.05 Biohazardous Waste 'Read & Understand' Training
VPF Manager	1/20/2016	12/27/2019	1/20/2016	12/27/2019
GxP Specialist #1	2/22/2019	12/23/2019	5/7/2019	12/19/2019
GxP Specialist #2	1/11/2018	12/18/2019	7/10/2017	12/18/2019
Research Assistant	2/14/2020	2/5/2020	2/28/2020	2/5/2020

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- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation: There were no deviations from the institutional or laboratory SOPs at the time of the incident.

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation: There were no deviations from the approved IBC containment level or other IBC approval conditions.

- The personal protective equipment in use at the time of the incident/violation: All personnel were wearing full cleanroom suits, including full zip-up coverall, high-top boots, hood, mask and splash eye protection (goggles or full-face shield), two pairs of gloves and Tyvek arm sleeves.

- The occupational health requirements for laboratory personnel involved in the research: Personnel working with human derived materials are required to receive the Hepatitis B vaccine. Record of the vaccines are to be kept on file in the employees' medical record files

- Any medical surveillance provided or recommended after the incident: Medical surveillance was not required after the incident.

- Any injury or illness associated with the incident: There were no injuries or illnesses associated with the incident.

- Equipment failures: There were no equipment failures.

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On 02JUL2020 in suite Redacted by agreement VPF Personnel GxP Specialist #2 & Research Assistant were executing section 10.0 of bpr V022.003 (Harvest #2) in BSC #1908 and the l VPF Manager and GxP Specialist #1 were executing section 12.0 of bpr V022.003 (Opticap filtration) in BSC #1578. Open manipulations were performed inside of biosafety cabinets inside of an ISO 7 cleanroom. All personnel were wearing full cleanroom suits, including a full zip-up coverall, high-top boots, hood, mask and splash eye protection (goggles or full-face shield), two pairs of gloves and Tyvek arm sleeves.

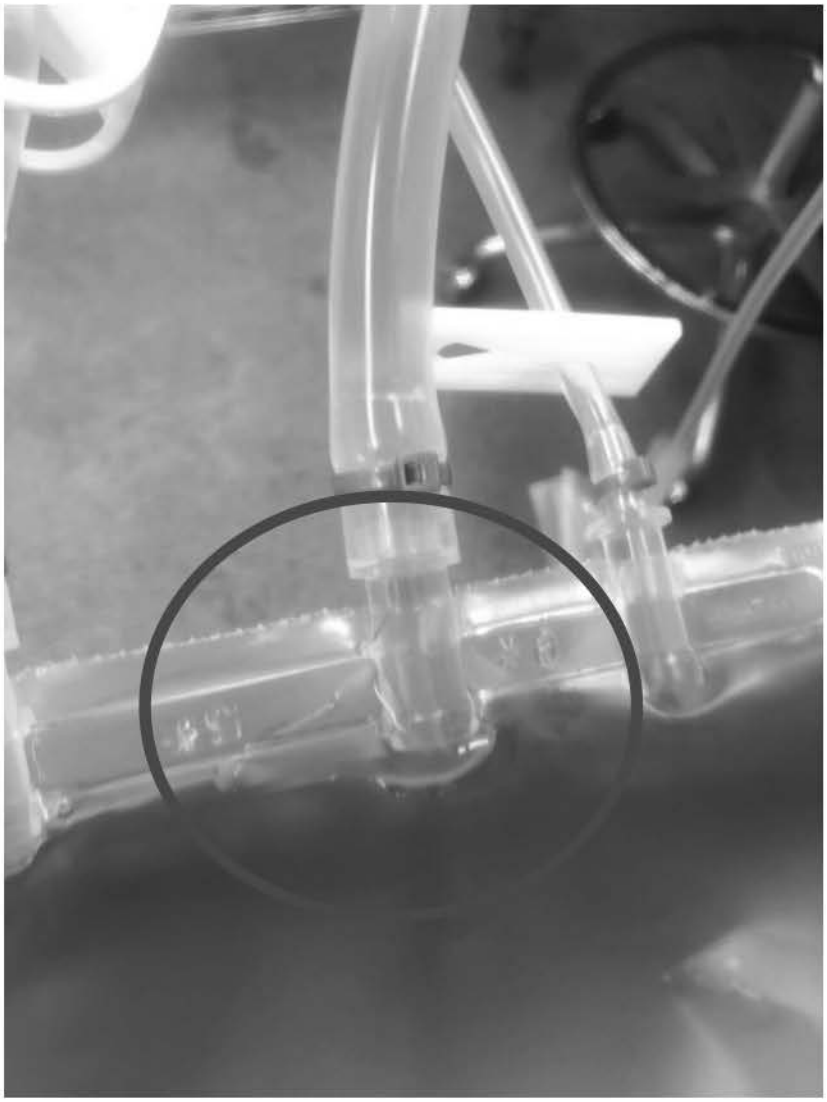
The spill was associated with the operations occurring in BSC 1578. Filtration using a 0.45 um closed filter assembly was running in the BSC. The second of four 20L labtainers containing unconcentrated vector supernatant was the supply bag to the filter assembly. This bag was outside of the BSC, but the quick connect tubing connection was located inside the BSC. There was a 50L labtainer collecting the filtered product lying flat on a solid-top cart to the right of the BSC in which the Opticap filtration assembly was located. The operations are under surveillance by the filtration team to ensure there are no pressure issues and no leaks. Bag #2 was started at 9:03 am and at approximately 9:15 am; The VPF Manager looked down on the floor in front of the BSC and saw some liquid that seemed to have color to it (as opposed to maybe 70% critical alcohol overspray). The VPF Manager placed a dry wipe on the spot, saw it had color, then looked at the 50L labtainer, and saw that liquid was pooling at the welded tubing port seam and dripping onto the floor.

The pump was immediately stopped, the outlet tubing line clamped just below the filter and the situation assessed. Material was slowly leaking from a weld seam on the labtainer. A picture and short video was taken. GxP Specialist #2 tried to stop the leak by clamping the weld seam adjacent to the tubing, but the hemostat was not large enough. This caused some tearing of the labtainer where the hemostat was clamped. Because the labtainer was so large and lying flat, the leak was not apparent until there was sufficient pressure on the weld seam from the labtainer filling up. At most, 50 mL leaked out of the bag onto the cart and onto the floor. The spill was contained. It was absorbed with dry cleanroom wipes and the floor area under BSC 1578 was cleaned with LpH disinfectant.

The VPF Director and Biosafety Officer were notified. The Opticap team was directed to remove the compromised bag and continue with the processing. The outlet tubing line was emptied from where it was clamped and a new 50L labtainer (different manufacturer's lot number) was connected. The remainder of the Harvest #1 – Bag 2 post-LRF material was filtered (approximately 3 liters) and the full 30L of Harvest #2 was processed and collected in the second 50L labtainer.

Obtained via FOIA by Judicial Watch Inc.

Weld Seam Leak



Obtained via FOIA by Judicial Watch Inc.

Remediation – GxP Specialist #1 cleaned the floor under BSC 1578 where the spill occurred with prepared disinfectant prior to continuing to process. Due to contractor activity scheduled, the room, as a whole [Redacted by agreement] was cleaned at the end of V022.003 operations as outlined in the SOP for Cleanroom Cleaning (AL-04-10) following the post-production cleaning regimen. The 50L labtainer containing approximately 27 liters of vector supernatant was double-bagged using the large biohazard bags, positioned so that the compromised seam was not under pressure and removed from the cleanroom facility using a cart. The 50L labtainer was moved to lab [Redacted by agreement] and treated with bleach according to the CCHMC biosafety protocol for treatment of biohazardous waste.

The VPF Manager called institutional safety hotline,803-SAFE, to report the incident. There were no personnel exposures.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	✓YES ☐NO The incident was discussed and reviewed at the July 14, 2020 IBC meeting.
Please describe the root cause of this incident:	The root cause of the incident was a defective labtainer.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The remaining labtainers with the same lot number were taken out of service and tagged as "Rejected". In addition, a customer complaint was initiated with the labtainer manufacturer on 7/15/2020.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
Sent: Thursday, July 2, 2020 3:21 PM
To: NIH guidelines
Cc: Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Corsmo, Jeremy
Subject: Notification of Incident at CCHMC 7/2/2020

Good afternoon,

I am notifying you as required by the NIH Guidelines of a spill that occurred at the Cincinnati Children's Viral Vector Production Facility this morning. During opticap, one of the technicians observed a leak in the post-filter collection bag after most of the product had gone through. The product contained a lentiviral vector. Less than 10 mL spilled onto the floor. The manager was in the room and notified the VVP Director. The technicians cleaned up the spill per their departmental standard operating procedure.

I am currently in investigating the incident. A formal report will be submitted upon completion.

Please feel free to contact me with any questions.

Best regards,

Tammy

Tamara B. Rausch, SLS(ASCP)CM
Biosafety Officer
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
240 Albert Sabin Way, MLC 7040, Cincinnati, OH 45229
Phone: 513.636.4843
Fax: 513.636.3959 **Pager:** Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, July 29, 2020 2:31 PM
To: Coulson, Garry Brian; NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident Report - Preliminary

Dear Dr. Garry Coulson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Wednesday, July 1, 2020 3:25 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: RE: NIH Incident Report - Preliminary

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a potential exposure involving recombinant DNA that occurred in an ABSL-1 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599

Obtained via FOIA by Judicial Watch Inc.

Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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From: Coulson, Garry Brian
Sent: Monday, June 29, 2020 5:44 PM
To: NIH guidelines <NIHGuidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of an exposure to recombinant DNA involving a worker in an ABSL-1 laboratory. Our initial investigation indicates a researcher received a needlestick from a from a syringe containing a recombinant murine breast cancer cell line expressing GFP/luciferase used to inoculate C57/Bl6 mice.

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of North Carolina at Chapel Hill
Date of Report:	07/01/2020
Reporter name and position:	Garry Coulson, Biosafety Officer
Telephone number:	919.962.5722
Email address:	garry.coulson@ehs.unc.edu
Reporter mailing address:	Environment, Health and Safety 1120 Estes drive Campus Box 1650 Chapel Hill, NC 27599
Date of incident:	06/26/2020
Name of Principal Investigator:	Dr. Stephen Hursting
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* CA197627 *NIH funding institute or center:* NCI *NIH program officer (name, email address):* Phil Daschner daschnep@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 10/4/2018
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	E0771 murine breast cancer cells transfected with a pRetroX-Tight-Pur vector expressing GFP/luciferase. pRetroX-Tight-Pur is an inducible, self-inactivating (SIN) retroviral expression vector.

Obtained via FOIA by Judicial Watch Inc.

Description of the incident:

At approximately 12:30 pm on Friday, June 26, 2020 a Surgical Technician was being assisted by a coworker in injecting recombinant mouse cells (E0771 murine breast cancer cells transfected with a pRetroX-Tight-Pur vector that contains GFP/luciferase) in the tails of C57BL/6 mice within a ventilated change hood in a ABSL-1 space when the incident occurred.. The Technician finished using a Tuberculin syringe used to inject the recombinant cells into a mouse and attempted to discard the used syringe into the sharps container. As they were discarding the syringe into the container, they averted their eyes to another task, so did not see if the syringe bounced out of the container, or if they had actually missed the container opening while attempting to dispose of the syringe in the sharps container. The consequence was that the syringe fell from the sharps container and pricked their right thumb. At the time of the incident, the Technician was wearing the required personal protective equipment (PPE), including a surgical gown, a pair of nitrile gloves, safety glasses, and a surgical mask.

When the incident occurred, the Technician went to the closest sink in the adjacent procedure room, removed their gloves and examined their wound. Blood was observed at the wound site. The Technician rinsed the wound with soap and water for approximately five minutes. They also performed a leak test on their glove and verified that the needle had punctured their glove. The Technician covered their wound with a paper towel, put on fresh gloves, and finished their task in the animal facility. When they finished their task, they exited their facility and went to their Supervisor's office to report the incident.

The Technician then sought medical attention at the University Employee Occupational Health Clinic (UEOHC) where the wound was examined and necessary care provided.

Since the self-inactivating vector used to transduce the murine cells used in these experiments lacks the structural genes (gag, pol and env) necessary for particle formation and replication, the vector is considered replication-incompetent. Therefore, exposure to cells modified with this vector, in the absence the missing genes, is considered a low-risk for exposure to infectious material.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC is aware of the incident and will review it at the 7/1/2020 IBC meeting
Please describe the root cause of this incident:	The root cause of the incident appears to be related to Surgical Technician not paying attention while they were disposing of the Tuberculin syringe into the sharps container.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As part of the corrective and preventative actions to be taken, an internal Incident Report will be submitted from the Department of Environment, Health and Safety (EHS) to the Principal Investigator (PI) and the Manager of the Animal Studies Core detailing the incident and including recommendations to mitigate future reoccurrence of the incident.

While the Technician was performing all duties according to established laboratory procedure and was wearing all required PPE, as part of our Incident Report, we will recommend that the Animal Studies Core Manager review the incident with their group, and discuss the importance of sharps safety. As part of the discussion, the group should review an internal safety PDF on “Preventing Cuts and Punctures”. While working with biohazardous materials, particularly with sharps, it’s critical that personnel remain focused on the task at hand and ensure that sharps are disposed of safely before moving onto subsequent tasks.

It will also be discussed with the PI that approval of the research involving modification of murine cells with the retroviral vector, and subsequent injection into mice was approved at BSL-2 containment. A PI may not change the containment level approved by the IBC without prior review and approval by the IBC.

Furthermore, while not directly related to preventing the reoccurrence of the incident, our recommendations to the Animal Studies Core Manager will also include the need for discussions with their group about the appropriate steps to take when exposure incident occurs, emphasizing the need to immediately cease working and seek medical care at the University Employee Occupational Health Clinic (UEOHC).

The expected date of completion for recommendations will be 7/20/2020.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Wednesday, July 1, 2020 3:25 PM
To: NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.
Subject: RE: NIH Incident Report - Preliminary
Attachments: NIH_Incident_Report_07012020.pdf

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a potential exposure involving recombinant DNA that occurred in an ABSL-1 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Sent: Monday, June 29, 2020 5:44 PM
To: NIH guidelines <NIHGuidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of an exposure to recombinant DNA involving a worker in an ABSL-1 laboratory. Our initial investigation indicates a researcher received a needlestick from a from a syringe containing a recombinant murine breast cancer cell line expressing GFP/luciferase used to inoculate C57/Bl6 mice.

Obtained via FOIA by Judicial Watch Inc.

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Monday, June 29, 2020 5:44 PM
To: NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.
Subject: NIH Incident Report - Preliminary

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We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

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Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, July 29, 2020 2:22 PM
To: Melvin, Denise M; NIH guidelines
Cc: Clayton, April; IBC; Harrison, Shatira M; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident report - recombinant mouse release

Dear Denise Melvin,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Melvin, Denise M <MELVIND@email.chop.edu>
Sent: Wednesday, July 1, 2020 2:12 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Melvin, Denise M <MELVIND@email.chop.edu>; Clayton, April <CLAYTONA@EMAIL.CHOP.EDU>; IBC <IBC@email.chop.edu>; Harrison, Shatira M <HARRISONSM@EMAIL.CHOP.EDU>
Subject: NIH Incident report - recombinant mouse release

Good Afternoon,

Please find attached an incident report detailing the accidental release of recombinant mice at our research facility.

Should you have any questions, please feel free to contact me.

Sincerely,
Denise

Denise M. Melvin, MSM, RBP
Redacted by agreement
Director, Research Safety Programs
Institutional Biosafety Officer, IBC Manager

Abramson Research Center (ARC)
1st Floor Administration Suite, Office #144
O 267-426-7597 - C [redacted] F 267-426-7219
melvind@email.chop.edu

Obtained via FOIA by Judicial Watch Inc.



Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO 2 IBC protocols
Institution Name:	Children's Hospital of Philadelphia Research Institute
Date of Report:	7/1/2020
Reporter name and position:	Denise M. Melvin Director, Research Safety Programs / Institutional Biosafety Officer
Telephone number:	267-426-7597
Email address:	melvind@email.chop.edu
Reporter mailing address:	3615 Civic Center Blvd Abramson Research Center, Office 144 Philadelphia, PA 19104
Date of incident:	6/19/2020, 6/22/2020, 6/23/2020
Name of Principal Investigator:	Craig Bassing, Ph.D. (IBC 2013-09-002) Adele Harman (IBC 2008-07-004)
Is this an NIH-funded project?	☒YES ☐NO There are four separate grants tied to the research. This only applies to IBC 2013-09-002 (Bassing). IBC 2008-07-004 (Harman) in internally funded. *NIH grant of contract number:* 5R01AI112621-05 *NIH funding institute or center:* National Institute of Allergy and Infectious Diseases

Obtained via FOIA by Judicial Watch Inc.

	NIH program officer (name, email address): Qian Liu, liujoy@mail.nih.gov, 301-761-6621 *NIH grant of contract number:* 5R01AI130231-03 *NIH funding institute or center:* National Institute of Allergy and Infectious Diseases *NIH program officer (name, email address):* Mercy R. Prabhudas, mprabhudas@niaid.nih.gov, 301 496 7551 *NIH grant of contract number:* 5R21A135435-02 *NIH funding institute or center:* National Institute of Allergy and Infectious Diseases *NIH program officer (name, email address):* Qian Liu, liujoy@mail.nih.gov, 301-761-6621 *NIH grant of contract number:* 1R01A143661-01A1 *NIH funding institute or center:* National Institute of Allergy and Infectious Diseases *NIH program officer (name, email address):* David R. Johnson, drjohnson@niaid.nih.gov, 301-627-3499

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☒Loss of a transgenic animal (3) ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: Initial approval date for Bassing 9/18/2013 Initial approval date for Harman 7/28/2008

Obtained via FOIA by Judicial Watch Inc.

What was the approved biosafety level of the research?	☒BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-4-a, III-E-1 for Bassing (BSL-1 and BSL-2) III-E-3 for Harman (BSL-1)
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Mouse line that has a Neomycin resistance gene inserted into the Rag1 locus (purchased from Jackson Labs) and then used CRISPR to delete three CTCF binding elements from the Tcrb locus.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event

Obtained via FOIA by Judicial Watch Inc.

- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On 6/19/2020, 6/22/2020, and 6/23/2020, the Office of Research Safety (ORS) was notified that research mice with ear tags were found on the 4th floor, Colket Translational Research Building (CTRB).

- On 6/19 the notification came from the Department of Veterinary Resources (DVR) after a lab staff member notified them. It was a young black female mouse with ear tag #0717 and was found in lab area Redacted by agreement
- On 6/22, Environmental Services notified ORS via page that they had trapped a mouse under a trash can in CTRB Redacted by agreemen This was another black, young female mouse with ear tag # 0719.
- On 6/23, a black young female mouse with ear tag # 0714 was also found in the 4th floor lab area. ORS was notified by the IACUC who was notified by DVR.

Immediately after the first notification, ORS/IBC, DVR and the IACUC began their investigation into who the mice might belong to as well as sent out numerous communications to

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Investigators who both had approval to transport mice to their lab and to those didn't in the event someone was transporting without approval. IACUC was also able to target Investigators who had approval to use ear tags and who were located on the 4th floor, CTRB. After communications were sent, the mice were identified to be part the Bassing lab, who had IBC approval (IBC 2013-09-002) for the creation of the mice and who provided the construct to the Transgenic Core covered under Adele Harman's IBC protocol (IBC 2008-07-004) utilizing CRISPR techniques.

The lab's technician sent a detailed email explaining what she thought may have occurred after discovering the mice belonged to her lab (names have been removed):

> *In response to today's emails, I have gone through my records and believe that there is a high probability that these three mice would be genetically modified strain (TKO:Rag1-/-) of C57BL/6 mice from my colony. I have generated a large number of these animals for my experiments that require I pool thymocytes from several mice for molecular analyses of the TCRbeta locus. Last week, I brought up many more mice than I typically do because I wanted to conduct many different analyses, and was working on the evening shift and did not want to go back to the mouse room after 8 pm to collect more mice. I had four litters of TKO:Rag1-/- mice that I had tagged (including the numbers of the animals found - 714, 717, or 719). I brought up many of these mice including a few potential extra mice so I would get enough cells for my analyses. Of the remaining mice, I weaned some for breeding and euthanized a few I wouldn't need. Of the ones I brought up to lab, I euthanized a few mice at a time so cells would not die as I dissected the mice and processed cells, and when I had enough cells for what I needed, I euthanized the rest of mice. I did not note the tag numbers of these extra mice, nor of the mice I euthanized last week on C level. However, I didn't note that 714, 717, or 719 were ones that I used in my experiments, and I just checked this afternoon and these numbers are not in the cage of weaned mice, so it is possible that these got out while I was dissecting the others. I didn't notice any chewed holes, but maybe they slipped out through the top holes as they were on the bench behind me while I was working and moving about the lab processing cells, and no one else was present in the lab that might have seen escaped mice. They have the following genetic modifications: a neomycin resistance rDNA KO'd into the Rag1 gene as made nearly 30 years ago and we purchase from Jackson Labs; and deletion of three different CTCF binding sites within the TCRb locus, which I made with the CHOP Transgenic Core by giving them guide RNAs and they mixing with Cas9 protein, deleting less than 100 bp for each deletion and not introducing any rDNA. If the carcasses or tissue from these mice is available, I am happy to isolate DNA and genotype for these mutations to determine if they were my mice.*
>
> *I just spoke with my PI about this. We talked about ways to ensure that this does not happen again and keep better records to facilitate more rapid identification if mice escape. These include bringing up smaller batches of mice in the future, making sure I record the ear tag numbers and total numbers of mice I bring up and confirm I euthanize the same, and putting transport containers into a larger plastic container with lid on so mice have sufficient air and can't escape during the hour I am euthanizing and processing samples for big experiments.*
>
> *My PI also asked me to inform you all that he would like to invite the IACUC, DVR, and/or PAM groups to attend our virtual lab meeting to go over policies and best practices, as this worked well last summer to help us reduce the numbers of overcrowded cages we had by adopting new practices (software) of tracking cages and animals. Regardless, I am happy to myself meet with these entities to answer any questions and discuss how to avoid escaped animals in the future.*
>
> *I am sorry I did not look into this issue last week, but I did not think I could have lost any mice. But, in investigating this and typing this email, I now realize that it's very likely they are mine, and I need to be more careful moving forward. I take full responsibility for my actions and mistakes.*

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The lab's technician and PI offered to genotype the mice. At the time, only one mouse was available as the other two had already been properly disposed by DVR. Results of the genotyping confirmed that one of the mice was the TKO:Rag1-/- genotype that was previously described. Since all ear tag #'s were identified as used by the technician, we assume the other two mice were also from their colony and would have genotyped the same.

There was no deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident, and the lab has IACUC authorization to transport mice to their lab.

The IACUC office met with the technician one-on-one on 6/29/2020 for retraining and incident review. A routine post approval monitoring (PAM) session will occur with the PI on July 7th. A meeting with the entire lab will occur on July 8th.

There were no deviations to any PPE worn at the time, nor were there any outstanding occupational health requirements or medical surveillance that were not met at the time of this incident.

No injuries were sustained as a result of the event.

There were no equipment failures noted, however it seems that the transport container used for these younger mice may need to be evaluated. If the mice did escape through the air holes as suspected, ORS recommends that the IACUC and DVR evaluate whether these containers are suitable for the transport of young (smaller) mice. DVR will evaluate the containers based on the age and size of the mice and report back on their findings.

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Has the IBC reviewed this incident?	☐YES ☒NO Will be discussed at the IBC meeting on 7/28/2020.
Please describe the root cause of this incident:	It is likely that this incident occurred as a result of having too many mice in the lab at one time in order to limit the amount of trips back and forth to the animal facility. Improper tracking of mice may have also led to lack of awareness regarding the animals that were already analyzed versus animals that were still remaining for analysis. Additionally, a potential issue with the transport container could have led to the escape of the mice. This has not yet been confirmed, and DVR is looking into whether this is a possibility. If so, we will look for alternative containers suitable for transport of younger (smaller) mice.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The IACUC office met with the technician one-on-one on 6/29/2020 for retraining and incident review. A routine post approval monitoring (PAM) session will occur with the PI on July 7th. A meeting with the entire lab to review transport practices along with other precautionary practices that can be performed will occur on July 8th.

If potential container issues are found, ORS will work with DVR to find suitable containers for younger (smaller) populations of mice. Communications will also be sent reminding staff to attend to containers at all times.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Melvin, Denise M <MELVIND@email.chop.edu>
Sent: Wednesday, July 1, 2020 2:12 PM
To: NIH guidelines
Cc: Melvin, Denise M; Clayton, April; IBC; Harrison, Shatira M
Subject: NIH Incident report - recombinant mouse release
Attachments: Incident Report Bassing-Harman 07012020.pdf

Good Afternoon,

Please find attached an incident report detailing the accidental release of recombinant mice at our research facility.

Should you have any questions, please feel free to contact me.

Sincerely,
Denise

Denise M. Melvin, MSM, RBP
Director, Research Safety Programs
Institutional Biosafety Officer, IBC Manager

Abramson Research Center (ARC)
1st Floor Administration Suite, Office #144
O 267-426-7597 · C [redacted] F 267-426-7219
melvind@email.chop.edu

Redacted by agreement

Please Report Compliance Concerns:
All reports are anonymous. Please call 1-866-246-7456 or visit www.mycompliancereport.com (use "CHOP" as the access ID)

Children's Hospital of Philadelphia
RESEARCH INSTITUTE

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, July 29, 2020 3:09 PM
To: Smith, David (RED+F-Facility Mgt-EHS); NIH guidelines
Cc: # biosafety; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report involving recombinant nucleic acid molecules

Dear Dr. David Smith,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Smith, David (RED+F-Facility Mgt-EHS) <David.Smith3@nyulangone.org>
Sent: Wednesday, July 8, 2020 3:14 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: # biosafety <biosafety@nyulangone.org>
Subject: Incident Report involving recombinant nucleic acid molecules

Hello,

Please see the attached report, and let me know if there are any questions.

Thank you,

David
David E. Smith, PhD, ASP
Environmental Health and Safety
Real Estate Development and Facilities
NYU Langone Health
545 First Avenue, GBH, C-117
New York, NY 10016
David.Smith3@nyulangone.org
biosafety@nyulangone.org

T 212-263-5159

Obtained via FOIA by Judicial Watch Inc.

M Redacted by agreement

NYU Langone Health

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	NYU Langone Health
Date of Report:	June 30, 2020
Reporter name and position:	David E. Smith Institutional Biosafety Officer
Telephone number:	212 263 5159
Email address:	David.Smith3@nyulangone.org
Reporter mailing address:	545 1st Avenue New York, NY 10016
Date of incident:	June 29, 2020
Address of Incident:	430 East 29th St Alexandria Center for Life Science West Tower – Room 324 New York, NY 10016
Name of Principal Investigator:	Dr. Bo Shopsin
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known)

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	Grant: NIH 1 R01 AI137336-01A1

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: February 13, 2020
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-d-1-a
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation,	Selected virulence regulators of Staphylococcus Aureus transformed into the Methicillin Resistant Staphylococcus Aureus (MRSA) clinical isolates CC5 and CC8.

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etc.)	
Has the IBC reviewed this incident?	☐YES ☒NO IBC has been informed and this report will be presented at the July 2020 IBC meeting
Please describe the root cause of this incident:	Accidental Needlestick due to placing used syringes/needles on the benchtop after use instead of immediate disposal into sharps container.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation

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- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Redacted by agreement

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Location: the Alexandria Center for Life Science Building, West Tower, room [redacted] a post-doc, working in a BSL2 lab, was performing the procedure described below using several recombinant strains of *Staphylococcus aureus*. The post-doc wore lab coat, disposable gloves, and a surgical mask to perform the work. While de-clumping a suspension of the bacteria (pushing the suspension through an insulin syringe several times to decrease clumping) the post-doc placed the syringe on the bench. A sharps container was not in a convenient location. As a result, the post-doc placed the needle on the bench after use with the intention of disposing later. The post-doc used a fresh needle for each strain, resulting in multiple needles being placed on the bench. Over the course of the procedure the post-doc stuck themselves in the thumb with a used syringe. The inoculum had already been expelled.

The post-doc had 9 strains to de-clump and was half-way through the process when the Needlestick occurred. As a result, there were several used needles present so the post-doc could not be sure which strain the needle was contaminated with.

Following the Needlestick, the post-doc washed the affected area with water for several minutes. They then notified their supervisor and contacted the Occupational Health Services (OHS) department through NYU's 24-hour emergency Needlestick hotline. A Registered Nurse (RN) took this person's contact information as well as the details from the incident. The RN advised the post-doc to gather more information. The post-doc returned during the morning of June 30 for an in-person consultation with an Infectious Disease doctor who is part of NYU's OHS department. In addition, the post-doc completed an Employee Occupational Illness/Injury Report, making a documented record of the incident. To date the post-doc has not demonstrated any adverse health event due to the needlestick.

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The post-doc indicated that they are feeling fine and did not indicate that they had suffered any injuries.

NYU's Environmental Health and Safety (EHS) department and OHS department were made aware of the incident during the afternoon of June 29. Respond and follow-up began immediately. The Institutional Biosafety Committee was notified on June 30.

EHS met with the lab on July 6th to discuss the incident and future solutions. The de-clumping procedure cannot be substituted for a lower risk procedure. However, the lab agree to multiple precautions for the future. They will purchase small sharps containers. They will place these containers in a location that allows disposal of used syringes immediately following use. Furthermore, they will adopt use of safety needles to reduce exposure risk during disposal.

The incident does not appear to be a result of an equipment failure. The incident appears to be a departure from NYU policy, which is to dispose of sharps immediately after use. The changes implemented by the lab should reduce risk of similar incidents in the future. EHS will work with departments as well interdepartmental organizations to spread a wide-reaching reminder of the importance of immediate disposal of sharps as well as general housekeeping. .

Procedure Description: Below is the section of protocol describing when the insulin syringe is used.

Bacterial uptake by Monocyte-derived Macrophages

Pre-opsonization of bacteria

1. Dilute o/n culture 1:100 and grow for 3 hr in 5 ml TSB (in 15ml-tubes).
2. Spin bacteria (10' @ 4000 rpm) and resuspend in RPMI - 0.05% HSA - 10 mM Hepes and OD.
3. Dilute to an OD of ~1
4. Opsonize bacteria in 20% fresh human serum ($5x10^7$ bacteria in 100 µl ($5x10^8$ bacteria/mL) + 25 µl of 100% serum in eppendorf tubes) for 30 minutes at 37°C under shaking conditions.

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5. Wash 2x in RPMI + 0.05% HSA + 0.01M Hepes (@ 13000 rpm 2'), resuspend the bacterial pellets in 125 µl media RPMI + 10% FBS (giving ~5 x 10^8 cfu/ml) **and pass through an insulin syringe to reduce clumping.**
6. Dilute the bacteria 5-fold to ~1 x 10^8 cfu/ml to get the stock for MOI 10.
7. Dilute the 1x10^8/mL stock by 2 fold to get the stock for MOI 5
8. Dilute the 5x10^7/mL stock by 10 fold to get the stock for MOI 1.
9. Place on ice until you are ready to infect. After you infect plate in duplicate fraction of the inoculum to enumerate CFU/ml.

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Hunter, Renee (NIH/OD) [C]

From: Smith, David (RED+F-Facility Mgt-EHS) <David.Smith3@nyulangone.org>
Sent: Wednesday, July 8, 2020 3:14 PM
To: NIH guidelines
Cc: # biosafety
Subject: Incident Report involving recombinant nucleic acid molecules
Attachments: Incident Report 7_8_20 final.pdf

Hello,

Please see the attached report, and let me know if there are any questions.

Thank you,

David
David E. Smith, PhD, ASP
Environmental Health and Safety
Real Estate Development and Facilities
NYU Langone Health
545 First Avenue, GBH, C-117
New York, NY 10016
David.Smith3@nyulangone.org
biosafety@nyulangone.org

T 212-263-5159
M Redacted by agreement



Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, July 29, 2020 3:02 PM
To: ANDREA N LADD; NIH guidelines
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report attached

Dear Dr. Andrea Ladd,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Monday, July 20, 2020 5:50 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: Incident report attached

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the needle stick initially reported on 07/08/20 (below). The Office of Biological Safety has carefully investigated the incident cause, materials, and response.

Please let me know if you have any questions or need additional information.

UW-Madison personnel included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Obtained via FOIA by Judicial Watch Inc.

Andrea N. Ladd, Ph.D.
Pronouns: she/her/hers
Assistant Director, EH&S
Biological Safety Officer
University of Wisconsin-Madison
30 East Campus Mall | Madison, WI 53715
(608) 263-9013 office/ Redacted by agreement mobile
andrea.ladd@wisc.edu

From: ANDREA N LADD
Sent: Wednesday, July 8, 2020 6:24 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: RE: Initial notification of incident

Kathryn,

I still need to confirm many of the specifics, but from what I've been told thus far the incident involves an animal that had previously been administered a recombinant strain of *Mycobacterium tuberculosis*. Please let me know if you need additional details prior to the submission of the full report.

Thanks,
Andrea

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Wednesday, July 8, 2020 2:59 PM
To: ANDREA N LADD <andrea.ladd@wisc.edu>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: RE: Initial notification of incident

Hi Andrea:

Thanks for the email. Can let me know what agent ASAP when you get the details confirmed if it is reportable?

Thanks,

Kathryn

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Wednesday, July 8, 2020 3:55 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: Initial notification of incident

Dear Kathryn or Whom It May Concern,

Obtained via FOIA by Judicial Watch Inc.

We were notified today of needle stick involving recombinant materials in one of our BSL3 laboratories. The employee has been directed to University Health Services for medical follow-up.

At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Pronouns: she/her/hers
Biological Safety Officer
Assistant Director, EH&S
University of Wisconsin-Madison
30 East Campus Mall
Madison, WI 53715
(608) 263-9013 office
Redacted by agreement mobile
andrea.ladd@wisc.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

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Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Wisconsin-Madison
Date of Report:	07/08/20 (initial email to OSP) 07/20/20 (final report filed)
Reporter name and position:	Andrea N. Ladd, Biological Safety Officer
Telephone number:	(608) 263-9013
Email address:	andrea.ladd@wisc.edu
Reporter mailing address:	Environment, Health and Safety 30 East Campus Mall Madison, WI 53715
Date of incident:	07/07/20
Name of Principal Investigator:	Matyas Sandor
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 09/04/19
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☒BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-b
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA X Not applicable
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	*Mycobacterium tuberculosis* strain H37Rv, containing hygromycin resistance gene and tdTomato fluorescent protein gene

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

Location: BSL3 laboratory

Persons involved: UW-Madison employee

Training received by individual: Lab-specific training according to approved biosafety protocol was done and documented. Institutional UW-Madison Required Biosafety Training was completed.

PPE in use at time of event: scrubs, Tyvek coveralls, two pairs of gloves, Tyvek sleeves, shoe covers, and powered air purifying respirator (PAPR)

Event description: Late in the evening, an experienced researcher was injecting dimethyl sulfoxide (DMSO) into the peritoneal cavity of a wildtype mouse inside a biosafety cabinet. The mouse had been infected with the recombinant *Mycobacterium tuberculosis* H37Rv strain five days prior to the DMSO administration via an intracranial inoculation. During the intraperitoneal injection of DMSO, the mouse kicked the needle out of its peritoneal cavity and the needle pierced the researcher's gloves and stuck the base of their thumb.

Note: The chance of the *M. tuberculosis* bacteria in the peritoneal cavity five days following an intracranial inoculation is low.

Immediate follow-up and medical follow-up: The laboratory followed its established emergency response procedure. The employee immediately returned the mouse to its cage, disinfected their PPE with Vesphene, exited the BSL3 lab, and removed the PPE in the anteroom following the lab's doffing SOP. The employee milked the wound and washed the puncture site with a 4% chlorhexidine-gluconate sponge for 15 minutes. This was followed by a 15 minute wash with soap and water. Finally, they applied a bandage, donned fresh PPE, and reentered the BSL3 lab to finish the mouse work and clean up. When finished, the employee informed the principal investigator and the incident was reported to the Office of Biological Safety and University Health Services/Occupational Medicine the following morning. The employee connected with Occupational Medicine for medical follow-up. The BSO submitted an initial report to the NIH-OSP via email.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC Chair was aware of the incident upon initial

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	report to OSP. The IBC will be apprised at the next monthly meeting on August 5, 2020.
Please describe the root cause of this incident:	The root cause is the natural instinct of an animal to be uncooperative with a procedure it dislikes. A contributing factor was incomplete restraint of the mouse that allowed it to kick the needle.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The institution followed approved emergency and reporting procedures.

The Office of Biological Safety met with the employee and PI to discuss the incident and review the emergency follow-up. The employee and PI had reviewed the incident. To prevent reoccurrence the employee reviewed the restraint method, including watching videos of the hold technique and practicing the hold on additional mice. When applied successfully, the restraint hold used should fully immobilize a mouse's legs. The PI emphasized the importance of focus when working in the lab. Taking microbreaks to prevent inattention or fatigue was discussed. Emergency response procedures were reviewed with others in the laboratory.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Wednesday, July 8, 2020 7:24 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
Subject: RE: Initial notification of incident

Kathryn,

I still need to confirm many of the specifics, but from what I've been told thus far the incident involves an animal that had previously been administered a recombinant strain of *Mycobacterium tuberculosis*. Please let me know if you need additional details prior to the submission of the full report.

Thanks,
Andrea

From: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Sent: Wednesday, July 8, 2020 2:59 PM
To: ANDREA N LADD <andrea.ladd@wisc.edu>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: RE: Initial notification of incident

Hi Andrea:

Thanks for the email. Can let me know what agent ASAP when you get the details confirmed if it is reportable?

Thanks,

Kathryn

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Wednesday, July 8, 2020 3:55 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: Initial notification of incident

Dear Kathryn or Whom It May Concern,

We were notified today of needle stick involving recombinant materials in one of our BSL3 laboratories. The employee has been directed to University Health Services for medical follow-up.

At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Individuals included on this email:

- Kristen Bernard, Chair of IBC

Obtained via FOIA by Judicial Watch Inc.

- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Pronouns: she/her/hers
Biological Safety Officer
Assistant Director, EH&S
University of Wisconsin-Madison
30 East Campus Mall
Madison, WI 53715
(608) 263-9013 office
Redacted by agreement mobile
andrea.ladd@wisc.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Monday, July 20, 2020 5:50 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
Subject: Incident report attached
Attachments: Sandor_070820_OSP Reportable.docx

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the needle stick initially reported on 07/08/20 (below). The Office of Biological Safety has carefully investigated the incident cause, materials, and response.

Please let me know if you have any questions or need additional information.

UW-Madison personnel included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Pronouns: she/her/hers
Assistant Director, EH&S
Biological Safety Officer
University of Wisconsin-Madison
30 East Campus Mall | Madison, WI 53715
(608) 263-9013 office/ Redacted by agreement mobile
andrea.ladd@wisc.edu

From: ANDREA N LADD
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To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
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Andrea

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Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Pronouns: she/her/hers
Biological Safety Officer
Assistant Director, EH&S
University of Wisconsin-Madison
30 East Campus Mall
Madison, WI 53715
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andrea.ladd@wisc.edu

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Sent: Wednesday, July 8, 2020 3:55 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: Initial notification of incident

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Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

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Redacted by agreement mobile
andrea.ladd@wisc.edu

Obtained via FOIA by Judicial Watch Inc.

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Hunter, Renee (NIH/OD) [C]

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Wednesday, July 8, 2020 3:55 PM
To: NIH guidelines; Harris, Kathryn (NIH/OD) [C]
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
Subject: Initial notification of incident

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At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
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Assistant Director, EH&S
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30 East Campus Mall
Madison, WI 53715
(608) 263-9013 office
Redacted by agreement mobile
andrea.ladd@wisc.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, July 29, 2020 3:48 PM
To: Camille.King4@va.gov; NIH guidelines
Cc: Debbie.Lindquist@va.gov; Theresa.Bjorness@UTSouthwestern.edu; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Dallas VA 549 Incident Report

Dear Camille King,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: King, Camille N. <Camille.King4@va.gov>
Sent: Monday, July 13, 2020 11:01 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Lindquist, Debbie A <Debbie.Lindquist@va.gov>; 'Theresa Bjorness' <Theresa.Bjorness@UTSouthwestern.edu>
Subject: Dallas VA 549 Incident Report

Please see attached incident report from the IBC at Dallas VA-549.

If you have any questions, please let me know.

Thanks,

Camille King
VMU & Research Safety Supervisor
IACUC, SRS, & IBC Coordinator
VA North Texas Health Care System
Office of Research and Development
4500 S. Lancaster Road, Mail Code 151
Dallas, Texas 75216

Obtained via FOIA by Judicial Watch Inc.

Redacted by agreement cell
(214)857-0269 office

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Dallas VA Medical Center
Date of Report:	07/02/2020
Reporter name and position:	Redacted by agreement Assistant Professor at UT Southwestern Medical Center
Telephone number:	214-645-4673
Email address:	Redacted by agreement @utsouthwestern.edu
Reporter mailing address:	Division of Oncology 5323 Harry Hines Blvd Dallas, TX 75390
Date of incident:	June 12,2020
Name of Principal Investigator:	David Wang
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 06/27/2020 last approval
What was the approved biosafety level of the research?	☒BL1 ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	One gene in the exposed human esophageal cancer cell line (FLO-1) called CD44 was genetically knockout using crispr cas9 system.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

The incident happened in a procedure room of the Dallas VA medical center animal house Redacted by agreement Bldg. 43). FLO-1 cells were injected subcutaneously into NOD-SCID animals. The animals were anesthetized and kept in an isoflurane induction chamber. The isoflurane induction chamber was quite small. When a male research scientist was carrying out the procedure the needle accidently stuck into his finger and caused bleeding. The needle of the syringe may have contained some cancer cells. He was wearing gloves when performing the procedure. After the needle stick, he immediately took off the glove and washed his fingers with liquid soap and water in the procedure room. On the same day of the incident happened, he went to the occupational health center at Dallas VA Medical Center. He was treated by a physician in the office. Blood was drawn to test for HBV, HCV and HIV. He was also asked to come back to have a second blood test 6 weeks later.

The SOP was followed when this incident happened. This research scientist has several years of subcutaneous injection experience. His last animal training date is December 30, 2019. To prevent this happening again, a tweezer will be used to lift the skin of the animal when performing subcutaneous injection in the future.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Upon review of the incident, it was determined that the likely source of the needle poke was due to injecting within the small isoflurane induction chamber that is used to anesthetize the animal [space for the researcher's fingers was relatively cramped]. The researcher followed all procedures following the needle stick (washing the area, going to Occupational Health, reporting to the PI) and the IBC committee was notified about the incident in a timely manner.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Given that the incident was likely caused by the small size of the induction chamber, it was suggested that tweezers by used in the future to hold the skin while the animal is in the induction chamber. Isoflurane anesthesia is used with the NON-SCID mice due to the presence of hair. The small size of the induction chamber is generally useful for inducing animals but is problematic when attempting to inject mice when in the induction chamber. Use of tweezers will allow the animal to be held inside the induction chamber by the researcher's fingers placed outside the induction chamber. Switching to a non-touch procedure will add an engineering control to reduce the likelihood of a needle stick incident. The researcher and PI are agreeable to this change in procedure. An alternate option would be to use a larger induction chamber for this procedure though this option will not currently be pursued since the tweezers offer a superior option (fingers are further away from the needle) than would be provided by a larger induction chamber.

IACUC will be reviewing this incident and reporting back to the IBC in regards to the SOP being followed with animal use and their recommendations about procedural changes in the future.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: King, Camille N. <Camille.King4@va.gov>
Sent: Monday, July 13, 2020 11:01 AM
To: NIH guidelines
Cc: Lindquist, Debbie A; 'Theresa Bjorness'
Subject: Dallas VA 549 Incident Report
Attachments: Incident Reporting [Redacted by agreement] IBC review_v3.docx

Please see attached incident report from the IBC at Dallas VA-549.

If you have any questions, please let me know.

Thanks,

Camille King
VMU & Research Safety Supervisor
IACUC, SRS, & IBC Coordinator
VA North Texas Health Care System
Office of Research and Development
4500 S. Lancaster Road, Mail Code 151
Dallas, Texas 75216

[Redacted by agreement] cell
(214)857-0269 office

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, July 29, 2020 2:41 PM
To: lydia SOHN; NIH guidelines
Cc: Chips Hoai; Bso Departmental; Brandon DEFRANCISCI; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: recombinant DNA spill

Dear Dr. Lydia Sohn,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: lydia SOHN <sohn@berkeley.edu>
Sent: Tuesday, July 14, 2020 5:36 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chips Hoai <chips@berkeley.edu>; Bso Departmental <bso@berkeley.edu>; Brandon DEFRANCISCI <defran@berkeley.edu>; lydia SOHN <sohn@berkeley.edu>
Subject: recombinant DNA spill

Dear Dr. Harris,

I would like to send in the report of an incident in the lab of Dr. Qiang Zhou at UC Berkeley. On June 30, 2020, an equipment failure of the laboratory shaker resulted in a spill of Recombinant BL21 E. coli culture expressing human CyclinT1-Taz vector. Research personnel have been retrained on proper spill clean-up procedures. Please find attached the detailed incident report.

If you have any questions or would like further clarification, please let me know.

Thank you.

Lydia Sohn

Obtained via FOIA by Judicial Watch Inc.

****

Lydia L. Sohn
Chancellor's Professor
CLEB Chair
Dept. of Mechanical Engineering
Faculty Assistant to the Vice Chancellor for Research
UC Berkeley

Core Member
UCSF-UC Berkeley Joint Graduate Program in Bioengineering
Berkeley, CA 94720-1740

5118 Etcheverry Hall
Berkeley, CA 94720-1740
Redacted by agreement (cell)
http://srl.berkeley.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

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Please Note:

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A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of California, Berkeley
Date of Report:	July 14, 2020
Reporter name and position:	Chips Hoai Biosafety Officer
Telephone number:	510-849-7142
Email address:	chips@berkeley.edu
Reporter mailing address:	317 University Hall #1150 Office of Environment, Health & Safety UC Berkeley Berkeley, CA 94720
Date of incident:	6/30/2020
Name of Principal Investigator:	Qiang Zhou
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☒Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?Gis	☒YES ☐NO If yes, date of approval: 02/06/2018
What was the approved biosafety level of the research?	☒BL1 ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-E
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Recombinant BL21 E. coli culture expressing human CyclinT1-Taz vector

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of

Obtained via FOIA by Judicial Watch Inc.

the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

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On June 30, 2020, 4 L beaker containing culture of Recombinant BL21 E. coli culture expressing human CyclinT1-Taz vector was placed in a clasp on the shaker platform in the BSL-1 laboratory and left to shake for three hours. When the student researcher returned after three hours to retrieve the culture, she found that the clasp had broken off the platform and the beaker had broken on the floor, spilling the culture. The spill had mostly dried by the time it was found. The remaining liquid was absorbed and disinfected with 10% bleach. The floor, shaker and glassware were cleaned with 10% bleach. Broken glass was handled using tools and disposed in the sharps waste. The student researcher wore nitrile gloves to clean the spill.

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Has the IBC reviewed this incident?	☒YES ☐NO On July 07, 2020
Please describe the root cause of this incident:	Clasp insecurely attached to shaker platform, causing flask to knock over.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Lab members have been re-trained to:

1. Review biological spill procedures and locate biological spill kit provided by Environmental Health & Safety.
2. Visually inspect equipment to ensure it is safe for use before each use.
3. Wear proper PPE when cleaning spills, including lab coat, gloves and eye/face protection.

Obtained via FOIA by Judicial Watch Inc.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: lydia SOHN <sohn@berkeley.edu>
Sent: Tuesday, July 14, 2020 5:36 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Chips Hoai; Bso Departmental; Brandon DEFRANCISCI; lydia SOHN
Subject: recombinant DNA spill
Attachments: Zhou, Q. - NIH Spill Report-2020.06.docx

Dear Dr. Harris,

I would like to send in the report of an incident in the lab of Dr. Qiang Zhou at UC Berkeley. On June 30, 2020, an equipment failure of the laboratory shaker resulted in a spill of Recombinant BL21 E. coli culture expressing human CyclinT1-Taz vector. Research personnel have been retrained on proper spill clean-up procedures. Please find attached the detailed incident report.

If you have any questions or would like further clarification, please let me know.

Thank you.

Lydia Sohn

****

Lydia L. Sohn
Chancellor's Professor
CLEB Chair
Dept. of Mechanical Engineering
Faculty Assistant to the Vice Chancellor for Research
UC Berkeley

Core Member
UCSF-UC Berkeley Joint Graduate Program in Bioengineering
Berkeley, CA 94720-1740

5118 Etcheverry Hall
Berkeley, CA 94720-1740
Redacted by agreement (cell)
http://srl.berkeley.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, August 13, 2020 1:34 PM
To: McFarland Christine Tetzlaff; NIH guidelines
Cc: Gonzalez, Carlos F; Institutional Biosafety Committee; Bourquin, Jessica; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report per Appendix G-II-B-2-k

Dear Dr. Christine Tetzlaff McFarland,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: McFarland Christine Tetzlaff <ctmcfarland@tamu.edu>
Sent: Wednesday, July 29, 2020 3:01 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Gonzalez, Carlos F <cf-gonzalez@tamu.edu>; Institutional Biosafety Committee <ibc@tamu.edu>; Bourquin, Jessica <jrbourquin@tamu.edu>
Subject: Incident Report per Appendix G-II-B-2-k
Importance: High

Dear NIH OSP colleagues,

Per Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,* and on behalf of the College Station – TAMU Institutional Biosafety Committee (IBC), I am writing to provide a final report in follow up to the initial report submitted on July 22, 2020.

I spoke to the researcher on July 22, 2020 and gathered the following additional information. The incident occurred while the researcher was harvesting bone marrow cells from the leg bone of a mouse previously injected with a human cell line (Raji cells– derived from Burkitt lymphoma) transduced with a luciferase-expressing lentiviral vector. The

Obtained via FOIA by Judicial Watch Inc.

researcher was holding the bone to stabilize it with their left hand, and while inserting a needle into the bone with their right hand, they stuck the tip of their left middle finger with the contaminated needle. The researcher was wearing gloves during the procedure, but the needle punctured the glove. The researcher indicated that they immediately removed their glove and washed the injured finger for 10 minutes with soap and water. The researcher stated that they worked to bleed the finger during this time but the stick was very small and bled very little. The researcher used 70% ethanol to sanitize the puncture wound. The researcher reported the incident to their supervisor and to the Office of Biosafety. The researcher was instructed to follow up with the Occupational Health (OH) provider, which they did on July 22, 2020. The incident was reported to the College Station – TAMU IBC on July 22, 2020.

The root cause of this accidental needlestick was determined to be the result of the researcher using their hand, rather than employing mechanical means, to stabilize the bone. To mitigate recurrence, the researcher stated that they will use forceps or tweezers to stabilize the bone in the future.

The OH provider believes this incident presents a very low risk of bloodborne pathogen exposure and prescribed antiretroviral therapy to address the potential risk of exposure to lentiviral vector transduced cancer cells. The researcher agreed to participate in post-exposure lab surveillance testing including baseline bloodborne pathogen surveillance and medication monitoring at four weeks and three months from the exposure date. The researcher was instructed to contact the medical provider to report any unexplained symptoms. The medical provider stated there were no work restrictions and released the researcher to return to work at full capacity.

Please let me know if additional information is needed.

Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety
Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
Office: 979-845-6475| Fax: 979-458-2669 | ctmcfarland@tamu.edu | http://rcb.tamu.edu

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From: McFarland Christine Tetzlaff
Sent: Wednesday, July 22, 2020 11:51 AM
To: 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
Cc: 'Carlos' <cf-gonzalez@tamu.edu>; Institutional Biosafety Committee <ibc@tamu.edu>; Bourquin, Jessica <jrbourquin@tamu.edu>
Subject: Initial notification per Appendix G-II-B-2-k
Importance: High

Dear NIH OSP colleagues,

Per Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and on behalf of the College Station – TAMU Institutional Biosafety Committee (IBC), I am writing to provide initial notification of a needle stick incident involving a researcher who was manipulating tissues from a mouse previously injected with recombinantly modified human cancer cell line. The incident occurred late Monday afternoon, July 20, 2020, in a BSL-2 lab as the researcher was attempting to retrieve bone marrow cells from a mouse leg bone. I was only made aware of this accident this morning. Our occupational medical provider has been notified and we await his recommendation for this researcher. A complete report will follow once we have all the details.

Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety

Obtained via FOIA by Judicial Watch Inc.

Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
Office: 979-845-6475 | Fax: 979-458-2669 | ctmcfarland@tamu.edu | http://rcb.tamu.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McFarland Christine Tetzlaff <ctmcfarland@tamu.edu>
Sent: Wednesday, July 29, 2020 3:01 PM
To: NIH guidelines
Cc: Gonzalez, Carlos F; Institutional Biosafety Committee; Bourquin, Jessica
Subject: Incident Report per Appendix G-II-B-2-k

Importance: High

Dear NIH OSP colleagues,

Per Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,* and on behalf of the College Station – TAMU Institutional Biosafety Committee (IBC), I am writing to provide a final report in follow up to the initial report submitted on July 22, 2020.

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Please let me know if additional information is needed.

Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety
Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
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Sent: Wednesday, July 22, 2020 11:51 AM
To: 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
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Subject: Initial notification per Appendix G-II-B-2-k
Importance: High

Dear NIH OSP colleagues,

Per Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and on behalf of the College Station – TAMU Institutional Biosafety Committee (IBC), I am writing to provide initial notification of a needle stick incident involving a researcher who was manipulating tissues from a mouse previously injected with recombinantly modified human cancer cell line. The incident occurred late Monday afternoon, July 20, 2020, in a BSL-2 lab as the researcher was attempting to retrieve bone marrow cells from a mouse leg bone. I was only made aware of this accident this morning. Our occupational medical provider has been notified and we await his recommendation for this researcher. A complete report will follow once we have all the details.

Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety
Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
Office: 979-845-6475 | Fax: 979-458-2669 | ctmcfarland@tamu.edu | http://rcb.tamu.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McFarland Christine Tetzlaff <ctmcfarland@tamu.edu>
Sent: Wednesday, July 22, 2020 12:51 PM
To: NIH guidelines
Cc: Gonzalez, Carlos F; Institutional Biosafety Committee; Bourquin, Jessica
Subject: Initial notification per Appendix G-II-B-2-k

Importance: High

Dear NIH OSP colleagues,

Per Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and on behalf of the College Station – TAMU Institutional Biosafety Committee (IBC), I am writing to provide initial notification of a needle stick incident involving a researcher who was manipulating tissues from a mouse previously injected with recombinantly modified human cancer cell line. The incident occurred late Monday afternoon, July 20, 2020, in a BSL-2 lab as the researcher was attempting to retrieve bone marrow cells from a mouse leg bone. I was only made aware of this accident this morning. Our occupational medical provider has been notified and we await his recommendation for this researcher. A complete report will follow once we have all the details.

Sincerely,
Christine

Christine Tetzlaff McFarland, Ph.D.| Executive Director, Office of Biosafety
Biological Safety Officer/Alternate Responsible Official
Office of Biosafety | Division of Research | Texas A&M University
750 Agronomy Road, Suite 2701, 1186 TAMU, College Station, Texas 77843-1186
Office: 979-845-6475 | Cell: Redacted by agreement | Fax: 979-458-2669 | ctmcfarland@tamu.edu | http://rcb.tamu.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, August 13, 2020 1:21 PM
To: David Emery; NIH guidelines
Cc: Chris Jenkins; Jami Sentissi; Marala McCallister; Jensen, Justin; James A. Ruhlmann; Brian Voth; mmoodie@gglawks.com; Henderson, Kristen; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident Report of Unapproved Research

Dear Dr. David Emery,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: David Emery <demery@clinicalbiosafety.com>
Sent: Friday, July 24, 2020 10:56 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Chris Jenkins <cjenkins@clinicalbiosafety.com>; Jami Sentissi <jsentissi@clinicalbiosafety.com>; Marala McCallister <mmccallister@sabaiglobal.com>; Jensen, Justin <Justin.jensen@avacare.com>; James A. Ruhlmann <RuhlmannJ@hutchclinic.com>; Brian Voth <VothB@hutchclinic.com>; mmoodie@gglawks.com; Henderson, Kristen <Kristen.Henderson@Quintiles.com>
Subject: Incident Report of Unapproved Research

To whom it may concern,

Please find attached an Incident Report of unapproved research, conducted in violation of the *NIH Guidelines*, at the Hutchinson Clinic, P.A., located in Hutchinson, KS.

I am submitting this Report in my capacity as chair of the externally administered Institutional Biosafety Committee for this Institution.

Please let me know if any additional information or actions on our part are required in this matter.

Sincerely,

Obtained via FOIA by Judicial Watch Inc.

David

DAVID W. EMERY, PhD
Director of IBC Operations
Clinical Biosafety Services
16759 Main St., Suite #208
Wildwood, MO 63040
O: 888-442-2472 ext. 703 | C: Redacted by agreement
E: demery@clinicalbiosafety.com | W: clinicalbiosafety.com



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Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	✓ YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Hutchinson Clinic P.A.
Date of Report:	07-24-2020
Reporter name and position:	David W. Emery Director of IBC Operations, Clinical Biosafety Services IBC Chair
Telephone number:	(206) 427-8734 (Cell) (888) 442-2472, ext. 703 (Office)
Email address:	demery@clinicalbiosafety.com
Reporter mailing address:	Clinical Biosafety Services 16759 Main St., Suite #208 Wildwood, MO 63040
Date of incident:	CBS was notified on 06-17-2020 Issue was on-going from approximately August 2019 to 09-19-2019
Name of Principal Investigator:	Dr. James Ruhlmann, MD
Is this an NIH-funded project?	✓ NO ☐YES If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	✓ Failure to follow approved containment conditions ✓ Failure to obtain IBC approval ✓ Incomplete inactivation ✓ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	✓ YES ☐NO If yes, date of approval: 06-17-2019
What was the approved biosafety level of the research?	BL1 ✓ BL2 ☐BL2+ (describe specific enhancement in report) BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D Section III-C
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): None ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	The recombinant study agent Ad26.RSV.preF consists of a recombinant, replication-defective adenoviral vector. This vector is replication-defective due to deletion of the essential E1 and E3 adenoviral genes and is prepared with a novel Ad26 serotype in the human cell line PER.C6. This vector expresses a recombinant form of the highly immunogenic RSV protein preF, derived from the common RSV serotype A2. This recombinant preF protein differs from the wild-type form of the preF protein by 5 amino acids designed to improve protein stability. The preF expression cassette makes use of a promoter from cytomegalovirus (CMV) and transcript termination sequence from simian virus 40 (SV-40), both commonly used regulatory elements.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of: **PLEASE REFER TO THE ATTACHED REPORT FOR THE DETAILS.**

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

PLEASE REFER TO THE ATTACHED REPORT FOR THE DETAILS

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	✓ YES ☐NO
Please describe the root cause of this incident:	Failure to the Principal Investigator to notify clinical trial staff that the clinical trial is being overseen by the IBC, and the requirements established by the IBC for this trial.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

PLEASE REFER TO THE ATTACHED REPORT FOR THE DETAILS

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Report to Institutional Biosafety Committee
on Janssen VAC1819RSV2001 Study (the "Study")

Submitted by:

Hutchinson Clinic, P.A., Hutchinson, Kansas
and PI James Ruhlmann, M.D.[1]

On June 17, 2019, Clinical Biosafety Services, the Institutional Biosafety Committee ("IBC"), approved the above-referenced study for Janssen Vaccines & Prevention B.V. ("Sponsor") to be conducted at Hutchinson Clinic with an IBC approval expiration date of June 16, 2020. The Study was conducted at the Hutchinson Clinic under the direction of Dr. James Ruhlmann, Principal Investigator, with drug preparation and dosing occurring from August through September 2019. The Hutchinson Clinic is proceeding with the annual review given that the IBC requires the approval to be maintained for one year after the last dosing, which took place on September 19, 2019. However, the investigational product ("IP" or "Study agent") is no longer on site, and no additional dosing is expected to occur as part of the Study.

In preparing for the annual review, site staff learned that several of the approved biosafety standard operating procedure requirements and procedures reflected in the approved biosafety checklist may not have been followed or there may have been deviations from the prescribed practices. An investigation into the biosafety practices utilized during the Study was conducted and the observations from that investigation are reported herein. We note that none of the below observations resulted in any occupational exposures, spills or reported accidents or illnesses.

The primary authorities reviewed as part of the investigation include the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (April 2019) (the "NIH Guidelines"), the IBC Determination Letter to Dr. Ruhlmann (dated August 1, 2019), the Standard Operating Procedure for Janssen Ad26.RSV.preF (dated May 14, 2019) (hereafter the "Biosafety SOP" or "SOP") and the Biosafety Checklist (dated May 30, 2019).

This report is comprised of two sections. The first section presents observations from the investigation against applicable provisions in the NIH Guidelines and the second section presents observations from the investigation against the Biosafety SOP.

I. THE NIH GUIDELINES

1. Biohazard signage

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[1] On September 5, 2017, the Hutchinson Clinic outsourced the site management and clinical research support staff services at its facility to Qcare Site Services Inc. (now doing business as Avacare). As a result of that outsourcing, a number of Hutchinson Clinic employees involved in site management and clinical research support transitioned over to and became employees of Qcare. Thus, all Study Coordinators performing tasks referred to in this report were formally Hutchinson employees until September 2017. In accordance with the parties' relationship, Avacare assisted and partnered with Hutchinson Clinic and Dr. Ruhlmann in the preparation of this report.

Obtained via FOIA by Judicial Watch Inc.

***NIH G-II-B-2-d*:** *When the organisms containing recombinant or synthetic nucleic acid molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the laboratory work area. The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator or other responsible person(s), and indicates special requirement(s) for entering the laboratory.*

Observation: The Laboratory entry door has a sign on it that reads "CAUTION [Biohazard Symbol] Biological Hazard. Authorized Personnel Only." The sign, however, does not identify the Study agent, list the name and telephone number of the Principal Investigator or other responsible person(s), or indicate any special requirements for entering the laboratory. In addition, numerous other biohazard signs are posted in the main area of the laboratory, and there is a biohazard sign in the mixing room where the biological safety cabinet is located. We understand that there was a specific biohazard sign that the IBC approved for use during the Study, and that sign included the agent, names and phone numbers. However, it is not currently posted at the site and, due to passage of time or employee departure, we are unable to confirm that it was or was not posted.

2. Personal Protective Equipment ("PPE")

***NIH G-II-B-2-f*:** *Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory. Before exiting the laboratory for non-laboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.*

Observation: Laboratory coats were worn while in the laboratory. However, the lab coats were stored on the back of the door to an Unblinded Study Coordinator's office in the Clinical Trials Department in separate plastic dry cleaning covers.

3. Training or instruction on hazards

***NIH IV-B-1-H*:** *Responsibilities of the Institution. Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the NIH Guidelines. The Institutional Biosafety Committee Chair is responsible for ensuring that Institutional Biosafety Committee members are appropriately trained. The Principal Investigator is responsible for ensuring that laboratory staff are appropriately trained. The institution is responsible for ensuring that the Principal Investigator has sufficient training; however, this responsibility may be delegated to the Institutional Biosafety Committee.*

Observation: The Study Coordinators, who were all former Hutchinson Clinic employees, had been trained on the Safety Manual and bloodborne pathogens by Hutchinson Clinic at the time of their prior employment by the Clinic. In addition, site staff has had ongoing access to the Safety Manual at all times via the HCNews (internal Hutchinson Clinic)

Obtained via FOIA by Judicial Watch Inc.

website. It cannot be confirmed that they have had training on implementation of the NIH Guidelines.

Observation: The Principal Investigator (PI) had access to the Safety Manual but it cannot be confirmed that he has had training on laboratory safety and implementation of the NIH Guidelines. The Principal Investigator did not process or handle any IP for the Study.

NIH IV-B-7-d-(1): *Prior to initiating research, the Principal Investigator shall make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.*

Observation: The Study Coordinators were provided with the Study protocol, Protocol VAC18193RSV2001; Phase 2B VAC18193 (JNJ-64400141/JNJ-64213175), from the Sponsor but were not provided additional instruction on the potential biohazard of the investigational product (IP) and the precautions to be taken as outlined in the Biosafety SOP and checklist approved by the IBC. Laboratory staff were provided training on the Hutchinson Clinic Safety Manual (including bloodborne pathogen training), which was serving as the Exposure Control Plan for the Study and received bloodborne pathogen training. In addition, the Study Coordinators had been trained on the Hutchinson Clinic Safety Manual and (including bloodborne pathogens) through Hutchinson at the time of their prior employment by the clinic.

NIH IV-B-7-d-(3): *Prior to initiating research, the Principal Investigator shall inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).*

Observation: The Biosafety SOP and Biosafety Checklist require certain precautionary medical practices for the performance of the Study. The Study Coordinators were not provided formal instruction on the potential biohazard of the Study agent or how it should be treated with additional or special biosafety precautions as set forth in the Biosafety SOP and checklist.

NIH G-I*: Consequently, all personnel directly or indirectly involved in experiments using recombinant or synthetic nucleic acid molecules shall receive adequate instruction . . . At a minimum, these instructions include training in aseptic techniques and in the biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated. Any research group working with agents that are known or potential biohazards shall have an emergency plan that describes the procedures to be followed if an accident contaminates personnel or the environment. The Principal Investigator shall ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan.*

Observation: The Study Coordinators did not receive instruction on biosafety requirements applicable to the Study given the potential hazards of the Study agent.

4. Supervision of safety performance and containment measures

Obtained via FOIA by Judicial Watch Inc.

NIH IV-B-7-d-(2): *During the research, the Principal Investigator shall supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.*

Observation: During the performance of the Study, the PI did not personally supervise the safety performance of the Study Coordinators to ensure that required biosafety practices and techniques specified in the Biosafety SOP and the Biosafety Checklist were employed. However, it was his understanding and belief the Clinical Trials Site Manager was performing the review of the Study Coordinators to ensure the safety practices and techniques were followed and that he would report any concerns or deviations he saw to Dr. Ruhlmann. Dr. Ruhlmann does not recall any concerns having been raised or reported related to biosafety or techniques being used.

II. THE BIOSAFETY SOP

1. Receiving and Storage

SOP RS 3: *The AD26.RSV.preF is received in the Laboratory area. The study agent will be transported in the shipping container to Laboratory area where it is unpacked and inspected by the unblinded Study Coordinator wearing a lab coat and gloves.*

Observation: The AD26.RSV.preF (same as the IP) was not received in the Laboratory area. Upon its arrival to the site, the IP was received in the Clinical Trials Department, where it was unpacked and placed in the freezer in the Clinical Trials Department by the unblinded Study Coordinator wearing a lab coat and gloves.

SOP RS 4: *The AD26.RSV.preF is stored in a -70 freezer (between -85°C and -55°C). The RSV preF protein is stored in a refrigerator between 2-8°C. The Laboratory has restricted access limited to the staff and the freezer itself is restricted to study personnel only with keyed and requires a pin number to enter. The freezer is monitored by a min/max temperature monitoring system. The study team personnel monitor daily for any temperature excursions.*

Observation: During the period of time when the IP was stored in the freezer, there were several temperature excursions (temperatures were slightly lower than -85°C). All excursions were timely reported to the Sponsor.

Observation. During the period between August 29, 2019 and September 19, 2019, the min/max monitoring system for the freezer was not working. While the monitoring system was not working, the Study Coordinators conducted daily monitoring of the temperature displayed on the door of the freezer. Excursions were timely reported to the Sponsor, and, if required, remedial actions were taken.

SOP RS 5: *The AD26.RSV.preF is removed from the freezer and hand carried in the same room (Laboratory Area) for preparation inside of a fume hood.*

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Observation: The IP was removed from the freezer in the Clinical Trials Department and brought to the Laboratory on the first floor for thawing and preparation inside a Biosafety Cabinet (fume hood).

2. Preparation

SOP P 4: *The preparer must don the following PPE: Gown and gloves (for preparation inside of a fume hood).*

Observation. The Unblinded Study Coordinators preparing the IP wore cloth lab coats and vinyl gloves. The gloves were worn so that they overlapped with the sleeves of their lab coats to avoid any exposure of skin.

SOP P 9: *The prepared syringe with capped needle is placed inside of a Ziploc®-like bag, and then into hard-walled transport container (labeled with a biohazard sticker), before being hand-carried to the Dosing Room 2 that is non-carpeted for administration.*

Observation: A Ziploc-like bag was not used.

3. Administration

SOP A 1: *Administration will take place in Dosing Room 2.*

Observation: The SOP refers to drug administration occurring in Dosing Room 2. However, Dosing Room 2 was confirmed to actually be Dosing Room 3 in the Clinical Trials Department. Dosing also occurred in Dosing Room 1 immediately across from Dosing Room 3. Dosing Room 1 has the same flooring and general appearance of Dosing Room 3.

SOP A 3: *The closest eyewash station is portable and located in the Dosing Room 2.*

Observation: There was no portable eyewash station in Dosing Room 2. The closest eyewash station (stationary) was located outside the Dosing Rooms.

SOP A 4: *All work surfaces will be decontaminated before and after administration with Cavi-Cide.*

Observation: All work surfaces were decontaminated before and after administration but Cavi-Cide was not used. Instead, Lysol Disinfecting Wipes, Lysol Disinfecting Aerosol Spray and/or Clorox Multipurpose Disinfecting Spray were used to clean work surfaces.

SOP A 5: *Unblinded study coordinator will administer the study agent and must don the following PPE: Disposable gown, gloves and safety glasses.*

Observation: The Blinded Study Coordinators administering the IP wore scrubs and gloves.

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SOP A 8: *The injection site will remain undressed during the 30-minute observation period provided that the subject remains in the private exam room during this time. After the 30-minute observation period, the injection site will be dressed with an adhesive bandage. If the subject is moved to a common area, e.g., a common waiting room, a bandage will be placed over the injection site prior to the subject being escorted from the exam room to the common area. If the injection site must be inspected during or at the end of the 30-minute observation period, the subject must be returned to a private room before removing the bandage, and the bandage must be replaced before the subject departs.*

SOP A 9: *After the 30-minute observation period, the injection site will be dressed with an adhesive bandage.*

> **Observation:** Subjects remained in the private exam room for the 30-minute observation period. Some subjects had band-aids applied immediately after injection and others elected to forego application of a band-aid. Study Coordinators inspected the injection sites of all subjects at the end of the 30-minute observation period.

SOP A 10: *Subjects will be instructed to leave the bandage on for at least 24 hours, to place the soiled bandage in a plastic bag before disposal in their household garbage, and to wash their hands with warm water and soap after doing so.*

> **Observation:** The Study subjects were not instructed to leave the bandage on for at least 24-hours, nor were they instructed how to properly dispose of the bandage.

SOP A 11: *Following dosing in the Dosing Room 2, the unblinded study coordinator will remove their gloves and deposit them in a biohazardous waste container before moving to the hand washing sink inside the room to wash their hands with soap and water.*

> **Observation:** The Blinded Study Coordinators who administered IP indicated that, after dosing, their gloves were either disposed of in a biohazard trash can or a regular trash can, depending on what kind of trash can was available in the dosing room on that particular day.

SOP A 12: *All used PPE and contaminated materials will be placed into a hard-walled container with a lid labeled with biohazard stickers on all 4 sides and the lid.*

> **Observation:** Durable biohazard waste containers were present in the Clinical Trials Department but gloves periodically may not have been disposed inside of them. Other contaminated materials (e.g., needles) were disposed in Sharps containers.

SOP A 14: *When whole blood samples are taken, trained study staff will wear the following PPE: lab coat and gloves. Samples will be stored labeled and segregated until prepared by an IATA/DOT trained staff for shipping.*

> **Observation**: The staff drawing blood samples wore scrubs and gloves.

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4. Emergencies

Eye Exposure: *Flush the eyes for at least 15 minutes using the nearest eyewash. (The eyewash must meet the current ANSI/ISEA Z358.1 Standard for eyewash stations. The plumbed eyewash is flushed weekly and records are documented.).*

Observation: There were no eye exposure emergencies. We are unable to confirm how often the plumbed eyewash station closest to the Dosing Rooms was flushed.

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APPENDIX

Corrective and Preventive Action (CAPA) Plan

Actions taken/in progress:

- Conducting a refresh of the Safety Manual training for site staff involved in IP preparation and dosing in the study
- Bloodborne pathogen training has been completed by all staff involved in IP preparation and dosing in the study and will be renewed annually
- The study-specific biohazard sign has been updated and will be posted as necessary
- Update Biosafety SOP through the annual IBC review process to reflect that EPA-approved virucides are used at the Hutchinson Clinic
- The eyewash station closest to the Dosing Rooms in the Clinical Trials Department has been inspected and flushed, and a log will be kept weekly.

Actions planned (contingent on whether any further dosing is contemplated for this study)

- Formally train all applicable staff on all biosafety requirements applicable to the Study. All current site staff who performed IP preparation and dosing administration on the Study have been made aware of the Biosafety SOP and Checklist requirements.
- Site Manager and Dr. Ruhlmann will regularly perform compliance checks to ensure compliance with Biosafety SOP and biosafety measures
- Develop a policy/procedure with Dr. Ruhlmann to restrict access to the mixing room within the Lab during IP preparation and the Dosing Rooms where the IP will be administered.
- Create a checklist to verify all decontamination/disposal equipment and procedures required by the Biosafety SOP and Checklist are in place for Blinded and Unblinded Study Coordinators' use prior to any further subject visits for dosing, if applicable.
- If the IBC determines an additional eyewash station is required for any further dosing on this study, Hutchinson Clinic will either install a faucet mounted eyewash unit in the Clinical Trials Department or purchase a portable eyewash station.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: David Emery <demery@clinicalbiosafety.com>
Sent: Friday, July 24, 2020 10:56 AM
To: NIH guidelines
Cc: Chris Jenkins; Jami Sentissi; Marala McCallister; Jensen, Justin; James A. Ruhlmann; Brian Voth; mmoodie@gglawks.com; Henderson, Kristen
Subject: Incident Report of Unapproved Research
Attachments: Incident-Reporting - CBS on behalf of Hutchinon Clinic P.A. 07-24-2020.pdf; IBC Report and CAPA.pdf

To whom it may concern,

Please find attached an Incident Report of unapproved research, conducted in violation of the *NIH Guidelines*, at the Hutchinson Clinic, P.A., located in Hutchinson, KS.

I am submitting this Report in my capacity as chair of the externally administered Institutional Biosafety Committee for this Institution.

Please let me know if any additional information or actions on our part are required in this matter.

Sincerely,

David

DAVID W. EMERY, PhD
Director of IBC Operations
Clinical Biosafety Services
16759 Main St., Suite #208
Wildwood, MO 63040
O: 888-442-2472 ext. 703 | C: Redacted by agreement
E: demery@clinicalbiosafety.com | W: clinicalbiosafety.com



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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, August 13, 2020 1:46 PM
To: Cook, Susan; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report

Dear Dr. Susan Cook,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Cook, Susan <shcook@wustl.edu>
Sent: Monday, July 27, 2020 3:22 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Incident report

I am attaching a report of an incident in a BSL3 laboratory. Please let me know if you have any questions or need any additional information.

-Susan

Susan Cook, PhD, CBSP
Director, Office of Biological Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: shcook@wustl.edu; Web: ehs.wustl.edu
(pronouns: she/her/hers)

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Washington University in St. Louis
Date of Report:	July 27, 2020
Reporter name and position:	Susan Cook, Biosafety Officer
Telephone number:	314-747-0309
Email address:	shcook@wustl.edu
Reporter mailing address:	660 South Euclid Ave Campus Box 8229 St. Louis, MO 63110
Date of incident:	7/24/2020
Name of Principal Investigator:	Christina Stallings
Is this an NIH-funded project?	X YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* R01 AI132697 *NIH funding institute or center:* NIAID *NIH program officer (name, email address):* Eichelberg, Katrin, KEICHELBERG@niaid.nih.gov

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☒ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒ YES ☐ NO If yes, date of approval: Most recent renewal approved 6/22/2020
What was the approved biosafety level of the research?	☐ BL1 ☐ BL2 ☐ BL2+ (describe specific enhancement in report) ☒ BL3 ☐ BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ Funding agency/sponsor ☐ USDA ☐ State or local Public Health ☐ FDA ☐ Law enforcement ☐ EPA ☐ Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Mycobacterium tuberculosis, Erdman strain, carrying a plasmid expressing GFP and kanamycin resistance.

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

On the afternoon of 7/24/2020, a post-doc entered the BSL3 and noticed that a roller bottle used for growing Mycobacterium tuberculosis had leaked inside the incubator. He immediately exited and posted a "do not enter" sign on the door to the BSL3. He notified the PI, who waited 30 minutes before entering to clean the spill by wiping down all surfaces with Vesphene and leaving Vesphene-soaked towels on the incubator surfaces for approximately two hours. Following the Vesphene treatment, all surfaces were rinsed with water to remove the Vesphene residue.

All individuals who have entered the BSL3 between the time the roller bottle was loaded and the discovery of the leak were wearing appropriate personal protective equipment, including powered air-purifying respirators. They will also undergo Tb testing in a month to determine if any exposure occurred. (Of note, all Tb researchers are tested twice a year regardless of overt incidents in the lab.)

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Has the IBC reviewed this incident?	☒YES ☐NO The IBC chairs were notified on 7/24/2020. This will be discussed with the full committee at 8/19/2020 meeting.
Please describe the root cause of this incident:	The leak appears to have been caused by a failure of the roller bottle.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Following established protocol, the bottle was pre-rolled for two hours with only media and no leaks were detected. It is possible that there was a very slow leak that the pre-rolling did not identify or that the bottle developed the leak after the pre-rolling stage. The PI will remind all lab members to be very thorough when examining the bottles.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

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Hunter, Renee (NIH/OD) [C]

From: Cook, Susan <shcook@wustl.edu>
Sent: Monday, July 27, 2020 3:22 PM
To: NIH guidelines
Subject: Incident report
Attachments: Incident-Report-WUSTL-200724.docx

I am attaching a report of an incident in a BSL3 laboratory. Please let me know if you have any questions or need any additional information.

-Susan

Susan Cook, PhD, CBSP
Director, Office of Biological Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: shcook@wustl.edu; Web: ehs.wustl.edu
(pronouns: she/her/hers)

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Harris, Kathryn (NIH/OD) [C]

From: Rengarajan, Kalpana <krengar@emory.edu>
Sent: Wednesday, August 5, 2020 8:14 AM
To: NIH guidelines; Harris, Kathryn (NIH/OD) [C]
Cc: Thomaston, Scott W; Lyon III, G Marshall
Subject: Incident

Good morning. A researcher had a needle stick while using INA-6 cells stably transduced with a green fluorescent protein to inject a mouse. A detailed report will be submitted soon.

Thank you

Kalpana



Kalpana Rengarajan, Ph.D, MPH, JM, RBP (ABSA)
Director- Research Safety, Biosafety Officer
Environmental Health and Safety Office
Emory University
1762 Clifton Road NE, Suite 1200
Atlanta, GA 30322

Phone: (404)727-8863
Cell: Redacted by agreement
FAX: (404) 727-9778

You may visit www.ehso.emory.edu for updated information.

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Harris, Kathryn (NIH/OD) [C]

From: Sarah Byers <byerssa@ohsu.edu>
Sent: Thursday, July 2, 2020 7:40 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Kara Drolet
Subject: OHSU initial report of two incidents

Dear Dr. Harris,

This email serves as the initial notification of two potential exposures that occurred on 6/24/2020 at Oregon Health & Science University.

1. A staff member was splashed in the eye while working with two non-human primates that had been infected with a recombinant SIV.
2. A staff member was cut on the arm while working with a non-human primate that had been infected with a recombinant SIV.

My apologies for the delay in initial reporting. A complete report of the incident and follow up will be provided at a later date.

Sarah

Sarah A. Byers, PhD
IBC Program Manager
Research Integrity Office (ORIO)
Oregon Health & Science University
503-494-9763
byerssa@ohsu.edu

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Harris, Kathryn (NIH/OD) [C]

From: Sarah Byers <byerssa@ohsu.edu>
Sent: Thursday, July 2, 2020 7:40 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Kara Drolet
Subject: OHSU initial report of two incidents

Dear Dr. Harris,

This email serves as the initial notification of two potential exposures that occurred on 6/24/2020 at Oregon Health & Science University.

1. A staff member was splashed in the eye while working with two non-human primates that had been infected with a recombinant SIV.
2. A staff member was cut on the arm while working with a non-human primate that had been infected with a recombinant SIV.

My apologies for the delay in initial reporting. A complete report of the incident and follow up will be provided at a later date.

Sarah

Sarah A. Byers, PhD
IBC Program Manager
Research Integrity Office (ORIO)
Oregon Health & Science University
503-494-9763
byerssa@ohsu.edu

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Harris, Kathryn (NIH/OD) [C]

From: Sarah Byers <byerssa@ohsu.edu>
Sent: Monday, July 13, 2020 7:33 PM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Kara Drolet
Subject: OHSU 7/11/2020 initial report of potential exposure

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 7/11/2020 at Oregon Health & Science University. A staff member cut their hand on a cage housing two non-human primates that had been infected with a recombinant SIV.

A complete report of the incident and follow up will be provided at a later date.

Sarah

Sarah A. Byers, PhD
IBC Program Manager
Research Integrity Office (ORIO)
Oregon Health & Science University
503-494-9763
byerssa@ohsu.edu

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UNIVERSITY OF MINNESOTA

Office of the Vice President for Research
Office of Biotechnology Activities Oversight

420 Delaware ST SE
D192 Mayo MMC 820
Minneapolis, MN 55455

E-mail: ibc@umn.edu
Main line: 612-626-2161
Fax: 612-626-6061 (shared)

August 11, 2020

Attention: Incident Reports
NIH Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20817
Phone: 301-496-9838
Email: NIHGuidelines@od.nih.gov

Dear NIH OSP Representative,

Please find attached a preliminary incident report from the University of Minnesota. The Incident Reporting Template has been completed with as much information as possible to meet an "immediate" reporting timeline.

The reported incident involved a spill of 1-2 ml that contained a risk group 2 recombinant Zika virus, but occurred in a BSL3 facility. Our University Health and Safety Department is performing an investigation into the incident. After a final report is submitted to the IBC office, a final incident report will be sent to the NIH-OSP.

If you have any questions about this information, please feel free to contact me.
Thank you.

Sincerely,

Redacted by agreement

Gregory Park, Ph.D.
Associate Director
Office of Biotechnology Activities Oversight
IBC Administration

c: Christopher Cramer
Masato Yamamoto
Frances Lawrenz
Betty Kupskay

Enc: NIH-OSP Preliminary Incident Report

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	X YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Minnesota
Date of Report:	08/11/2020
Reporter name and position:	Gregory Park, Associate Director IBC
Telephone number:	651-387-4585
Email address:	parkx479@umn.edu
Reporter mailing address:	420 Delaware ST SE D192 Mayo Memorial BLDG – MMC820 Minneapolis, MN 55455
Date of incident:	08/10/2020
Name of Principal Investigator:	Matthew Aliota
Is this an NIH-funded project?	☐ YES X NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure X Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	X YES ☐NO If yes, date of approval: 11/27/2018
What was the approved biosafety level of the research?	☐ BL1 ☐ BL2 ☐BL2+ (describe specific enhancement in report) X BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-A
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	A semi-solid spill of 1-2 mL occurred from a waste bag that consisted of agar plates that may have contained molecularly-barcoded Zika virus. This is a population of recombinant viruses produced from a Zika virus infectious molecular clone derived from the Puerto Rican isolate ZIKV-PRVABC59, in which a run of eight consecutive degenerate codons are used in a region of NS2A (amino acids 144–151) allows for every possible synonymous mutation to occur.

Obtained via FOIA by Judicial Watch Inc.

Redacted by agreement

DESCRIPTION OF INCIDENT:

A student worker in the BSL-3 facility was removing double-bagged waste from a waste container inside room [redacted] (Dr. Aliota's BSL-3 lab space). When the bag was lifted out of the waste bin, a small amount (1-2 mL) of solid agar waste dripped from the bag onto the floor. She proceeded to spray the bag with disinfectant prior to setting it in the containment corridor to prepare it for autoclaving. At that point, she noticed the spill on the floor and told the BSL-3 lab manager about it, as he was on the other end of the containment corridor. The student was instructed to stay in the containment corridor and she did not enter room [redacted] again. None of the spill/waste fell onto the student's clothing at any point. At this time, a graduate student in Dr. Aliota's lab entered room [redacted] wearing an N-95, and the BSL-3 lab manager asked her to lay paper towels on the spill and to pour Synergize disinfectant (quaternary ammonium product) onto the towels. The graduate student stayed in the room during the time that that the lab manager left to make a phone call to BSL-3 Program Director. The graduate student was asked to leave the room after the phone call and she exited using normal procedures. After 30 minutes disinfectant contact time, the BSL-3 lab manager cleaned up the paper towels and placed them into an autoclave waste bin and the entire room was mopped with Synergize disinfectant and allowed 30 minutes contact time again. The waste bag (now in the containment corridor) was placed in a secondary container. The containment corridor where that bag rested on the floor momentarily also contained a small amount (1-2mL) of liquid from the same bag, and this was also covered with paper towels and Synergize disinfectant was placed on it. After 30 minutes contact time, these towels were cleaned up and the entire containment corridor was mopped with Synergize and allowed 30 minutes contact time again. Both student's and the lab manager's facility shoes were cleaned by stepping into liquid disinfectant placed on the floor and both showered out of the facility before exiting.

Redacted by agreement

Redacted by agreement

The PI, Dr. Aliota, was notified after the incident by the lab manager and the graduate student.

The lab manager reported the incident and a short investigation by the lab manager and Associate Director of the OBAO revealed that the semi-solid agar waste may have contained a recombinant Zika virus.

The spill occurred within the laboratory and there was no environmental release or breach of containment. Standard entry/exit procedures were followed and there were no equipment failures.

Has the IBC reviewed this incident?	☐ YES X NO
Please describe the root cause of this incident:	The incident is under investigation at this time.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet

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taken, please include a timeline for their implementation (use additional space as necessary):

The incident is under investigation at this time.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Gregory Park <parkx479@umn.edu>
Sent: Tuesday, August 11, 2020 5:02 PM
To: NIH guidelines
Cc: Chris Cramer; Frances Lawrenz; Masato Yamamoto; Betty Kupskay
Subject: NIH Guidelines-related incident report from U of MN
Attachments: Prelim NIH Incident Aliota 20200811.pdf

Dear NIH-OSP,
Please find attached a cover letter with a preliminary NIH incident report. Do not hesitate to contact me if you have any further questions.
Regards,
Greg

--
**Please note, the OBAO is currently working remotely
. The best way to contact the office is to send email to ibc@umn.edu. If you need to contact me directly, my contact information is below:

Redacted by agreement

Gregory Park, PhD
parkx479@umn.edu
[redacted] (mobile)
+1 651-636-0017 (home)

Associate Director
Office of Biotechnology Activities Oversight
https://research.umn.edu/units/obao
Office of the Vice President for Research

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Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Zara Llewellyn <zaral@uw.edu>
Sent: Thursday, August 6, 2020 12:38 PM
To: NIH guidelines
Cc: Zara Llewellyn
Subject: Incident Involving Recombinant Nucleic Acid at University of Washington

Dear NIH,

This message is to inform you that a laboratory worker experienced an injury while working with recombinant nucleic acid on August 4, 2020.

We will be investigating the incident and submitting a formal report to the NIH.

Please let me know if you have any questions before then.

Thank you,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager
Alternate Responsible Official
Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
Direct: 206.221.2676 | Main: 206.221.7770 | Fax: 206.221.3068
zaral@uw.edu | www.ehs.washington.edu

UNIVERSITY of WASHINGTON

This information is intended for the individual named above. If you are not the intended recipient, any disclosure, copying, distribution, or use of the contents of this information is prohibited. Please notify the sender by reply email and then destroy all copies of the message and any attachments.

The above email may contain patient identifiable or confidential information. Because email is not secure, please be aware of associated risk of email transmission. If you are a patient, communication to a UW Medicine (or applicable) Provider via email implies your agreement to email communication; see http://uwmedicine.washington.edu/Global/Compliance/Pages/Notice-Of-Privacy-Practices.aspx .

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Cardwell, Marissa M <marissa_cardwell@harvard.edu>
Sent: Thursday, July 30, 2020 9:59 AM
To: NIH guidelines
Cc: Reid, Angela
Subject: Initial report of incident at BL2 involving rDNA - Harvard University

To OSP:

I would like to make an initial report of an incident that occurred at Harvard University involving human cells transduced with a 3rd generation lentiviral vector carrying CRISPR/Cas9 components. While preparing for injection of these cells into rodents, a researcher sustained a needlestick.

We are gathering more details about the incident and will follow with a formal report early next week.

Please let me know if you have any further questions at this time.

Regards,
Marissa

Marissa M. Cardwell, PhD, RBP
Director of Laboratory Safety & Biosafety
Harvard University
Environmental Health & Safety
107 Avenue Louis Pasteur
Boston, MA 02115
Office: (617) 432-0022
Cell: Redacted by agreement
ehs.harvard.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Harvard University
Date of Report:	Initial e-mail notification: 7/30/2020 Formal written report: 8/3/2020
Reporter name and position:	Marissa M. Cardwell Director of Laboratory Safety & Biosafety
Telephone number:	(617) 432-0022
Email address:	marissa_cardwell@harvard.edu
Reporter mailing address:	Harvard University / EHS 107 Avenue Louis Pasteur Boston, MA 02115
Date of incident:	7/27/2020 (Biosafety office informed on 7/29/2020)
Name of Principal Investigator:	Dr. Joan Brugge
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☒Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐YES ☒NO The specific cell line and vector systems in use were not described in the registration.
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-3, III-D-4
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☒State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Exposure via needlestick to lung cancer cells (H1568) from ATCC previously transduced with a 3rd generation lentiviral vectors to produce a pool of cells with gene deletions. Cells first underwent transduction with lentiCas9-Blast. The vector expresses human codon-optimized *S. pyogenes* Cas9 protein and blasticidin resistance from EFS promoter. Cells were subsequently transduced with custom lentivirus based CRISPR pools (from Sigma) to introduce 350 guide RNAs into the cell line (targeting a total of 60 genes).

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

On July 27, 2020, a post doc stuck herself with a needle connected to a syringe being loaded with recombinant human cells. The cells were lung cancer cells (H1568) that had been transduced in two steps with 3rd generation lentiviral vectors. First, the cells were transduced with lentiviral vectors carrying human codon-optimized *S. pyogenes* Cas9 protein and blasticidin resistance from EFS promoter. This was followed by transduction with lenti-CRISPR pools (from Sigma) to introduce 350 guide RNAs into the cell (targeting a total of 60 genes). A mixed set of 58 genes were found to prevent growth of tumor cells in culture when knocked out by the CRISPR technology, plus the TSC1 and KCTD9 genes. The modified cells were kept in selection media for a week and expanded before injecting into the mouse.

When the incident occurred, the researcher was holding a chilled tube containing the lung cancer cells (H1568) in her left hand and a syringe in her right hand. She tried to pull up the cells from the tube through the needle into the syringe but encountered resistance. She took the needle out of the tube to adjust the plunger but missed while putting the needle back in the tube and pricked her left index finger. Upon feeling the needle strike the index finger of her left hand, the researcher doffed her gloves and verified the gloves had been punctured. The researcher proceeded to rinse the area with 70% ethanol. As only a small drop of blood appeared, the researcher donned new gloves and kept working. Upon completing work, the research notified the lab manager, who filed the incident report through Harvard's online reporting system. The lab manager recommended the researcher go to Harvard University Health Services, where she was seen by a physician and antibiotic ointment was applied. No further illness associated with this injury has been reported.

The incident occurred within a BL2-N animal facility on campus. At the time of the exposure, the researcher was wearing a hair bonnet, double shoe covers, Tyvek suit, and double gloves while working in a biological safety cabinet and following the standard operating procedures required by the animal facility for BL2-N work. The researcher attributed difficulty in hand-eye coordination and the coldness of the iced-cells to the exposure.

Harvard Biosafety was made aware of the incident on July 29, 2020. The biosafety officer immediately reached out to the researcher to glean more information (the initial report did not indicate the source of the cells nor the recombinant nature of the cells). The interview with the researcher revealed that the injury was an exposure to recombinant material. Upon further investigation, the biosafety office also determined the researcher and cell line she was using were not included on the laboratory's IBC registration.

Risk associated with exposure to these cells takes into account the source (human) and their genetic modifications. Packaged lentiviral vector used for the initial transduction of the cells would have likely been washed away prior to the initial injection into animals.

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Additionally, there is the low risk of exposure to bloodborne pathogens. The testing status of the specific lung cancer cells is unknown. It is unlikely that HBV or HIV would be present in the cells, as the lung cancer cell types do not support HIV entry or HBV replication. The laboratory is in compliance with the OSHA Bloodborne Pathogen Standard including offering the Hepatitis B vaccine to those with occupational risk. The researcher verified she was offered the vaccine.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The biosafety office notified the Principal Investigator that the person performing this work was not indicated on their IBC registration. In addition, although one lung cancer cell line and third generation lentiviral vectors were included in the IBC registration, the general category of lung cancer cell lines and the overall approach involving the specific vector utilized in the study associated with this incident were not included. The lab was required to cease all work with the recombinant cells until they are properly registered. The lab indicated confusion about registering the new work that was similar experimentally to previously approved work, genes of interest and cell lines. The biosafety officer clarified that new biological materials—such as use of new cell types, vector systems, and distinct classes of genes of interest—and techniques both warrant review, as the risks could change. An amendment to the registration was immediately filed to update the personnel listing and to add the cell line.

Following the incident, the biosafety officer explained the use of the occupational exposure hotline that is available 24/7 to the labs performing animal work. Proper emergency response protocols were reviewed with the researcher, including the need to wash the site of injury with soap and water instead of 70% ethanol, as this is not an effective disinfectant against all bloodborne pathogens.

The researcher completed initial training for biological safety on August 1, 2019 and has begun her annual refresher training for this course. Safe sharps practices and injury prevention are emphasized in the new biosafety refresher training. Other completed and relevant laboratory safety trainings for this individual are outlined below in Table A.

Course Title	Completion
General Laboratory Safety	01-AUG-2019
Laboratory Biosafety	01-AUG-2019

Table A. Trainings completed by the injured researcher.

The biosafety officer has discussed potential changes to work practices and sharps usage to minimize the risk of future sharps injuries, including switching to Luer lock syringes for drawing up the cells, with the needle being attached immediately prior to injection. The laboratory also

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agreed to a hands-free technique for extracting cells from the tube by utilizing a tube holder.

Has the IBC reviewed this incident?	☐YES ☒NO The incident will be reviewed at an upcoming meeting. However, the committee has been informed of the incident.
Please describe the root cause of this incident:	Human error and inattention to safe sharps practices were determined to be the root cause of this injury.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Cardwell, Marissa M <marissa_cardwell@harvard.edu>
Sent: Monday, August 3, 2020 3:45 PM
To: NIH guidelines
Cc: Reid, Angela; Brugge, Joan S.
Subject: RE: Initial report of incident at BL2 involving rDNA - Harvard University
Attachments: 2020_0803_NIH_Incident_Report_Brugge.pdf

To NIH/OSP:

Attached, please find the complete report detailing an incident at Harvard University involving exposure to transduced human cells at BL2. This report follows the initial notification to NIH/OSP made on 7/30/2020.

Please let me know if you have any questions.

Regards,
Marissa

Marissa M. Cardwell, PhD, RBP
Director of Laboratory Safety & Biosafety
Harvard University
Environmental Health & Safety
107 Avenue Louis Pasteur
Boston, MA 02115
Office: (617) 432-0022
Cell: Redacted by agreement
ehs.harvard.edu

From: Cardwell, Marissa M
Sent: Thursday, July 30, 2020 9:59 AM
To: NIHGuidelines@od.nih.gov
Cc: Angela Reid (angela_reid@harvard.edu) <angela_reid@harvard.edu>
Subject: Initial report of incident at BL2 involving rDNA - Harvard University

To OSP:

I would like to make an initial report of an incident that occurred at Harvard University involving human cells transduced with a 3rd generation lentiviral vector carrying CRISPR/Cas9 components. While preparing for injection of these cells into rodents, a researcher sustained a needlestick.

We are gathering more details about the incident and will follow with a formal report early next week.

Please let me know if you have any further questions at this time.

Obtained via FOIA by Judicial Watch Inc.

Regards,
Marissa

Marissa M. Cardwell, PhD, RBP
Director of Laboratory Safety & Biosafety
Harvard University
Environmental Health & Safety
107 Avenue Louis Pasteur
Boston, MA 02115
Office: (617) 432-0022
Cell: Redacted by agreement
ehs.harvard.edu

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Baumann, Richard (NIH/OD/ORS) [E]
Sent: Wednesday, July 29, 2020 11:28 AM
To: Harris, Kathryn (NIH/OD) [C]
Cc: Potts, Jeffrey (NIH/OD/ORS) [E]
Subject: OSP report: NIH Incident Report July 10, 2019
Attachments: OSP Incident Report NIH 2019 July 10 - Final.docx

Dear Kathryn,

I hope this email finds you well. A recent review over the last four years of incidents revealed one incident from July 2019 that involved a recombinant organism and research that was registered under the NIH Guidelines. I reported it (and the investigation follow-up) to the IBC at the September 2019 meeting, but apparently and regrettably failed to report it to the OSP. In my defense: one thing I can deduce is that we have an automated email alert system from our OMS incident module to let the BSO know immediately when certain incidents happen involving certain activities like rDNA, and apparently that failed because I have no record of this alert email. It is from those emails that I submit something preliminary to the OSP, usually. In my preparation for the September 2019 meeting, I obviously came across it in my review of July incidents that I report on, and I discussed this particular incident with the IBC as appropriate, however failed to also report it to OSP. My apologies for this late submission from last year, please find it attached.

Rick

Richard Baumann, Ph.D.
NIH Biological Safety Officer
Building 13; Rm. 3W-65
Bethesda, MD 20892
Off. 301-496-1987

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	National Institutes of Health (NIH), Bethesda campus
Date of Report:	July 28th, 2020 (#101674) FINAL
Reporter name and position:	Richard G. Baumann, Ph.D. Biological Safety Officer
Telephone number:	301-496-1987 (office)
Email address:	baumannrg@mail.nih.gov
Reporter mailing address:	Division of Occupational Health and Safety Building 13; Rm. 3W-65
Date of incident:	July 10th, 2019
Name of Principal Investigator:	Soohyun Lee
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: December 7th, 2016
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-3-a / III-D-4-a
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Genetically modified G deleted replication incompetent rabies virus SAD B19(deltaG)

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of

Obtained via FOIA by Judicial Watch Inc.

the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

While using pipette with manufactured genetically modified rabies virus sourced from Salk Institute GTTT Core (SAD B19 dG) employee did not remove pipette from plunger and did not place the pipette in sharp container prior to turning from the cabinet. Pipette had only 0.5

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microliters. Put pipette on capillary tube holder, turned around to replug the electric cord in order to retract plunger, and the tip of pipette penetrated tyvek lab coat and clothing covering stomach and made small wound in abdomen. Pipette contained residual amount of attenuated replication-incompetant rabies virus and healthy mouse brain tissue.

The laboratory was registered for this work and the worker was a veteran with over 14 years of experience and was trained directly by the PI with at least 2 years performing these types of injections. The worker was wearing appropriate PPE laboratory attire including a tyvec labcoat, hair bonnet, protective eyewear, and nitrile gloves and was up to date with their laboratory training having last completed it 2/27/2019.

In discussion, it was found the laboratorian was perhaps overconfident due to the repetitive procedure and also excited and rushing through the work over the good results of the experiment

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO December 7th, 2016
Please describe the root cause of this incident:	Root cause for this incident was not following the correct procedure to remove the pipette immediately after use and before turning to re-plug in the instrument, also there was complacency in performing the repetitive procedure and possible rushing due to favorable results.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Safety has spoken with the employee and also with the Principal Investgator (PI), to review all proper procedures for handling the pipettors during this procedure. SOPs were reviewed.

Prevention recommendations (What can be done to prevent this incident from happening again?):

- Slow down for awareness and take breaks if necessary, during highly repetitive operations
- **Remove pipette from plunger and place pipette in sharps container before removing plunger from device or turing away from the BSC for other tasks.**
- **Don't remove plunger with pipette in place.**

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Harris, Kathryn (NIH/OD) [C]

From: Andrea D Hall <ahall@northwestern.edu>
Sent: Thursday, July 23, 2020 5:15 PM
To: NIH guidelines
Cc: Greg A Smith
Subject: Incident Report
Attachments: LABSAFE_Incident_Reports_2020_Savas_Ellwood_NIH_Report_FINAL_071520.pdf

Please find the attached incident report for Northwestern University. If you have any question, please feel free to contact me using the information below. Thank you.

Sincerely,
Andrea D. Hall, PhD, SM(NRCM), CBSP (she/her/hers)
Director, Research Safety Chicago Office
Biosafety Officer
Research Safety
Northwestern University
345 E. Superior St.
Suite 1522
Chicago, IL 60611
ahall@northwestern.edu
O: 312.503.8300
F: 312.503.0547
Office for Research Safety Website

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Northwestern University, Feinberg School of Medicine
Date of Report:	July 16, 2020
Reporter name and position:	Jeffrey Savas, Ph.D. Assistant Professor, Department of Neurology
Telephone number:	(312) 503-3089
Email address:	jeffrey.savas@northwestern.edu
Reporter mailing address:	**Jeffrey N. Savas, PhD** Assistant Professor Department of Neurology Northwestern University, Feinberg School of Medicine 303 East Chicago Avenue, Ward 12-102 Chicago, IL 60611-4296 Email: jeffrey.savas@northwestern.edu Web: http://www.savaslab.com/ Phone: 312-503-3089
Date of incident:	July 15, 2020
Name of Principal Investigator:	Jeffrey Savas, Ph.D. Assistant Professor, Department of Neurology
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known)

Obtained via FOIA by Judicial Watch Inc.

	NIH grant of contract number: *NIH funding institute or center:* *NIH program officer (name, email address):*

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval:
What was the approved biosafety level of the research?	☒BL1 ☐BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section IIID4
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☒Other (please describe): NU only ☐OSHA

Obtained via FOIA by Judicial Watch Inc.

Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	A C57/B6 mouse transduced an AAV (rh10) expressing GFP and a recombinant synaptic probe (intracranially injected one day before the bite).

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)

  Northwestern University, Feinberg School of Medicine, Biological safety cabinet in Ward Redacted by agreement (vivarium).

- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

  Female, laboratory technician in the Savas Lab.

  No one else was present.

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event

  Redacted by agreement was sent to Northwestern Medicine Corporate Health immediately after the incident. She was bit at 8:30am and was in the clinic from 9:26 – 10:35am.

  She was seen by Rasa R. Tijunelis, MD. Dr. Tijunelis cleaned the small and superficial bite on her left index finger.

- The training received by the individual(s) involved and the date(s) the training was conducted

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Redacted by agreement	TypeDate	Comment	Class	Type	Class Dates & Notes
	OHS 5/18/2020				
			2020 Orientation-Chicago	Orientation	5/20/2020
			2020 Rodent Euthanasia	Orientation	5/21/2020
			ALL- Aseptic Technique for Rodent Surviv	AALAS Learning Library	5/22/2020
			ALL- Intro to Rats	AALAS Learning Library	5/11/2020
			ALL- Microisolator Training	AALAS Learning Library	5/6/2020
			ALL- New Research Staff Orientation	AALAS Learning Library	5/6/2020
			ALL- Occupational Health and Safety	AALAS Learning Library	5/6/2020
			ALL- Pain Management in Lab Animals	AALAS Learning Library	5/22/2020
			ALL- Post Procedure Care of Mice and Rat	AALAS Learning Library	5/7/2020

Obtained via FOIA by Judicial Watch Inc.

ALL- Public Health Service Policy on Hum	AALAS Learning Library	5/6/2020
ALL- Working with Laboratory Mouse	AALAS Learning Library	5/11/2020

Redacted by agreement received in person training June 19th on the proper methods of mouse "scruffing" and IP injection. She has successfully performed this procedure more than 15 times and has been bitten only once.

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation

Redacted by agreement was following the proper SOP but failed to "scuff" the mouse and properly immobilize it. As a consequence, it could turn its' head and bite her left index finger.

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation

  N/A

- The personal protective equipment in use at the time of the incident/violation

Redacted by agreement was wearing the proper PPE (gown, face mask, and double nitrile gloves), she could have been wearing bite proof gloves.

- The occupational health requirements for laboratory personnel involved in the research

  None – return to regular duty. However Redacted by agreement took the remainder of the day off to recuperate.

- Any medical surveillance provided or recommended after the incident

  The MD suggested that she monitor the wound for signs of infection and go to urgent care if fever, swelling, drainage, tenderness, difficulty using hand appears.

- Any injury or illness associated with the incident

Obtained via FOIA by Judicial Watch Inc.

Superficial bite on the left index finger, initial encounter (S60.471A).

- Equipment failures

N/A

DESCRIPTION OF INCIDENT: (use additional space as necessary)

While scruffing a mouse with her left hand, and performing IP injection with the right, the mouse began to fidget and bit left index finger through double gloved hand and caused minimal skin breakage.

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Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Improper scruffing of the mouse.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The IBC discussed the incident at our monthly meeting on Wednesday, July 22, 2020. The IBC agreed that the root cause of the incident was improper handling of the mouse and agreed with the PIs actions of retraining the lab technician and providing additional oversight when she's working with the mice. No further action was taken against the PI. The BSO will submit the incident report to NIH OSP.

Obtained via FOIA by Judicial Watch Inc.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, August 26, 2020 3:35 PM
To: Wilson, Zachary R; NIH guidelines
Cc: Finucane, Marcia; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: rDNA incident report- CU Anschutz

Dear Zachary Wilson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Wilson, Zachary R <ZACHARY.WILSON@CUANSCHUTZ.EDU>
Sent: Tuesday, August 18, 2020 7:35 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Finucane, Marcia <MARCIA.FINUCANE@CUANSCHUTZ.EDU>
Subject: rDNA incident report- CU Anschutz

Hello,
Please find attached an incident report form for an incident involving rDNA at CU Anschutz on 13Aug2020. Let us know if you have any further questions or requests.
Thank you,

Zachary R. Wilson, MS, CBSP
Assistant Biological Safety Officer
CU Denver | Anschutz Medical Campus
Environmental Health and Safety
1784 Racine St. Mailstop F484, Bldg 401, Rm. 204, Aurora, CO 80045
Voice (303) 724-5954 | Mobile Redacted by agreement
zachary.wilson@cuanschutz.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

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This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Colorado Denver | Anschutz Medical Campus
Date of Report:	18Aug2020
Reporter name and position:	Zachary Wilson, MS, CBSP Assistant Biological Safety Officer
Telephone number:	303-724-5954
Email address:	Zachary.Wilson@cuanschutz.edu
Reporter mailing address:	1784 Racine Street Mail Stop F484, Building 401 Aurora, CO 80045
Date of incident:	13Aug2020
Name of Principal Investigator:	Nicholas Foreman
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 27Aug2018
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	IIID4
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Material from mice that had been administered human T cells, transduced with a replication incompetent lentiviral vector made to express HER2 CAR, several months prior.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of

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the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: A male Professional Research Assistant was washing surgical tools that had been used during euthanization and surgery of mice the day prior. These mice

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had been administered human T cells, transduced with a lentiviral vector made to express HER2 CAR, several months prior. While washing tweezers in soapy water the individual's hand slipped and the tweezers pierced their glove and broke the skin of their index finger. The individual He then contacted the University Hospital Infectious Disease department for further medical evaluation.

The individual is up to date on all required university training such as Bloodborne Pathogens, Regulated Medical Waste and Lab Safety.

The individual is up to date on all Occupational Health requirements, including vaccines.

The individual and PI have been instructed to disinfect any surgery tools immediately after use and before washing in soap and water.

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Has the IBC reviewed this incident?	☐YES ☒NO IBC meeting on 24Aug2020
Please describe the root cause of this incident:	Lack of proper disinfection of surgical tools. Was not careful while cleaning tools.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The individual and PI have been instructed to disinfect any tools that may be contaminated with biological hazards, such as rDNA and BBP, prior to cleaning. Individual has been reminded to take more care while cleaning tools.

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- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Wilson, Zachary R <ZACHARY.WILSON@CUANSCHUTZ.EDU>
Sent: Tuesday, August 18, 2020 7:35 PM
To: NIH guidelines
Cc: Finucane, Marcia
Subject: rDNA incident report- CU Anschutz
Attachments: NIH Incident Report CU Anschutz 18Aug2020.docx

Hello,
Please find attached an incident report form for an incident involving rDNA at CU Anschutz on 13Aug2020. Let us know if you have any further questions or requests.
Thank you,

Zachary R. Wilson, MS, CBSP
Assistant Biological Safety Officer
CU Denver | Anschutz Medical Campus
Environmental Health and Safety
1784 Racine St. Mailstop F484, Bldg 401, Rm. 204, Aurora, CO 80045
Voice (303) 724-5954 | Mobile Redacted by agreement
zachary.wilson@cuanschutz.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, August 26, 2020 3:21 PM
To: Trucks, Holley M.; NIH guidelines
Cc: Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Injury report

Dear Holley Trucks,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Trucks, Holley M. <holley.trucks@uky.edu>
Sent: Wednesday, August 19, 2020 4:27 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Subject: Injury report

Dear OSP,

Please see the attached injury report.

Best regards,

Holley

****

Obtained via FOIA by Judicial Watch Inc.

Holley Trucks, MPH, RBP (ABSA), MT(AAB)

Assistant Biological Safety Officer

University of Kentucky

Department of Biological Safety
505 Oldham Court
Lexington, KY 40502-0473
Office: (859) 257-8655
Cell: Redacted by agreement
Fax: (859) 323-3838
Email: hmtr222@uky.edu
Website: http://ehs.uky.edu/biosafety/

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Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	**X** YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Kentucky
Date of Report:	8/18/2020
Reporter name and position:	Brandy Nelson, Biosafety Officer
Telephone number:	859-257-1049
Email address:	brandy.nelson@uky.edu
Reporter mailing address:	University of Kentucky Department of Biological Safety 505 University of Kentucky Lexington, KY 40502
Date of incident:	8/13/20
Name of Principal Investigator:	Olivier Thibault
Is this an NIH-funded project?	**X** YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* **AG033649** *NIH funding institute or center:* **National Institute on Aging** *NIH program officer (name, email address):* **Brad Wise, wiseb@NIA.NIH.gov**

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill **X** Other (please describe): Animal bite from animal previously administered recombinant nucleic acid materials
Did the Institutional Biosafety Committee (IBC) approve this research?	**X** YES ☐NO If yes, date of approval: 2/14/2020
What was the approved biosafety level of the research?	**X** BL1 for the activity during which the injury occurred ☐ BL2 ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	NIH Appendix C-II 13.1.2 NIH Appendix G-II-A 13.1.6 NIH Appendix C-I 13.1.7 NIH Section III-D-4-a 13.1.8 NIH Section III-F-8 13.1.9 NIH Section IV-B-7 13.1.10
Has a report of this incident been made to other agencies? If so, please indicate N/A	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	AAV9 for a calcium indicator (AAV.CamKII.GCaMP6s.WPRE.SV40, for map, see https://www.addgene.org/107790/)

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)

  Laboratory space Redacted by agreement where surgeries are typically conducted under ABSL1 conditions.

- Who was involved in the incident/violation, including others present at the incident location?

  Scientist (male, injured party) and 2 male graduate students

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event

  Squeezed blood out from the injury point, washed hand with running water, and then treated with an alcohol prep. The injury was then immediately reported by employee's supervisor to UK Worker's Care (per university SOP) as well as the department chair.

- The training received by the individual(s) involved and the date(s) the training was conducted

  Refresher: Working with the IACUC 2019-03-14
  AVMA Guidelines for the Euthanasia of Animals: 2013 Edition 2019-03-15
  Laboratory Animal Allergy 2019-03-15
  Bloodborne Pathogens, Researchers 2020-01-13
  Hazardous Waste, General 2020-01-13
  Chemical Hygiene Plan / Laboratory Safety - Refresher 2020-01-13
  Chemical Hygiene Plan / Laboratory Safety - General Awareness 2020-01-13

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation

  No deviation from laboratory and IACUC mouse injection SOP's
  Intraperitoneal (IP) Injection SOP for rats (University of Kentucky Department of Lab Animal Resources): When restraining the mouse or rat, you should have the animal's body tilted at an angle with the head pointing down to allow the organs to fall slightly forward. injections should be given in the lower quadrant of the mouse just to the left of the midline. You should always aspirate prior to injection to be certain that you are not in a vital organ or a blood vessel. You should use as short a needle as possible to avoid damage to internal organs.

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- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation

  None

- The personal protective equipment in use at the time of the incident/violation

  Mask, gloves, lab coat, eye glasses.

- The occupational health requirements for laboratory personnel involved in the research

  Per Occupational Health and the Department of Laboratory Animal Resources directives for working with laboratory animals: "ALWAYS wear gloves and other personal protective clothing as indicated while handling animals. Wash your hands before leaving the area or use the hand sanitizers located throughout the facility… Avoid injury by learning how to properly handle and restrain animals; if you are unsure about correct procedures or need assistance, ask at the DLAR office, or contact the DLAR Training Coordinator to arrange for training in the procedures. If you are bitten or scratched, regardless of the perceived severity of the injury: ⟨ Clean the injured area appropriately, remembering that any bite or scratch wound can easily become infected. ⟨ Report the accident to an Animal Care Supervisor as well as your own Supervisor, lab manager or Principal Investigator. ⟨Contact UK Workers Care for further instructions 1-800-440-6285. ⟨ Remember that ALL accidents regardless of the severity should be reported to UK Environmental Health and Safety. If the injury involves an animal bite or other injury, you must fill out the Accident Report involving animal injury and forward it to the UK Biosafety officer. https://ehs.uky.edu/ohs/accident.php"

- Any medical surveillance provided or recommended after the incident

  Employee visited the UK Health Services as directed by Worker's Care.

- Any injury or illness associated with the incident

  None

- Equipment failures

  None

DESCRIPTION OF INCIDENT: (use additional space as necessary):

Employee was bitten on the left pinky finger while administering an intraperitoneal injection of anesthesia cocktail to an experimental rat. The lab rat had been intracranially administered AAV expressing a protein calcium sensor close to a month prior to the bite incident (on July 16, 2020).

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Has the IBC reviewed this incident?	☐YES XNO **Will be reviewed at the 9/2/20 meeting**
Please describe the root cause of this incident:	The bite was a simple accident. The root cause may be a need for improvement in animal handling. This is being evaluated.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The injured individual followed all procedures related to the IP injection and incident follow-up properly. This incident indicates that there may be potential for improvement in our current practices. The BSO is working with one of UK's research veterinarians to determine if puncture resistance gloves would be an appropriate safety measure to adopt for this procedure or if simply changing stabilizing hand position would be possible. Exploration of this will also include input from the affected lab to ensure the procedure could still be effectively carried out with that additional PPE in place. Review of the procedure and determination if additional safety measures are necessary will occur over the next several months.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Trucks, Holley M. <holley.trucks@uky.edu>
Sent: Wednesday, August 19, 2020 4:27 PM
To: NIH guidelines
Subject: Injury report
Attachments: 2020-0819 University of Kentucky Injury Report.pdf

Dear OSP,

Please see the attached injury report.

Best regards,

Holley

****

Holley Trucks, MPH, RBP (ABSA), MT(AAB)
Assistant Biological Safety Officer

University of Kentucky
Department of Biological Safety
505 Oldham Court
Lexington, KY 40502-0473
Office: (859) 257-8655
Cell: Redacted by agreement
Fax: (859) 323-3838
Email: hmtr222@uky.edu
Website: http://ehs.uky.edu/biosafety/

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Please consider the environment before printing this email.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, September 3, 2020 3:24 PM
To: Coulson, Garry Brian; NIH guidelines
Cc: Cyr, Douglas M.; Brennan, Catherine; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident Report - FINAL

Dear Dr. Garry Coulson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and no further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Tuesday, August 25, 2020 12:59 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>
Subject: RE: NIH Incident Report - FINAL

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a potential exposure involving recombinant DNA that occurred in a BSL-1 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

From: Coulson, Garry Brian
Sent: Thursday, August 20, 2020 5:49 PM
To: NIH guidelines <NIHGuidelines@od.nih.gov>

Obtained via FOIA by Judicial Watch Inc.

Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of an exposure to recombinant DNA involving a needlestick received by a worker from a syringe used to inject mice with a recombinant replication-defective AAV vector (risk group 1).

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of North Carolina at Chapel Hill
Date of Report:	08/24/2020
Reporter name and position:	Garry Coulson, Biosafety Officer
Telephone number:	919.962.5722
Email address:	garry.coulson@ehs.unc.edu
Reporter mailing address:	Environment, Health and Safety 1120 Estes drive Campus Box 1650 Chapel Hill, NC 27599
Date of incident:	08/17/2020
Name of Principal Investigator:	Dr. Jiandong Liu
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 04/19/2019
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Replication-incompetent RG1 adeno-associated viral vector (rAAV9.TNNT2) expressing green fluorescent protein (GFP)

Obtained via FOIA by Judicial Watch Inc.

Description of the incident:

At approximately 2:00 pm on Monday, August 17, 2020 the Researcher was cleaning up their work area after completing an animal experiment within a biosafety cabinet (BSC) when the incident occurred. For personal protective equipment (PPE), the Researcher was wearing the prescribed PPE for the space, including a surgical gown and a pair of nitrile gloves. While cleaning up the BSC, the Researcher attempted to recap and dispose of a used tuberculin syringe in the sharps container outside the BSC when the needle missed the cap and pricked the Researcher's left index finger.

The syringe had previously been used to inject a replication-deficient adeno-associated viral vector (rAAV9.TNNT2 vector) expressing GFP into a wildtype neonatal mouse.

Immediately following the incident, the Researcher disposed of the needle in the sharps container and exited the BSC, removed their PPE, and proceeded to the closest sink where the Researcher washed the wound with soap and water for approximately 30 seconds. The Researcher then returned to their main laboratory and discussed the incident with the Laboratory Manager. The Laboratory Manager advised the Researcher to call the University Employee Occupational Health Clinic (UEOHC) to report the incident. The Researcher reported the incident to the UEOHC.

The Researcher was up-to-date and compliant on all their requisite EHS training and had completed the UNC Mouse Handling course.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC is aware of this incident and will discuss it at the next meeting on 9/2/2020.
Please describe the root cause of this incident:	The Researcher attempted to recap a needle.

Obtained via FOIA by Judicial Watch Inc.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As part of the corrective and preventative actions to be taken, an internal Incident Report will be submitted from the Department of Environment, Health and Safety (EHS) to the Principal Investigator (PI) detailing the incident and including recommendations for the lab to follow to mitigate future reoccurrence of the incident.

While the Researcher was performing all duties according to established laboratory procedure and wearing the required PPE for the laboratory, as part of our Incident Report, we will require the PI to review with their lab an internal safety PDF on “Preventing Cuts and Punctures” and Chapter 3 of the Laboratory Safety Manual which stress the importance of good sharps safety practices, including not recapping syringes prior to disposal in sharps containers. If recapping is required or unavoidable for a particular procedure, a mechanical device or one-handed technique should be used. Additionally, it will be recommended to the PI to ensure that the sharps container is placed inside the BSC, and not outside, to avoid moving uncapped syringes out of the BSC and over greater distances increasing the risk for accidental needlestick. The PI will also be required to review “Hand Washing” described in the UNC Biological Safety Manual with their lab.

The expected date of completion for the recommendations will be 9/4/2020.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Tuesday, August 25, 2020 12:59 PM
To: NIH guidelines
Cc: Cyr, Douglas M.; Brennan, Catherine
Subject: RE: NIH Incident Report - FINAL
Attachments: NIH Incident Report_08252020.pdf

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a potential exposure involving recombinant DNA that occurred in a BSL-1 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

From: Coulson, Garry Brian
Sent: Thursday, August 20, 2020 5:49 PM
To: NIH guidelines <NIHGuidelines@od.nih.gov>
Cc: Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Brennan, Catherine <crbrennan@ehs.unc.edu>
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of an exposure to recombinant DNA involving a needlestick received by a worker from a syringe used to inject mice with a recombinant replication-defective AAV vector (risk group 1).

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Hunter, Renee (NIH/OD) [C]

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We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Wednesday, August 26, 2020 3:15 PM
To: Harding, Beverly; NIH guidelines
Cc: IBO; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Guidelines - Incident Reporting for UPitt IR-20-03

Dear Beverly Harding,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP, NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Harding, Beverly <beverlyh@pitt.edu>
Sent: Thursday, August 20, 2020 4:42 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: IBO <ibo@pitt.edu>
Subject: NIH Guidelines - Incident Reporting for UPitt IR-20-03

Dear OSP staff,

Attached please find an incident report and corresponding summary for the University of Pittsburgh.

Thank you,
Beverly Harding, MSL
Director, IBC Office
University of Pittsburgh
beverlyh@pitt.edu or ibo@pitt.edu

Obtained via FOIA by Judicial Watch Inc.

Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to the IBC and the NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to the IBC and the NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible.

Send completed reports to the University of Pittsburgh IBC Office at ibo@pitt.edu

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the appropriate agency; They are no longer required to be sent to the IBC.

Email this completed form to the IBC Office at ibo@pitt.edu

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	National Institute on Drug Abuse
Date of Report:	July 16th, 2020
Reporter name and position:	Yan Dong, Professor at Department of Neuroscience
Telephone number:	Cell: 412-537-7279
Email address:	yandong@pitt.edu
Reporter mailing address:	Langley Hall A 210 Department of Neuroscience University of Pittsburgh, Pittsburgh, PA 15260
Date of incident:	July 16th 2020
Name of Principal Investigator:	Yan Dong
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number: DA047861; DA040620* *NIH funding institute or center: NIH-NIDA* *NIH program officer (name, email address): Roger Sorensen; rsorense@mail.nih.gov*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☒Other (please describe): worked under expired IBC protocol
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 2/5/2019
What was the approved biosafety level of the research?	☒BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Vertebrate animal research
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Using adeno-associated virus 2 for in vivo gene expression.

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Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident

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- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Our IBC protocol (IBC201800052, approved on 2/5/2019) became expired and was closed on 4/12/2020. However, due to the ignorance of the PI (Yan Dong), it was not renewed in time. We did not realize this until today, when I checked my IBC status and found it was closed. I also fund the emails that reminded me to renew this protocol, but unfortunately, was ignored at that time.

Without knowing that this IBC protocol was closed, 3 lab members (postdoctoral fellows) continued their animal research after lab was re-opened. They injected AAV2 into ~12 mice about 3 weeks ago. These surgeries were performed in the Redacted by agreement surgery room within the LSA animal facility in Redacted by agreement (our designated animal space).

As soon as I realized this incident, I took a series of immediate actions. First, I emailed everybody in the lab to stop all the experiments that are supposed to be covered by the IBC protocol. Second, I contacted the IBC office and discussed the incident with Beverley to try to mitigate the impact. Third, I communicated with Dr. Debbie Chapman, Director of the Pitt IACUC, who has been working with us to sort out how to treat the animals that have already received viral injections. Forth, I scheduled a lab meeting tomorrow, in which I plan to go through the incident, apologize for my mistake, and use this incident to educate me and the rest of the lab. Fifth, we quickly submit a new application of the IBC protocol.

By submitting the new protocol, I have also asked everybody in the lab to complete all the related trainings indicated by the IBC website.

There was no deviation from our SOPs.

There was no violation in PPE use.

There was no violation in occupational health requirement.

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There was no violation in medical surveillance.

There was no injury or illness related to this incident.

There was no equipment failure.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☐YES ☒NO
Please describe the root cause of this incident:	This is completely my (PI) fault for ignoring the renewal request in the first place. Retrospectively, although there were enormous distractions such as managing lab lockdown, animal transfer, personnel safety education, and other chaotic events, when the reminding email was sent to me, they should NOT be the reasons for me to ignore this important renewal task. The root cause is that I failed my role as an effective PI this time.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As soon as we realized this violation, we stopped all operations that should be covered by this IBC protocol.

We are in the middle of discussion with the IACUC team how we should treat the animals that have received viral injections after the IBC protocol expired.

We submitted a new IBC protocol application.

We will have a specific lab meeting tomorrow to educate everybody, particularly myself, through discussion of this incident.

I requested everybody (including myself) to re-take the IBC training over the next two weeks.

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- ***Additional information may be requested by the IBC or NIH OSP after review of this report depending on the nature of the incident.***

- **Submitting this completed template to the IBC does NOT fulfill the reporting requirements of other compliance units or federal agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

August 20, 2020

Dear Dr. Harris/NIH OSP Incident Reporting,

The attached follow-up report (IR-20-03) is to inform the NIH OSP of the IBC deliberation of violations of the *NIH Guidelines* Sections *IV-B-2-a-(5)*, *IV-B-2-b-(4)* and reporting under Section *IV-B-2-b-(7)*.

The incident was reviewed at the August 10, 2020 IBC meeting. The initial reporting form was reviewed by the committee.

To summarize the incident (IR-20-03), the University of Pittsburgh's IBC became aware that the investigator failed to maintain approval for recombinant research, as it had expired in the midst of the closure of all research at UPitt from the COVID-19 pandemic emergency situation. Work continued without appropriate approvals in place.

Correspondence was sent to the investigator with instructions that any research involving the updated recombinant agents must be immediately ceased as there was no IBC approval for work with the recombinant materials and that the investigator must re-apply for IBC review as soon as possible.

The investigator provided the incident report and provided assurance to the committee that it was an error. In addition, the investigator provided a new research application which was sent out for initial review by members of the committee.

With respect to the violation, the committee was satisfied with the response from the investigator to prevent any future such occurrences, and that once the investigator has obtained approval of the application currently under review, that the research may be allowed to continue.

If there are any additional questions, please feel free to contact me.

Sincerely yours,

Beverly Harding, MSL
Director, IBC Office
University of Pittsburgh
Email: beverlyh@pitt.edu ; ibo@pitt.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Harding, Beverly <beverlyh@pitt.edu>
Sent: Thursday, August 20, 2020 4:42 PM
To: NIH guidelines
Cc: IBO
Subject: NIH Guidelines - Incident Reporting for UPitt IR-20-03
Attachments: IR-20-03 UPitt Report Summary 08-20-20.doc; IR-20-03 Y. Dong Incident Report Form 07-17-20.docx

Dear OSP staff,

Attached please find an incident report and corresponding summary for the University of Pittsburgh.

Thank you,
Beverly Harding, MSL
Director, IBC Office
University of Pittsburgh
beverlyh@pitt.edu or ibo@pitt.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, October 15, 2020 2:59 PM
To: Antony Schwartz, PhD; NIH guidelines
Cc: Frothingham, Richard; Wayne Thomann; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Final report: Percutaneous exposure to an AAV vector

Dear Dr. Antony Schwartz,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and no further information about this incident is required at this time.

However, we note that medical evaluation was not sought until after the researcher completed their work. We recommend reminding employees they should consult with or be evaluated by a medical care provider as soon as possible after an exposure incident in case treatment is warranted. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Antony Schwartz, PhD <antony.schwartz@duke.edu>
Sent: Sunday, September 20, 2020 11:25 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Frothingham, Richard <richard.frothingham@duke.edu>; Wayne Thomann <wayne.thomann@duke.edu>
Subject: Final report: Percutaneous exposure to an AAV vector

Dear Dr. Harris,

I am writing to provide a final report on a percutaneous exposure to a Duke researcher to an AAV vector. The event occurred on Monday, August 31, 2020 at approximately mid-day in the Duke vivarium. I sent you a preliminary report immediately on August 31, 2020 via email.

Event: A Duke researcher was preparing an insulin syringe with AAV vector material for an intramuscular injection into the tibialis anterior muscle of mice. Individual has been trained in this procedure and has performed it over 50 times already. The mice were under sedation. The syringe contained AAV vector with CRISPR/Cas9 and guide RNA targeting the mouse version of the gene encoding the protein involved in DMD, aka Duchenne Muscular Dystrophy. The researcher loaded approximately 40ul of material into the syringe and was attempting to remove air bubbles by flicking the syringe. While doing so, the individual scratched the bottom of their middle finger on the right hand. The scratch was very minor and a tiny amount of blood was visible at the site of the needle stick.

Obtained via FOIA by Judicial Watch Inc.

First aid and employee health response: The researcher immediately removed the double pair of gloves they were wearing and washed their hands thoroughly with soap and water. After donning new pairs of gloves and completing their work. Then the individual completed a worker injury report using the web form the same afternoon. The researcher was contacted by a Duke Employee Health nurse immediately for a follow up. It was determined that no additional treatment was needed.

Material description and risk assessment: The IBC conducted a comprehensive risk assessment including features of the material and the circumstances of the exposure event.

- **AAV vector:** The AAV vector contained CRISPR/Cas9 and guide RNA targeting the mouse version of the DMD gene involved in Duchenne Muscular Dystrophy (DMD). CRISPR/Cas9 will be used to edit the DMD gene in transgenic mice exhibiting DMD. The guide RNA was designed with specificity to the murine gene. The CRISPR/Cas9 was modified at 3' end to prevent immune response to the bacterial Cas9. The IBC reviewed and approved the rDNA registration and Standard Operating Procedure (SOP) document at the time of registration. The SOP called for BL2 containment with enhancements, including confining all open container work to a biological safety cabinet (BSC), and the use of facility specific PPE, which in the Duke vivarium includes coveralls, shoe covers, face mask, hair bonnet and double gloves.
- **Clinical evaluation and management:** The researcher completed an online incident report and was immediately contacted by Duke Employee Health nurse. No laboratory tests or treatment were recommended. The researcher was advised to contact employee health if any symptoms or signs arise at the needle stick site, or if the researcher had further questions.
- **Risk assessment:** The reported event provided potential for the transfer of a small volume to the researcher's skin. The AAV vector has the capacity to enter human cells and express the gene products (Cas9 and gRNA). Expression of Cas9 in the presence of gRNA poses some potential for off-target modification of human DNA. AAV vectors integrate into the human genome at low frequency so pose minimal risk for insertional mutagenesis. Wild type AAV does not replicate in the absence of helper virus. AAV vectors are further attenuated by the lack of *rep* and *cap* genes. Based on these factors, the IBC considered this event to pose minimal risk to the researcher.

Safety evaluation: This research was covered by an approved rDNA registration with an accompanying SOP describing BSL2/ABSL2 containment for the animal work. The exposure is not expected to cause significant adverse effects.

Corrective action: The researcher was advised to use a mechanical device to flick the syringe to remove the air bubbles rather than using their fingers. The researcher was also advised to take time and think through the process each time when working with a loaded syringe with a needle. Additionally, the research stated that they were looking into buying needles that would have a protective sheath that prevents the fingers from accidentally coming into contact with the needle.

IBC review: The Duke IBC reviewed this event at the September 16, 2020 meeting. The IBC agreed with the risk assessment, safety evaluation, and corrective action outlined above.

Please contact me with any questions.

Best,
Antony Schwartz

Obtained via FOIA by Judicial Watch Inc.

Biological Safety Officer, Duke IBC

--

Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA)
Director, Biological Safety Division, OESO
Adjunct Assistant Professor, Dept. of Family Medicine and Community Health
Biological Safety Officer, Duke IBC
Responsible Official, Duke Select Agent Program

Hock Plaza I, Suite 204
2424 Erwin Road, Box #2738 DUHS
Durham, NC 27710
Phone: 919-684-8822 / Fax: 919-681-7509
antony.schwartz@duke.edu / https://www.safety.duke.edu/biological-safety

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Antony Schwartz, PhD <antony.schwartz@duke.edu>
Sent: Sunday, September 20, 2020 11:25 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Frothingham, Richard; Wayne Thomann
Subject: Final report: Percutaneous exposure to an AAV vector

Dear Dr. Harris,

I am writing to provide a final report on a percutaneous exposure to a Duke researcher to an AAV vector. The event occurred on Monday, August 31, 2020 at approximately mid-day in the Duke vivarium. I sent you a preliminary report immediately on August 31, 2020 via email.

Event: A Duke researcher was preparing an insulin syringe with AAV vector material for an intramuscular injection into the tibialis anterior muscle of mice. Individual has been trained in this procedure and has performed it over 50 times already. The mice were under sedation. The syringe contained AAV vector with CRISPR/Cas9 and guide RNA targeting the mouse version of the gene encoding the protein involved in DMD, aka Duchenne Muscular Dystrophy. The researcher loaded approximately 40ul of material into the syringe and was attempting to remove air bubbles by flicking the syringe. While doing so, the individual scratched the bottom of their middle finger on the right hand. The scratch was very minor and a tiny amount of blood was visible at the site of the needle stick.

First aid and employee health response: The researcher immediately removed the double pair of gloves they were wearing and washed their hands thoroughly with soap and water. After donning new pairs of gloves and completing their work. Then the individual completed a worker injury report using the web form the same afternoon. The researcher was contacted by a Duke Employee Health nurse immediately for a follow up. It was determined that no additional treatment was needed.

Material description and risk assessment: The IBC conducted a comprehensive risk assessment including features of the material and the circumstances of the exposure event.

- **AAV vector:** The AAV vector contained CRISPR/Cas9 and guide RNA targeting the mouse version of the DMD gene involved in Duchenne Muscular Dystrophy (DMD). CRISPR/Cas9 will be used to edit the DMD gene in transgenic mice exhibiting DMD. The guide RNA was designed with specificity to the murine gene. The CRISPR/Cas9 was modified at 3' end to prevent immune response to the bacterial Cas9. The IBC reviewed and approved the rDNA registration and Standard Operating Procedure (SOP) document at the time of registration. The SOP called for BL2 containment with enhancements, including confining all open container work to a biological safety cabinet (BSC), and the use of facility specific PPE, which in the Duke vivarium includes coveralls, shoe covers, face mask, hair bonnet and double gloves.
- **Clinical evaluation and management:** The researcher completed an online incident report and was immediately contacted by Duke Employee Health nurse. No laboratory tests or treatment were recommended. The researcher was advised to contact employee health if any symptoms or signs arise at the needle stick site, or if the researcher had further questions.
- **Risk assessment:** The reported event provided potential for the transfer of a small volume to the researcher's skin. The AAV vector has the capacity to enter human cells and express the gene products (Cas9 and gRNA). Expression of Cas9 in the presence of gRNA poses some potential for off-target

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modification of human DNA. AAV vectors integrate into the human genome at low frequency so pose minimal risk for insertional mutagenesis. Wild type AAV does not replicate in the absence of helper virus. AAV vectors are further attenuated by the lack of *rep* and *cap* genes. Based on these factors, the IBC considered this event to pose minimal risk to the researcher.

Safety evaluation: This research was covered by an approved rDNA registration with an accompanying SOP describing BSL2/ABSL2 containment for the animal work. The exposure is not expected to cause significant adverse effects.

Corrective action: The researcher was advised to use a mechanical device to flick the syringe to remove the air bubbles rather than using their fingers. The researcher was also advised to take time and think through the process each time when working with a loaded syringe with a needle. Additionally, the research stated that they were looking into buying needles that would have a protective sheath that prevents the fingers from accidentally coming into contact with the needle.

IBC review: The Duke IBC reviewed this event at the September 16, 2020 meeting. The IBC agreed with the risk assessment, safety evaluation, and corrective action outlined above.

Please contact me with any questions.

Best,
Antony Schwartz
Biological Safety Officer, Duke IBC

--
Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA)
Director, Biological Safety Division, OESO
Adjunct Assistant Professor, Dept. of Family Medicine and Community Health
Biological Safety Officer, Duke IBC
Responsible Official, Duke Select Agent Program

Hock Plaza I, Suite 204
2424 Erwin Road, Box #2738 DUHS
Durham, NC 27710
Phone: 919-684-8822 / Fax: 919-681-7509
antony.schwartz@duke.edu / https://www.safety.duke.edu/biological-safety

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Antony Schwartz, PhD <antony.schwartz@duke.edu>
Sent: Monday, August 31, 2020 4:27 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Wayne Thomann; Frothingham, Richard
Subject: Preliminary report: Needle stick exposure to AAV construct, August 31st, 2020

Dear Dr. Harris,
I just received a report of an exposure to a needle containing adeno-associated virus (AAV) serotype 9 with the genetic sequence for SaCas9 and a gRNA specific to the dystrophin gene in mice in a Duke University vivarium. The event occurred on August 31, 2020, and we are in the process of gathering information. Since this event occurred in a BL2 containment environment, I am writing now to provide an immediate report. We will gather complete information and will review this event at our next scheduled IBC meeting. I will provide a final report after that review.

Thank you,
Antony
--
Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA)
Director, Biological Safety Division, OESO
Adjunct Assistant Professor, Dept. of Family Medicine and Community Health
Biological Safety Officer, Duke IBC
Responsible Official, Duke Select Agent Program

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2424 Erwin Road, Box #2738 DUHS
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antony.schwartz@duke.edu / https://www.safety.duke.edu/biological-safety

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, October 15, 2020 9:22 AM
To: Michael I. Betteken; NIH guidelines
Cc: Debra A. Dwyer; Colin Ross Parrish; Esther R. Angert; Joshua E. Turse; Jonathan T. Butcher; Christine A. Bellezza; Mark Hurwitz; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Cornell University - Report of incident with potential 3rd generation lentivirus exposure

Dear Dr. Michael Betteken,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and no further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
Bethesda, MD
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Michael I. Betteken <mib46@cornell.edu>
Sent: Wednesday, September 23, 2020 9:11 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Debra A. Dwyer <dad3@cornell.edu>; Colin Ross Parrish <crp3@cornell.edu>; Esther R. Angert <era23@cornell.edu>; Joshua E. Turse <joshturse@cornell.edu>; Jonathan T. Butcher <jtb47@cornell.edu>; Christine A. Bellezza <cab37@cornell.edu>; Mark Hurwitz <mfh37@cornell.edu>
Subject: RE: Cornell University - Report of incident with potential 3rd generation lentivirus exposure

To whom it may concern:

Please find attached the incident report for the below described incident that occurred at Cornell University on August 30th as initially reported by our Biosafety Officer Josh Turse. Please let us know if you have any additional questions.

Thanks,
Michael

Michael I. Betteken, PhD
IBC - Administrator

Obtained via FOIA by Judicial Watch Inc.

Institutional Biosafety Committee
Office of Research Integrity and Assurance
Suite 320-H, East Hill Office Building
395 Pine Tree Rd
Mib46@cornell.edu

NOTE: I am currently working remotely but am happy to setup Zoom calls to discuss research needs

Cornell researchers, please refer to this webpage for continuity planning guidance in light of the COVID-19 outbreak.



CornellResearch

From: Joshua E. Turse <joshturse@cornell.edu>
Sent: Monday, August 31, 2020 12:54 PM
To: NIHGuidelines@od.nih.gov
Cc: Michael I. Betteken <mib46@cornell.edu>; Debra A. Dwyer <dad3@cornell.edu>; Colin Ross Parrish <crp3@cornell.edu>; Esther R. Angert <era23@cornell.edu>
Subject: Cornell University - Report of incident with potential 3rd generation lentivirus exposure

To whom it may concern:

I am the Biosafety Officer with Cornell University, Ithaca.

I am writing to inform that on the evening of Sunday, August 30, a researcher in one of our was using a biopsy punch to extract gels made of porcine lentiviral-transfected cells and was injured. The porcine cell line had been transfected with a 3rd generation lentiviral vector which had been passaged once since transfection. Between samples the researcher cleaned the punch with ethanol. It was after cleaning the punch that the researcher managed to scratch their index finger, drawing blood. Basic first aid was performed onsite, with a medical consultation scheduled for the morning of August 31.

This email serves as the immediate notification of an exposure to a genetically modified risk-group 2 material as required under the NIH Guidelines, Appendix G-II-B-2-k. Our IBC has been informed of the incident. We will complete the formal incident report using the template on the NIH Guidelines website within the next 30 days, by Wednesday September 30, 2020.

Best regards,

Josh Turse

Joshua E. Turse, PhD
Biological Safety Officer & Select Agent Program Responsible Official
Cornell University Environment, Health and Safety

o.607.255.9401|c.Redacted by agreement|ehs.cornell.edu

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Cornell University
Date of Report:	9/23/2020
Reporter name and position:	Michael Betteken, IBC Administrator
Telephone number:	607-255-0741
Email address:	Cu_ibc@cornell.edu
Reporter mailing address:	Cornell University East Hill Office Building 395 Pine Tree Road Suite 320-H
Date of incident:	August 30, 2020
Name of Principal Investigator:	Jonathan Butcher
Is this an NIH-funded project?	☐YES ☒NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 8/14/2018
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-3
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Primary porcine cells transfected with 3rd generation lentiviral vector

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of

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the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

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The evening of August 30, 2020 a graduate student was working within a BSL2 research laboratory removing collagen I hydrogels from a spring apparatus system to process for PCR. To do this, a biopsy punch is used to cut the hydrogel out of a spring system, and then forceps are used to transfer the gel into 1mL centrifuge tubes in a biosafety cabinet. The tissue is then either flash frozen or digested in lysis buffer for RNA extraction. The cells in the hydrogel were primary porcine cells transduced with a replication deficient third generation lentiviral vector carrying human Notch1 intracellular domain (p LIX-hN1ICD, Addgene Plasmid #91897). During this process the biopsy punch is cleaned with ethanol between samples. The student was removing residual ethanol from the punch with a Kimwipe held in their hand. The graduate student was cut on the right index finger while cleaning the biopsy punch.



Figure 1. Biopsy punch used in procedure

This cell line had been created by a previous graduate student. These cells were transduced with the lentiviral vector, incubated for 24 hours. The medium was changed and cells were incubated an additional 48 hours. The previous graduate student selected for positive cells and froze the cells. The student who was injured expanded the cells from the frozen stock.

Immediately after the injury, the graduate student cleaned the cut with soap and water at the lab sink and applied antibacterial ointment and a Band-Aid. The student reported to their supervisor. The supervisor and student reviewed the Cornell University Institutional Biosafety Committee document - Guidance on the Use of Lentiviral-Based Vectors. This document includes information on how to handle accidental exposures which include reporting to Cornell Environment, Health and Safety as well as seeking medical attention. The same evening, the student contacted Cornell Health, our on-campus medical center and the university Biosafety Officer (BSO). The student and biosafety officer reviewed the incident. The cell line had been passaged and the procedure of cleaning the punch likely lowered risk. Exposure risk and the oncogenic potential of the transgene were discussed with the student.

The relevant institutional training completed by the student include Bloodborne Pathogen training and Laboratory Safety Training. The student was trained for this specific procedure by a previous graduate student over the course of one month from June-July 2020. Training included general handling and transduction of lentiviral cells. The student was performing this specific RNA isolation procedure independently for the first time. No in-person training was performed, although it was similar to a procedure the student was trained on. There was no apparent deviation from lab SOPs or institutional biosafety approval. Containment of materials was maintained at BSL2.

Personal protective equipment and engineering controls used at the time include a lab coat, pants, closed toed shoes, face mask, and nitrile gloves. Work was performed in a Type II A2

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biosafety cabinet. Face masks are currently required on Cornell's campus due to the COVID-19 pandemic. There were no apparent engineering control or PPE failures.

The morning after this incident (approximately 14 hours) medical practitioners saw the student. The consultation resulted in prophylaxis with Truvada(Emtricitabine) and Isentress (Raltegravir). Beyond the cut received by the student, there is currently no additional reported illness.

Has the IBC reviewed this incident?	☐YES ☒NO The IBC Chairs were informed of the incident by the BSO on August 31, 2020. The IBC met Sep 8, 2020 and was informed. The incident investigation was ongoing at the time of that meeting. The IBC will be updated October 13, 2020 with the full report.
Please describe the root cause of this incident:	During the sampling process, the biopsy punch is cleaned with ethanol between samples. The student was injured while wiping the residual ethanol from the punch with a Kimwipe in their hand. The lab SOP has been modified so that the absorbent material remains on the work surface of the biosafety cabinet, rather than in the researcher's hand.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Aside from the revision of the lab protocol, the Cornell University Institutional Biosafety Committee document - Guidance on the Use of Lentiviral-Based Vectors will be reviewed for potential updates.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Michael I. Betteken <mib46@cornell.edu>
Sent: Wednesday, September 23, 2020 9:11 AM
To: NIH guidelines
Cc: Debra A. Dwyer; Colin Ross Parrish; Esther R. Angert; Joshua E. Turse; Jonathan T. Butcher; Christine A. Bellezza; Mark Hurwitz
Subject: RE: Cornell University - Report of incident with potential 3rd generation lentivirus exposure
Attachments: Incident-Reporting-NIH-8.30.2020-Final.docx

To whom it may concern:

Please find attached the incident report for the below described incident that occurred at Cornell University on August 30th as initially reported by our Biosafety Officer Josh Turse. Please let us know if you have any additional questions.

Thanks,
Michael

Michael I. Betteken, PhD
IBC - Administrator
Institutional Biosafety Committee
Office of Research Integrity and Assurance
Suite 320-H, East Hill Office Building
395 Pine Tree Rd
Mib46@cornell.edu

NOTE: I am currently working remotely but am happy to setup Zoom calls to discuss research needs

Cornell researchers, please refer to this webpage for continuity planning guidance in light of the COVID-19 outbreak.

CornellResearch

From: Joshua E. Turse <joshturse@cornell.edu>
Sent: Monday, August 31, 2020 12:54 PM
To: NIHGuidelines@od.nih.gov
Cc: Michael I. Betteken <mib46@cornell.edu>; Debra A. Dwyer <dad3@cornell.edu>; Colin Ross Parrish <crp3@cornell.edu>; Esther R. Angert <era23@cornell.edu>
Subject: Cornell University - Report of incident with potential 3rd generation lentivirus exposure

To whom it may concern:

I am the Biosafety Officer with Cornell University, Ithaca.

I am writing to inform that on the evening of Sunday, August 30, a researcher in one of our was using a biopsy punch to extract gels made of porcine lentiviral-transfected cells and was injured. The porcine cell line had been transfected with a 3rd generation lentiviral vector which had been passaged once since transfection. Between samples the researcher cleaned the punch with ethanol. It was after cleaning the punch that the researcher managed to scratch their index finger, drawing blood. Basic first aid was performed onsite, with a medical consultation scheduled for the morning of August 31.

Obtained via FOIA by Judicial Watch Inc.

This email serves as the immediate notification of an exposure to a genetically modified risk-group 2 material as required under the NIH Guidelines, Appendix G-II-B-2-k. Our IBC has been informed of the incident. We will complete the formal incident report using the template on the NIH Guidelines website within the next 30 days, by Wednesday September 30, 2020.

Best regards,

Josh Turse

Joshua E. Turse, PhD
Biological Safety Officer & Select Agent Program Responsible Official
Cornell University Environment, Health and Safety

o.607.255.9401|c. Redacted by agreement |ehs.cornell.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Joshua E. Turse <joshturse@cornell.edu>
Sent: Monday, August 31, 2020 12:54 PM
To: NIH guidelines
Cc: Michael I. Betteken; Debra A. Dwyer; Colin Ross Parrish; Esther R. Angert
Subject: Cornell University - Report of incident with potential 3rd generation lentivirus exposure

To whom it may concern:

I am the Biosafety Officer with Cornell University, Ithaca.

I am writing to inform that on the evening of Sunday, August 30, a researcher in one of our was using a biopsy punch to extract gels made of porcine lentiviral-transfected cells and was injured. The porcine cell line had been transfected with a 3rd generation lentiviral vector which had been passaged once since transfection. Between samples the researcher cleaned the punch with ethanol. It was after cleaning the punch that the researcher managed to scratch their index finger, drawing blood. Basic first aid was performed onsite, with a medical consultation scheduled for the morning of August 31.

This email serves as the immediate notification of an exposure to a genetically modified risk-group 2 material as required under the NIH Guidelines, Appendix G-II-B-2-k. Our IBC has been informed of the incident. We will complete the formal incident report using the template on the NIH Guidelines website within the next 30 days, by Wednesday September 30, 2020.

Best regards,

Josh Turse

Joshua E. Turse, PhD
Biological Safety Officer & Select Agent Program Responsible Official
Cornell University Environment, Health and Safety
o.607.255.9401|c. Redacted by agreement |ehs.cornell.edu

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, October 15, 2020 1:47 PM
To: Arseneau, Linda Marie; NIH guidelines
Cc: Maddox, Carol W; Kraft, Mary L; Miller, Monica A; DRS-IBC; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Guidelines Incident Notice

Dear Linda Arseneau,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and no further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Arseneau, Linda Marie <lmarsene@illinois.edu>
Sent: Monday, September 14, 2020 5:37 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Maddox, Carol W <maddox@illinois.edu>; Kraft, Mary L <mlkraft@illinois.edu>; Miller, Monica A <mamiller@illinois.edu>; DRS-IBC <ibc@illinois.edu>
Subject: RE: NIH Guidelines Incident Notice

Dear OSP,
On behalf of Dr. Maddox, please find the attached completed NIH incident report that corresponds to the initial email sent on September 2, 2020. It's important to note that there was no exposure to replication deficient adenovirus. The incident involved the failure to follow approved containment conditions and corresponding loss of containment.

Please feel free to contact me if you have any additional questions.
Best,
Linda

Linda Arseneau
Assistant Director/Biosafety Officer
Division of Research Safety
Office of the Vice Chancellor for Research
University of Illinois at Urbana-Champaign
208 Environmental Health & Safety Building
101 S Gregory St | M/C 225
Urbana, IL 61801

Obtained via FOIA by Judicial Watch Inc.

217.244.1939 | lmarsene@illinois.edu
www.drs.illinois.edu

ILLINOIS

Under the Illinois Freedom of Information Act any written communication to or from university employees regarding university business is a public record and may be subject to public disclosure.

Sent from Mail for Windows 10

From: Arseneau, Linda Marie
Sent: Wednesday, September 2, 2020 6:43 PM
To: NIHGuidelines@od.nih.gov
Cc: Maddox, Carol W; Kraft, Mary L; Miller, Monica A (mamiller@illinois.edu); DRS-IBC
Subject: NIH Guidelines Incident Notice

Dear OSP,
On September 1, 2020, it was reported to the Division of Research Safety that Dr. Jongsook Kemper's laboratory had a breach of containment while performing an ABL-2 experimental sacrifice. The mice on study were previously injected with replication defective adenovirus (section III D-4). The breach of containment involved placing the mice into the biosafety cabinet without it running and leaving the mice unattended while a researcher left to retrieve laboratory supplies. There was no overt exposure to personnel. We are investigating the incident and will submit an NIH Incident template as soon as it is completed.

Please let me know if you have any questions.

Best,
Linda

Linda Arseneau
Assistant Director/Biosafety Officer
Division of Research Safety
Office of the Vice Chancellor for Research
University of Illinois at Urbana-Champaign
208 Environmental Health & Safety Building
101 S Gregory St | M/C 225
Urbana, IL 61801
217.244.1939 | lmarsene@illinois.edu
www.drs.illinois.edu

ILLINOIS

Under the Illinois Freedom of Information Act any written communication to or from university employees regarding university business is a public record and may be subject to public disclosure.

Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Illinois Urbana Champaign
Date of Report:	September 14, 2020
Reporter name and position:	Carol W. Maddox Co-Chair of IBC
Telephone number:	217-265-0399 – office Redacted by agreement - cell
Email address:	maddox@illinois.edu
Reporter mailing address:	1219 VMBSB MC002 College of Veterinary Medicine 2001 S. Lincoln Ave. Urbana, IL 61802
Date of incident:	09/02/2020
Name of Principal Investigator:	Dr. Jongsook Kemper
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☒Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☒Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 9/17/2017
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ (describe specific enhancement in report) ☐BL3 ☐BL3+ (describe specific enhancement in report) ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Sections III- D-3 and D-4 Sections III E-1, and III E, no subsection Section III F-8
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Replication deficient adenovirus vectors in mice. Adenovirus carry green fluorescent protein (control) and either: FincoR, or shRNA for FincoR. FincoR is an FXR-induced long noncoding RNA. The adenoviral sequences in these AdTrack vectors have the E1 and E3 gene deleted. The E1 gene is required for replication. For production of recombinant adenoviral particles, the virus is propagated in HEK293Ad cells which supply the E1 gene product and allow replication and packaging of the vector for use.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

After euthanizing a mouse, the Post Doc began dissections on a cart, outside of the BSC, in a designated ABL-2 room managed by the Division of Animal Resources (DAR). The BSC was not on and the Post Doc was not wearing eye protection, but was wearing gloves, a lab coat, and mask. The Post Doc forgot to bring liquid nitrogen for flash freezing tissues and left a dissected mouse on a cart. DAR staff discovered the unattended mouse out of containment, confronted the Post Doc and reported the issue to the Division of Research Safety. This mouse was injected with recombinant adenovirus 33 days prior. Although there was no chance of contamination from the virus, this work outside of a BSC was a deviation from what is described in the lab's IBC registration and thus a breach of the approved containment procedures.

Training:

- Laboratory Safety Training - ONLINE TRAINING – 4/17/2020
- Understanding Biosafety - ONLINE TRAINING – 5/22/2013
- NIH Guidelines Overview - ONLINE TRAINING – 9/9/2020
- Safe Handling of Human Cell Lines/Materials in a Research Laboratory – 2/19/2020
- Lab specific training: 2/18/2020

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Failure to include full risk assessment in IBC registration. Poor planning on the part of the post doc that led them to leave biohazardous materials unsecured.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Issues Discovered

1. Although lab training was carried out in February, with extra emphasis on rules in animal care facilities, the Post Doc performed their own risk assessment and decided they could work outside of containment without approved IBC documentation.
2. Transport containment of virus to, and transport of tissues from, the animal care facility is done in an ice bucket without a secured lid.

Recommendations from DRS and the IBC

1. Procedure specific training should be repeated. Timeline: before next IBC meeting.
2. The lab should update the IBC registration to reflect the lab's actual practices and gain IBC approval. DRS and IBC members suggested that the lab ask that these animals may be downgraded to ABL-1 after 72 hours and a cage change. Timeline: before next IBC meeting.
3. The lab should outline new transport guidelines for BL-2 materials to meet requirements for transporting these materials. Emphasis should be made on the transport of virus from the lab to the animal facility. Timeline: before next IBC meeting.

Obtained via FOIA by Judicial Watch Inc.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Arseneau, Linda Marie <lmarsene@illinois.edu>
Sent: Monday, September 14, 2020 5:37 PM
To: NIH guidelines
Cc: Maddox, Carol W; Kraft, Mary L; Miller, Monica A; DRS-IBC
Subject: RE: NIH Guidelines Incident Notice
Attachments: NIH Incident Report-Kemper 2020-09-02.pdf

Dear OSP,
On behalf of Dr. Maddox, please find the attached completed NIH incident report that corresponds to the initial email sent on September 2, 2020. It's important to note that there was no exposure to replication deficient adenovirus. The incident involved the failure to follow approved containment conditions and corresponding loss of containment.

Please feel free to contact me if you have any additional questions.
Best,
Linda

Linda Arseneau
Assistant Director/Biosafety Officer
Division of Research Safety
Office of the Vice Chancellor for Research
University of Illinois at Urbana-Champaign
208 Environmental Health & Safety Building
101 S Gregory St | M/C 225
Urbana, IL 61801
217.244.1939 | lmarsene@illinois.edu
www.drs.illinois.edu

ILLINOIS

Under the Illinois Freedom of Information Act any written communication to or from university employees regarding university business is a public record and may be subject to public disclosure.

Sent from Mail for Windows 10

From: Arseneau, Linda Marie
Sent: Wednesday, September 2, 2020 6:43 PM
To: NIHGuidelines@od.nih.gov
Cc: Maddox, Carol W; Kraft, Mary L; Miller, Monica A (mamiller@illinois.edu); DRS-IBC
Subject: NIH Guidelines Incident Notice

Dear OSP,
On September 1, 2020, it was reported to the Division of Research Safety that Dr. Jongsook Kemper's laboratory had a breach of containment while performing an ABL-2 experimental sacrifice. The mice on study were previously injected with replication defective adenovirus (section III D-4). The breach of containment involved placing the mice into the biosafety cabinet without it running and leaving the mice unattended while a researcher left to retrieve laboratory supplies. There was no overt exposure to personnel. We are investigating the incident and will submit an NIH Incident template as soon as it is completed.

Please let me know if you have any questions.

Obtained via FOIA by Judicial Watch Inc.

Best,
Linda

Linda Arseneau
Assistant Director/Biosafety Officer
Division of Research Safety
Office of the Vice Chancellor for Research
University of Illinois at Urbana-Champaign
208 Environmental Health & Safety Building
101 S Gregory St | M/C 225
Urbana, IL 61801
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www.drs.illinois.edu

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Arseneau, Linda Marie <lmarsene@illinois.edu>
Sent: Wednesday, September 2, 2020 7:44 PM
To: NIH guidelines
Cc: Maddox, Carol W; Kraft, Mary L; Miller, Monica A; DRS-IBC
Subject: NIH Guidelines Incident Notice

Dear OSP,
On September 1, 2020, it was reported to the Division of Research Safety that Dr. Jongsook Kemper's laboratory had a breach of containment while performing an ABL-2 experimental sacrifice. The mice on study were previously injected with replication defective adenovirus (section III D-4). The breach of containment involved placing the mice into the biosafety cabinet without it running and leaving the mice unattended while a researcher left to retrieve laboratory supplies. There was no overt exposure to personnel. We are investigating the incident and will submit an NIH Incident template as soon as it is completed.

Please let me know if you have any questions.

Best,
Linda

Linda Arseneau
Assistant Director/Biosafety Officer
Division of Research Safety
Office of the Vice Chancellor for Research
University of Illinois at Urbana-Champaign
208 Environmental Health & Safety Building
101 S Gregory St | M/C 225
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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, October 15, 2020 1:55 PM
To: Coulson, Garry Brian; NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH Incident Report - Final

Dear Dr. Garry Coulson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and no further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Tuesday, September 8, 2020 10:01 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: RE: NIH Incident Report - Final

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a potential exposure involving recombinant DNA that occurred in a BSl-2 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722

Obtained via FOIA by Judicial Watch Inc.

Email | garry.coulson@ehs.unc.edu

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From: Coulson, Garry Brian
Sent: Thursday, September 3, 2020 5:09 PM
To: 'NIH guidelines' <NIHGuidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of an exposure to recombinant DNA at BSL-2 involving a splash to the eye of a researcher with a recombinant, knock-out strain of N. gonorrhoeae. The individual was seen at the University Employee Occupational Health Clinic (UEOHC) and received prophylaxis as indicated.

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of North Carolina at Chapel Hill
Date of Report:	09/08/2020
Reporter name and position:	Garry Coulson, Biosafety Officer
Telephone number:	919.962.5722
Email address:	garry.coulson@ehs.unc.edu
Reporter mailing address:	Environment, Health and Safety 1120 Estes drive Campus Box 1650 Chapel Hill, NC 27599
Date of incident:	09/01/2020
Name of Principal Investigator:	Dr. Joseph Alex Duncan
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* 5U19AI144180 *NIH funding institute or center:* NIAID *NIH program officer (name, email address):* Tom Hiltke (thiltke@niaid.nih.gov)

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐YES ☒NO If yes, date of approval: N/A The Principal Investigator had mistakenly interpreted the NIH Guidelines in such a way that classified his research with a deletion mutant ("knockout") as falling under Section III-F and therefore exempt from the NIH Guidelines. It was discussed with the PI that the work with recombinant RG2 organisms is classified as III-D. The PI immediately submitted a protocol to the IBC for approval to remedy his accidental oversight.
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA

Obtained via FOIA by Judicial Watch Inc.

Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Recombinant "knock-out" strain of N. gonorrhoeae with gene deletion of NHBA (Neisseria Heparin Binding Antigen). Gene deletion is marked with spectinomycin-resistance cassette.

Description of the incident:

At approximately 1:30 pm on Tuesday, September 1, 2020 the Researcher was attempting to use a metal inoculating loop to collect an inoculum of *Neisseria gonorrhoeae* from a frozen glycerol stock tube (2ml tube) and inoculate an agar plate when the incident occurred. The bacterial strain that was being used for this experiment was a recombinant *N. gonorrhoeae* strain FA1090 with a $Spec^R$ marked gene deletion of the Neisseria Heparin Binding Antigen (NHBA) gene. For personal protective equipment (PPE), the Researcher was wearing a lab coat, a pair of nitrile gloves, and a surgical mask. The Researcher was wearing prescription glasses, but they were not wearing safety glasses or goggles when the incident occurred. The Researcher was working at the bench and was not working in a biosafety cabinet (BSC) in the BSL-2 laboratory. While using the loop to collect inoculum from the glycerol stock tube, which was held at arm's length and aimed away from their face, the malleable loop uncontrollably sprung out of the end of the tube and flung a small amount of liquid into/around the right eye of the Researcher.

The Researcher immediately placed the items on the bench top and proceeded to the closest eye wash station and flushed their eyes for approximately 3 to 4 minutes. They then called their Supervisor to report the incident, followed by calling the University Employee Occupational Health Clinic (UEOHC). The UEOHC staff instructed the Researcher to report to the clinic where they were examined by medical staff and provided indicated prophylaxis.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC is aware of this incident and will review it at the next IBC meeting
Please describe the root cause of this incident:	Research personnel not wearing prescribed PPE (i.e. protective glasses)

Obtained via FOIA by Judicial Watch Inc.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

As part of the corrective and preventative actions to be taken, an internal Incident Report will be submitted from the Department of Environment, Health and Safety (EHS) to the Principal Investigator (PI) detailing the incident and including recommendations for the lab to follow to mitigate future reoccurrence of the incident.

As part of the recommendations, the PI will be instructed to review the incident with their laboratory, emphasizing the importance of always wearing the required PPE when working in a BSL-2 laboratory. Specifically, the PI will be asked to review the "Laboratory Personal Protective Equipment" factsheet (https://ehs.unc.edu/files/2015/07/ppe_fact.pdf) and Chapter 5: Protective Clothing and Equipment (https://unc.policystat.com/policy/5809712/latest/) and Chapter 5: Eye and Face Protection (https://unc.policystat.com/policy/5927563/latest/) in the Laboratory Safety Manual with their lab which outlines the requirement of safety glasses in the laboratory. Additionally, the PI will be instructed to review with their lab the importance of using a BSC when working with biological agents to minimize risk for personnel exposure from spills and splashes of this nature.

Furthermore, the PI will be instructed to retake the UNC "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" training course (https://apps.fo.unc.edu/ehs/training/nih-guidelines-for-research/) and associated training materials, and to review the UNC "Recombinant DNA" webpage for research with recombinant DNA (https://ehs.unc.edu/biological/dna/#recombinant) which stresses the responsibility of the PI to register all research involving recombinant or synthetic nucleic acid molecules with the Institutional IBC prior to the research being conducted (regardless of whether the research is Exempt from the NIH Guidelines). As mentioned previously, the PI has already submitted a new protocol to the IBC to cover this work going forwards.

The expected date of completion for recommendations will be 09/18/2020.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Tuesday, September 8, 2020 10:01 AM
To: NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.
Subject: RE: NIH Incident Report - Final
Attachments: NIH_Incident_Report_09082020.pdf

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting an incident subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed the completed incident report of a potential exposure involving recombinant DNA that occurred in a BSl-2 laboratory at The University of North Carolina at Chapel Hill.

Please let me know if you require any further information.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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From: Coulson, Garry Brian
Sent: Thursday, September 3, 2020 5:09 PM
To: 'NIH guidelines' <NIHGuidelines@od.nih.gov>
Cc: Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of an exposure to recombinant DNA at BSL-2 involving a splash to the eye of a researcher with a recombinant, knock-out strain of N. gonorrhoeae. The individual was seen at the University Employee Occupational Health Clinic (UEOHC) and received prophylaxis as indicated.

Obtained via FOIA by Judicial Watch Inc.

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
Biosafety Officer | Institutional Biosafety Committee (IBC)
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Hunter, Renee (NIH/OD) [C]

From: Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
Sent: Thursday, September 3, 2020 5:09 PM
To: NIH guidelines
Cc: Brennan, Catherine; Cyr, Douglas M.
Subject: NIH Incident Report - Preliminary

Dear Office of Science Policy (OSP), National Institutes of Health (NIH)

We wanted to notify you of an exposure to recombinant DNA at BSL-2 involving a splash to the eye of a researcher with a recombinant, knock-out strain of N. gonorrhoeae. The individual was seen at the University Employee Occupational Health Clinic (UEOHC) and received prophylaxis as indicated.

We are currently investigating the incident and will submit a formal Incident Report to NIH OSP as soon as we have all the pertinent facts and details.

Please feel free to reach out to me if you have any questions.

Kind regards,
Garry

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Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5722
Email | garry.coulson@ehs.unc.edu

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, October 15, 2020 1:51 PM
To: Kirchhoff, Louis; NIH guidelines
Cc: Sinn, Haley W; 'Adam'; Jones, Bradley; Haim, Hillel; Len; Martino-Cardona, Maria C; Sheets, Jim T; Stapleton, Jack; Xiang, Jinhua; Piper, Robert C; Wu, Li; Manicassamy, Balaji; Lassner, Jennifer L; Miller, Norma J; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: University of Iowa Incident report for OSP/NIH

Dear Dr. Louis Kirchhoff,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). No further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Kirchhoff, Louis <louis-kirchhoff@uiowa.edu>
Sent: Tuesday, September 29, 2020 3:27 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Sinn, Haley W <haley-williams@uiowa.edu>; 'Adam' <aclore@idtdna.com>; Jones, Bradley <bradley-jones@uiowa.edu>; Haim, Hillel <hillel-haim@uiowa.edu>; Len <leonard-duncan@jmilabs.com>; Martino-Cardona, Maria C <maria-martino-cardona@uiowa.edu>; Sheets, Jim T <jim-sheets@uiowa.edu>; Stapleton, Jack <jack-stapleton@uiowa.edu>; Xiang, Jinhua <jinhua-xiang@uiowa.edu>; Piper, Robert C <robert-piper@uiowa.edu>; Wu, Li <li-wu@uiowa.edu>; Manicassamy, Balaji <balaji-manicassamy@uiowa.edu>; Lassner, Jennifer L <jennifer-lassner@uiowa.edu>; Miller, Norma J <norma-miller@uiowa.edu>; Kirchhoff, Louis <louis-kirchhoff@uiowa.edu>
Subject: University of Iowa Incident report for OSP/NIH

Please see the attached report of an incident that occurred at the University of Iowa.

Louis V. Kirchhoff, MD, MPH
Chair, Institutional Biosafety Committee (IBC)

Professor of Internal Medicine (Infectious Diseases),
Psychiatry, and Epidemiology
Carver College of Medicine and College of Public Health
University of Iowa
Iowa City, Iowa
☎ Office: 319-356-7227

Obtained via FOIA by Judicial Watch Inc.

☎ VM only: 319-855-4287
☎ Fax: 641-323-4537
: louis-kirchhoff@uiowa.edu

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Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	X YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Iowa
Date of Report:	September 24, 2020
Reporter name and position:	Louis V. Kirchhoff, MD, MPH; IBC Chair
Telephone number:	319-356-7227
Email address:	louis-kirchhoff@uiowa.edu
Reporter mailing address:	UIHC SW54 GH Department of Internal Medicine 200 Hawkins Dr Iowa City, IA 52242
Date of incident:	09/03/2020
Name of Principal Investigator:	Balaji Manicassamy, PhD, Associate Professor, Department of Microbiology
Is this an NIH-funded project?	☐YES X NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal X Personnel exposure ☐ Spill X Other (please describe): accidental puncture wound with a glass pipette; potential exposure to a human cancer cell line carrying recombinant DNA
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ X YES ☐NO If yes, date of approval: 06/28/2018 Protocol #180076
What was the approved biosafety level of the research?	☐ BL1 X BL2 ☐ BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	This experiment would fall under III-D-1.
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Human lung cancer epithelial cell line (A549) knockout for SLC35A1 gene. SLC35 A1 was knocked out with CRISPR/Cas9 sgRNA technology, which was introduced via self-inactivating lentivirus.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Redacted by agreement

Redacted by agreement

On 09/03/2020, an undergraduate University student was performing cell culture experiments with the A549 human lung carcinoma cell line in a BSC located in Bowen Science Building Room [redacted] At 11:15 AM, she accidently punctured her left thumb with the tip of a glass Pasteur pipette that had just been used to aspirate flasks containing the A549 cell line. She immediately reported the incident to the PI (Balaji Manicassamy), who was present in the lab at that time. This was a minor puncture wound that caused a small amount of bleeding. The wound was washed with soap and running water for ~15 min, treated with triple antibiotic gel, and covered with a small adhesive bandage.

At the time of the incident, the student was wearing a lab coat and gloves and had followed appropriate safety precautions. There was no deviation from the standard SOP.

The student is listed in the approved rDNA registration document (#180076) and had received her blood borne pathogens site-specific training from the PI on 10/8/2019. The student had also completed all Environmental Health & Safety (EHS) required courses including Basic Biosafety, Advanced Biosafety, Lab Chemical Safety, PPE Awareness for Labs, and rDNA Research – *NIH Guidelines*.

At 11:50 AM, a completed incident report form was submitted by the PI to the University through the online First Report of Injury portal. At 12:08 PM, an injury report was sent via email to Mr. Steve Paulsen, Occupational Safety Manger, in EHS. In addition, copies of the email were sent to Dr. Richard Roller, the exposure control officer in the Department of Microbiology, and to Ms. Robyn Dunkerley, in the Human Resources Department. Subsequently the PI discussed the incident by phone with Ms. Norma Miller, the EHS Associate Biosafety Officer, and Dr. Haley Sinn, the EHS Director. Dr. Sinn subsequently informed Dr. Louis Kirchhoff, IBC Chair, about the incident and provided an immediate email notification of a potential rDNA exposure to OSP/NIH. As per Dr. Kirchhoff's recommendation, the student was seen in clinic by Dr. Patrick Hartley, the director of University of Iowa Employee Health. At the end of his evaluation, Dr. Hartley released her to return to work without restrictions.

On 9/24/20, which was 21 days after the incident occurred, the student reported to Dr. Sinn that no signs or symptoms related to the puncture wound had appeared.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	X YES ☐NO
Please describe the root cause of this incident:	Leaving a contaminated glass pipette connected to the liquid aspiration vacuum line.

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Members of Dr. Manicassamy's laboratory have been instructed to discard glass pipettes in sharps containers immediately after use; in addition, signs have been posted near vacuum aspirators as a reminder to discard pipettes immediately after use. The PI has purchased several plastic alternatives and will be testing these in the lab as potential replacements for glass pipettes.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Kirchhoff, Louis <louis-kirchhoff@uiowa.edu>
Sent: Tuesday, September 29, 2020 3:27 PM
To: NIH guidelines
Cc: Sinn, Haley W; 'Adam'; Jones, Bradley; Haim, Hillel; Len; Martino-Cardona, Maria C; Sheets, Jim T; Stapleton, Jack; Xiang, Jinhua; Piper, Robert C; Wu, Li; Manicassamy, Balaji; Lassner, Jennifer L; Miller, Norma J; Kirchhoff, Louis
Subject: University of Iowa Incident report for OSP/NIH
Attachments: 200924 University of Iowa OSP-NIH incident report FINAL.pdf

Please see the attached report of an incident that occurred at the University of Iowa.

Louis V. Kirchhoff, MD, MPH
Chair, Institutional Biosafety Committee (IBC)

Professor of Internal Medicine (Infectious Diseases),
Psychiatry, and Epidemiology
Carver College of Medicine and College of Public Health
University of Iowa
Iowa City, Iowa
☎ Office: 319-356-7227
☎ VM only: 319-855-4287
☎ Fax: 641-323-4537
: louis-kirchhoff@uiowa.edu

Notice: This UI Health Care e-mail (including attachments) is covered by the Electronic Communications Privacy Act, 18 U.S.C. 2510-2521 and is intended only for the use of the individual or entity to which it is addressed, and may contain information that is privileged, confidential, and exempt from disclosure under applicable law. If you are not the intended recipient, any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately and delete or destroy all copies of the original message and attachments thereto. Email sent to or from UI Health Care may be retained as required by law or regulation. Thank you.

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Sinn, Haley W <haley-williams@uiowa.edu>
Sent: Friday, September 4, 2020 11:30 AM
To: NIH guidelines
Subject: potential exposure to rDNA

This is an email to notify you that we have been made aware of a potential exposure to a recombinant cell line.

Late yesterday afternoon, the Associate Biosafety Officer was notified of an injury resulting from a glass pipette tip while performing cell culture work. After additional follow-up with the laboratory and discussion with the IBC Chair, we have determined that there is a potential exposure to the recombinant cell line. The individual was removing supernatant from the cell flasks using a glass pipette. She had placed the dirty pipette to the side and reached over the pipette and somehow it slipped and punctured her glove and skin. The cells were an A549 knockout line made with recombinant lentivirus.

I will work with the laboratory and our IBC to complete the full report within the 30-day time frame. Please contact me with any questions.

Thank you,
Haley

Haley Sinn, PhD, CBSP, ARO (she/her/hers)
Director, Environmental Health & Safety Office
120 Grand Ave. Ct., Iowa City, Iowa 52242
Office: 319-335-9553
https://ehs.research.uiowa.edu/

IOWA

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, October 15, 2020 2:06 PM
To: Waggoner, Charlotte; NIH guidelines
Cc: Caswell, Clayton; Virginia Tech IBC; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Virginia Tech - BSL2 Lab - Exposure Incident

Dear Charlotte Waggoner,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). No further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Waggoner, Charlotte <ren@vt.edu>
Sent: Friday, October 2, 2020 7:46 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Caswell, Clayton <caswellc@vt.edu>; Virginia Tech IBC <ibc@vt.edu>; Waggoner, Charlotte <ren@vt.edu>
Subject: Virginia Tech - BSL2 Lab - Exposure Incident

NIH,

Please find attached the completed NIH report as required. Let know if you require any additional information.

Thank you.

Charlotte M. Waggoner, MS, RBP, SM(NRCM), CBSP
Assistant Director
University Biosafety Officer and Responsible Official
Environmental Health and Safety (0423)
575 Beamer Way
Blacksburg, Virginia 24061
http://www.ehss.vt.edu/

(540) 231-5864
(540) 231-3944 FAX

Obtained via FOIA by Judicial Watch Inc.

From: Waggoner, Charlotte <ren@vt.edu>
Sent: Friday, September 4, 2020 8:30 AM
To: NIHGuidelines@od.nih.gov
Cc: Waggoner, Charlotte <ren@vt.edu>; Allen, Regina <regina1@vt.edu>
Subject: Virginia Tech - BSL2 Lab - Exposure Incident

NIH,

A report came in indicating that a grad student accidentally stabbed herself with a needle contaminated with a bacterial suspension while trying to cap the needle. The material was:

> *S.* Typhimurium VNP20009 cheY^{+} RFP^{+}
> Attenuated strain of *S.* Typhimurium 14028 harboring an ampicillin resistant plasmid for expression of red fluorescent protein

Obtained via FOIA by Judicial Watch Inc.

We will be sending a full report as required.

Charlotte M. Waggoner, MS, RBP, SM(NRCM), CBSP
Assistant Director
University Biosafety Officer and Responsible Official
Environmental Health and Safety (0423)
575 Beamer Way
Blacksburg, Virginia 24061
http://www.ehss.vt.edu/

(540) 231-5864
(540) 231-3944 FAX

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

April, 2019

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	**X YES** ☐NO If no, this incident does not require reporting to OSP
Institution Name:	**Virginia Tech**
Date of Report:	**10/02/2020**
Reporter name and position:	**Charlotte M. Waggoner** **University Biosafety Officer/Responsible Official**
Telephone number:	**540-231-5864**
Email address:	**ren@vt.edu**
Reporter mailing address:	**575 Beamer Way** **MS 0423** **Blacksburg, VA 24061**
Date of incident:	• **09/02/2020** • **EHS notified 09/03/2020** • **NIH notified via email 09/04/2020 after clarification received from researchers on what material was being manipulated at the time of the incident**
Name of Principal Investigator:	**Dr. Bahareh Behkam**
Is this an NIH-funded project?	☐YES **X NO** If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal **X Personnel exposure** ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	**X YES** ☐NO If yes, date of approval: **02/12/2018 (IBC #18-014)**
What was the approved biosafety level of the research?	☐ BL1 **X BL2** ☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	**III-D-1, III-D-4**
Has a report of this incident been made to other agencies? If so, please indicate **N/A**	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ OSHA
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	***S.* Typhimurium VNP20009 cheY$^+$ RFP$^+$** **Attenuated strain of *S.* Typhimurium 14028 harboring an ampicillin resistant plasmid for expression of red fluorescent protein**

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

1. The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)

    - **BL2 laboratory, inside a certified biosafety cabinet**

2. Who was involved in the incident/violation, including others present at the incident location?
    - **One female graduate research assistant**

Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

3. Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
    - **First aid was administered to the injury site by the graduate research assistant herself. She treated the puncture wound "with excess 70% ethanol and a good amount of blood was purged out to remove any foreign material that may have entered." She applied a triple antibiotic ointment to the puncture and then a Band-Aid was applied.**

4. The training received by the individual(s) involved and the date(s) the training was conducted
    - **Initial university-level training was completed as part of the IBC review and approval process. The graduate student's detailed training record is provided on page 6.**
    - **Lab-specific training included protocol overview, bacteria culturing, characterization, microscopy, and proper waste disposal.**
    - **All university-level and lab-specific training occurred over the period of 10/13 – 10/30/2019.**

Obtained via FOIA by Judicial Watch Inc.

Training Details for Redacted by agreement

NOTE: This system updates training data every 30 minutes. Please wait at least 30 minutes after a training is completed to review training status on this site!

Training Type	Status	Expires?	Reason Training is Required
Biosafety Training for Research Labs (Biosafety)	✓	*Oct 13, 2022*	This training is required for all personnel on a protocol.
Safe Autoclave Use and Verification (Autoclave)	✓	*N/A*	This training is required for all personnel on a protocol.
Overview of the NIH Guidelines and VT IBC (NIH)	✓	*Jan 20, 2023*	This training is required because Redacted by agreement involved with the following: ▸ Handles recombinant, synthetic nucleic acids and/or gene editing sequences?
Medical Survey Questionnaire (Medical Survey)	✓	*Jan 20, 2021*	This training is required because Redacted by agreement involved with the following: ▸ Works in BSL-2 lab?
Bloodborne Pathogens (BBP)	✓	*Oct 13, 2020*	This training is required because Redacted by agreement involved with the following: ▸ Handles human and/or non-human primate agents including cell lines?
Introduction to Biological Safety Cabinets (BSC)	✓	*N/A*	This training is required because Redacted by agreement involved with the following: ▸ Works in BSL-2 lab?
Respiratory Protection (Resp)	⊘	*N/A*	N/A

⊘ Training is not required for this protocol ✓ Training is complete and up-to-date ✗ Training has not been completed ⚠ Training has expired

5. The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
    - **The graduate student incorrectly recapped the needle by using two hands rather than the one-handed technique. This was attributed to a "momentary lapse of judgment due to the long duration of the experiments on that day."**

6. Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
    - **N/A**

7. The personal protective equipment in use at the time of the incident/violation
    - **Lab coat, nitrile gloves**

Obtained via FOIA by Judicial Watch Inc.

8. The occupational health requirements for laboratory personnel involved in the research
    - **Entrance into the occupational health program**
    - **Annual update to medical surveillance questionnaire (noted on training record)**
    - **Review of questionnaire by occ health personnel for any medical concerns or changes; follow-up by occ health personnel as needed.**

9. Any medical surveillance provided or recommended after the incident
    - **Incident report and other information provided to occupational health personnel for follow-up based on consultation with occupational health physician.**
    - **The graduate research assistant did receive a call from the occ health office and was asked about her health post-incident.**

10. Any injury or illness associated with the incident
    - **Needlestick with bacterial suspension while trying to cap a needle.**

11. Equipment failures
    - **N/A**

Has the IBC reviewed this incident?	**X YES** ☐NO **Incident reviewed by IBC at 09/08/2020 meeting.**
Please describe the root cause of this incident:	**The incident was attributed to a "momentary lapse of judgment due to the long duration of the experiments on that day."**

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

- **Per the PI, "the graduate student and I went over the protocol in virtual meetings (including a phone conversation on 09/09 if my memory serves me right). She seems very clear on the correct practices and we both agree that the reported incident was due to a momentary lapse in judgement. Due to a health condition, I am working strictly remotely and could not complete the re-training in person."**
- **In addition, the PI indicates that she and the graduate student discussed "experiment planning to find out ways to minimize experimentations under fatigue."**
- **Also discussed by EHS and the PI were alternatives to the use of syringe needles as well as different and appropriate recapping techniques.**

Obtained via FOIA by Judicial Watch Inc.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Waggoner, Charlotte <ren@vt.edu>
Sent: Friday, October 2, 2020 7:46 AM
To: NIH guidelines
Cc: Caswell, Clayton; Virginia Tech IBC; Waggoner, Charlotte
Subject: Virginia Tech - BSL2 Lab - Exposure Incident
Attachments: VirginiaTech NIH Incident Report 10 02 2020.pdf

Categories: Green Category

NIH,

Please find attached the completed NIH report as required. Let know if you require any additional information.

Thank you.

Charlotte M. Waggoner, MS, RBP, SM(NRCM), CBSP
Assistant Director
University Biosafety Officer and Responsible Official
Environmental Health and Safety (0423)
575 Beamer Way
Blacksburg, Virginia 24061
http://www.ehss.vt.edu/

(540) 231-5864
(540) 231-3944 FAX

From: Waggoner, Charlotte <ren@vt.edu>
Sent: Friday, September 4, 2020 8:30 AM
To: NIHGuidelines@od.nih.gov
Cc: Waggoner, Charlotte <ren@vt.edu>; Allen, Regina <regina1@vt.edu>
Subject: Virginia Tech - BSL2 Lab - Exposure Incident

NIH,

A report came in indicating that a grad student accidentally stabbed herself with a needle contaminated with a bacterial suspension while trying to cap the needle. The material was:

> *S.* Typhimurium VNP20009 cheY^{+} RFP^{+}
> Attenuated strain of *S.* Typhimurium 14028 harboring an ampicillin resistant plasmid for expression of red fluorescent protein

Obtained via FOIA by Judicial Watch Inc.

We will be sending a full report as required.

Charlotte M. Waggoner, MS, RBP, SM(NRCM), CBSP
Assistant Director
University Biosafety Officer and Responsible Official
Environmental Health and Safety (0423)
575 Beamer Way
Blacksburg, Virginia 24061
http://www.ehss.vt.edu/

(540) 231-5864
(540) 231-3944 FAX

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Waggoner, Charlotte <ren@vt.edu>
Sent: Friday, September 4, 2020 8:30 AM
To: NIH guidelines
Cc: Waggoner, Charlotte; Allen, Regina
Subject: Virginia Tech - BSL2 Lab - Exposure Incident

NIH,

A report came in indicating that a grad student accidentally stabbed herself with a needle contaminated with a bacterial suspension while trying to cap the needle. The material was:

> *S.* Typhimurium VNP20009 cheY^{+} RFP^{+}
> Attenuated strain of *S.* Typhimurium 14028 harboring an ampicillin resistant plasmid for expression of red fluorescent protein

Obtained via FOIA by Judicial Watch Inc.

We will be sending a full report as required.

Charlotte M. Waggoner, MS, RBP, SM(NRCM), CBSP
Assistant Director
University Biosafety Officer and Responsible Official
Environmental Health and Safety (0423)
575 Beamer Way
Blacksburg, Virginia 24061
http://www.ehss.vt.edu/

(540) 231-5864
(540) 231-3944 FAX

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, October 15, 2020 2:02 PM
To: ANDREA N LADD; NIH guidelines
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Incident report attached

Dear Dr. Andrea Ladd,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). No further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Tuesday, September 29, 2020 6:42 PM
To: Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: Incident report attached

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the needle stick initially reported on 09/05/20 (below). The Office of Biological Safety has carefully investigated the incident cause, materials, and response.

Please let me know if you have any questions or need additional information.

UW-Madison personnel included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Obtained via FOIA by Judicial Watch Inc.

Andrea N. Ladd, Ph.D.
Pronouns: she/her/hers
Assistant Director, EH&S
Biological Safety Officer
University of Wisconsin-Madison
30 East Campus Mall | Madison, WI 53715
(608) 263-9013 office/ Redacted by agreement mobile
andrea.ladd@wisc.edu

From: STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>
Sent: Saturday, September 5, 2020 1:08 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>; NIHGuidelines@od.nih.gov
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; ANDREA N LADD <andrea.ladd@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: Initial Notification of Incident

Dear Kathryn or Whom It May Concern,

We were notified today of needle stick involving recombinant materials in one of our BSL2 laboratories. The employee has been directed to receive medical follow-up.

At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Andrea Ladd, Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,

Stephanie

Stephanie G. Kutz, MS, RBP
Assistant Biosafety Officer
IBC Operations Manager

Office of Biological Safety
Environment, Health & Safety
30 E. Campus Mall
Madison WI, 53715

Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Obtained via FOIA by Judicial Watch Inc.

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Wisconsin-Madison
Date of Report:	09/05/20 (initial email to OSP) 09/29/20 (final report filed)
Reporter name and position:	Andrea N. Ladd, Biological Safety Officer
Telephone number:	(608) 263-9013
Email address:	andrea.ladd@wisc.edu
Reporter mailing address:	Environment, Health and Safety 30 East Campus Mall Madison, WI 53715
Date of incident:	09/04/20
Name of Principal Investigator:	Laura Knoll
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 03/31/20
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-a
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA Not applicable
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	*Toxoplasma gondii* strain expressing mCherry for fluorescence (does not increase virulence or effect treatment)

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

Location: BSL2 laboratory

Persons involved: UW-Madison employee

Training received by individual: Lab-specific training according to approved biosafety protocol was done and documented.

PPE in use at time of event: lab coat, gloves

Event description: The employee was passing *Toxoplasma gondii* strains using a needle and syringe in a biosafety cabinet. As the employee was removing the needle from the flask, they stuck their finger.

Immediate follow-up and medical follow-up: The employee immediately stopped, removed their gloves, and washed the prick site with soap and water for 15 minutes while milking the wound. This was followed by a wash with ethanol. The employee informed the PI and they contacted an infectious disease physician at UW Health for medical follow up. The incident was reported to the Office of Biological Safety the following day and the Assistant Biological Safety Officer submitted an initial report to OSP.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC Chair was aware of the event upon initial report to OSP. The IBC will be fully apprised of the incident at the next IBC meeting on October 7, 2020.
Please describe the root cause of this incident:	Root cause was the proximity of the needle to the employee's hand. A contributing factor may have been rushing on the part of the employee as they were finishing up at the end of the day before a holiday weekend.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

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The institution followed approved emergency and reporting procedures. The Office of Biological Safety met with the employee and PI to review the incident.

The PI reviewed the incident with the employee one-on-one and will review emergency procedures at an all-hands lab meeting. Lab members will be reminded not to rush. The laboratory also evaluated their procedures. The laboratory found an eyedropper can be used rather than a needle and syringe for passing the *Toxoplasma* strain to remove the sharps hazard.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: ANDREA N LADD <andrea.ladd@wisc.edu>
Sent: Tuesday, September 29, 2020 6:42 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
Subject: Incident report attached
Attachments: Knoll_090420_OSP Reportable.docx

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the needle stick initially reported on 09/05/20 (below). The Office of Biological Safety has carefully investigated the incident cause, materials, and response.

Please let me know if you have any questions or need additional information.

UW-Madison personnel included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,
Andrea

Andrea N. Ladd, Ph.D.
Pronouns: she/her/hers
Assistant Director, EH&S
Biological Safety Officer
University of Wisconsin-Madison
30 East Campus Mall | Madison, WI 53715
(608) 263-9013 office/ Redacted by agreement mobile
andrea.ladd@wisc.edu

From: STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>
Sent: Saturday, September 5, 2020 1:08 PM
To: Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>; NIHGuidelines@od.nih.gov
Cc: Kristen Bernard <kristen.bernard@wisc.edu>; ANDREA N LADD <andrea.ladd@wisc.edu>; Christopher Strang <christopher.strang@wisc.edu>
Subject: Initial Notification of Incident

Dear Kathryn or Whom It May Concern,

We were notified today of needle stick involving recombinant materials in one of our BSL2 laboratories. The employee has been directed to receive medical follow-up.

At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Obtained via FOIA by Judicial Watch Inc.

Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Andrea Ladd, Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,

Stephanie

Stephanie G. Kutz, MS, RBP
Assistant Biosafety Officer
IBC Operations Manager

Office of Biological Safety
Environment, Health & Safety
30 E. Campus Mall
Madison WI, 53715

Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>
Sent: Saturday, September 5, 2020 2:08 PM
To: Harris, Kathryn (NIH/OD) [C]; NIH guidelines
Cc: Kristen Bernard; ANDREA N LADD; Christopher Strang
Subject: Initial Notification of Incident

Categories: Green Category

Dear Kathryn or Whom It May Concern,

We were notified today of needle stick involving recombinant materials in one of our BSL2 laboratories. The employee has been directed to receive medical follow-up.

At this time we do not have complete information. For now, we are considering the event as reportable and are notifying you of the situation. A full report will be submitted upon follow-up with the PI and laboratory. In the meantime, please let me know if you have any questions.

Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Andrea Ladd, Biological Safety Officer
- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety

Thank you,

Stephanie

Stephanie G. Kutz, MS, RBP
Assistant Biosafety Officer
IBC Operations Manager

Office of Biological Safety
Environment, Health & Safety
30 E. Campus Mall
Madison WI, 53715

Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Tuesday, November 3, 2020 2:22 PM
To: Zara Llewellyn; NIH guidelines
Cc: Katia Harb; Steve Libby; Deborah L Fuller; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: NIH reportable incident - University of Washington

Dear Dr. Zara Llewellyn,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and no further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Zara Llewellyn <zaral@uw.edu>
Sent: Tuesday, October 6, 2020 3:07 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Katia Harb <kharb@uw.edu>; Steve Libby <slibby@uw.edu>; Zara Llewellyn <zaral@uw.edu>; Deborah L Fuller <fullerdh@uw.edu>
Subject: NIH reportable incident - University of Washington

Dear NIH,

Please find attached an incident report involving an employee performing research subjected to the NIH Section III-D guidelines.

Please let me know if you have any questions or need additional information.

Sincerely,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager
Alternate Responsible Official

Obtained via FOIA by Judicial Watch Inc.

Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
Direct: 206.221.2676 | Main: 206.221.7770 | Fax: 206.221.3068
zaral@uw.edu | www.ehs.washington.edu

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Obtained via FOIA by Judicial Watch Inc.

National Institutes of Health
Office of Science Policy

Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	XYES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Washington
Date of Report:	October 6, 2020
Reporter name and position:	Zara Llewellyn, Assistant Director for Research and Occupational Safety
Telephone number:	206-221-2676
Email address:	zaral@uw.edu
Reporter mailing address:	University of Washington Environmental Health and Safety Department Research and Occupational Safety Section 1705 NE Pacific Street Box 357165 Seattle, WA 98195-7165
Date of incident:	September 9, 2020 Initially reported to NIH via email on September 11, 2020
Name of Principal Investigator:	Deborah Fuller, PhD
Is this an NIH-funded project?	☐XYES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* R56 AI141494-01A1 *NIH funding institute or center:* NIAID *NIH program officer (name, email address):* Lambros, Chris clambros@niaid.nih.gov

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal X Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ X YES ☐NO If yes, date of approval: June 19, 2019
What was the approved biosafety level of the research?	☐ BL1 ☐ BL2 X☐BL2+ (describe specific enhancement in report) ☐ BL3 ☐BL3+ (describe specific enhancement in report) ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D
Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐Funding agency/sponsor ☐ USDA ☐State or local Public Health ☐ FDA ☐Law enforcement ☐ EPA ☐Other (please describe): ☐ XOSHA OSHA log 300
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	SIVmac239M, a recombinant barcoded strain of SIVmac239, a wild virus.

Obtained via FOIA by Judicial Watch Inc.

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- The training received by the individual(s) involved and the date(s) the training was conducted
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPs at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- The personal protective equipment in use at the time of the incident/violation
- The occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A researcher was working in an ABSL-2 necropsy suite handling and cutting spleen tissue from a SIV-infected non-human primate (NHP). The researcher was using a scalpel blade to cut the tissue. The researcher prepped the work area by placing the used scalpel blade on the work surface, changed into new gloves, and went to obtain the collection tube for the tissue in another part of the room. The researcher returned with the collection tube. The researcher picked up the scalpel blade to start cutting the tissue with the right hand. The scalpel blade brushed up against the left index finger, which was double gloved. The researcher immediately noticed that the outer glove was punctured, removed the outer glove, and saw the inner glove also appeared punctured. The researcher performed the glove integrity test by filling up the glove with tap water to look for leakage to confirm if the glove was intact or had been compromised. The glove integrity test demonstrated that the inner glove had been cut. The researcher also had a burst blister on the left index finger. The researcher immediately washed and scrubbed the site of the exposure for 15 minutes with a NHP scrub kit which contains a surgical scrub brush with disinfectant. There were two other people in the room at the time of the incident, including a research coworker and the pathologist. The research coworker phoned the lead veterinarian about the incident. The researcher immediately went to the emergency room, was placed on post exposure prophylaxis and is being monitored by the University Employee Health Center.

The researcher was wearing the appropriate personal protective equipment (PPE): double nitrile gloves, hairnet, facility scrubs, Tyvek suit, face shield, mask, and facility shoes.

The NHP was inoculated with SIVmac239M on 11/14/2019 and was on cART from 12/04/2019 until 6/01/2020. The NHP demonstrated low viral amounts while on cART, but viral loads increased with the most recent viral load data of 1.826859 x 10^4 copies/ml in plasma on 6/29/2020. The NHP was consistently negative for herpes B virus, most recently tested on 4/20/20.

The researcher is current on all trainings, including biosafety and bloodborne pathogens.

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☐XYES ☐NO At the September 16, 2020 IBC meeting.
Please describe the root cause of this incident:	1. Reuse of scalpel and not securing the scalpel after use. The scalpel was placed down in the field of work and not in a designated contained tray and was not 'guarded' with a sheath after use. While the sharp was not misplaced, it was not placed in an appropriate sharps holder. 2. Distraction from the scalpel in the right hand while working with the vial containing tissue at left, causing quick pass-by of the blade (nicking her glove).

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The laboratory has revised the standard operating procedures (SOP) for dissection, which includes the use of scalpels or alternatives to include the use scissors for tissues that can be cut easily. The SOP also includes the use of forceps for use in the non-cutting hand. The laboratory is evaluating the use of Kevlar or similar types of cut resistant gloves that could be worn underneath the nitrile gloves to protect against similar cuts while maintaining dexterity. The lab will train employees and others in the lab on the new procedures.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does <u>NOT</u> fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Zara Llewellyn <zaral@uw.edu>
Sent: Tuesday, October 6, 2020 3:07 PM
To: NIH guidelines
Cc: Katia Harb; Steve Libby; Zara Llewellyn; Deborah L Fuller
Subject: NIH reportable incident - University of Washington
Attachments: Fuller_NIH Incident report_Sept_2020.pdf

Dear NIH,

Please find attached an incident report involving an employee performing research subjected to the NIH Section III-D guidelines.

Please let me know if you have any questions or need additional information.

Sincerely,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager
Alternate Responsible Official
Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
Direct: 206.221.2676 | Main: 206.221.7770 | Fax: 206.221.3068
zaral@uw.edu | www.ehs.washington.edu

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Obtained via FOIA by Judicial Watch Inc.

Hunter, Renee (NIH/OD) [C]

From: Zara Llewellyn <zaral@uw.edu>
Sent: Friday, September 11, 2020 1:06 PM
To: NIH guidelines
Cc: Zara Llewellyn
Subject: Incident Involving Recombinant Nucleic Acid at University of Washington

Categories: Green Category

Dear NIH,

This message is to inform you that a laboratory worker experienced an injury while working with recombinant nucleic acid on September 9th, 2020.

We will be investigating the incident and submitting a formal report to the NIH.

Please let me know if you have any questions before then.

Thank you,

Zara

ZARA LLEWELLYN, PHD, RBP
Assistant Director for Research & Occupational Safety
Biological Safety Manager
Alternate Responsible Official
Environmental Health & Safety Department

Magnuson Health Sciences Building, Box 357165
1705 NE Pacific Street T-287 | Seattle, WA 98195-7165
Direct: 206.221.2676 | Main: 206.221.7770 | Fax: 206.221.3068
zaral@uw.edu | www.ehs.washington.edu

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Hunter, Renee (NIH/OD) [C]

From: McKinney, Michelle (NIH/OD) [E]
Sent: Thursday, October 15, 2020 9:18 AM
To: Nancy Henderson; NIH guidelines
Cc: Jacobs, Bertram; Debra Murphy; ibc@asu.edu; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
Subject: RE: Arizona State University Incident Report 08.20.2020

Dear Nancy Henderson,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and no further information about this incident is required at this time.

Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP
Health Science Policy Analyst, OSP/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

From: Nancy Henderson <Nancy.J.Henderson@asu.edu>
Sent: Wednesday, September 16, 2020 12:49 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Jacobs, Bertram <bjacobs@asu.edu>; Debra Murphy <Debra.Murphy@asu.edu>; ibc@asu.edu
Subject: Arizona State University Incident Report 08.20.2020
Importance: High

Good Morning,

Attached is ASU's report of an incident that occurred on August 20, 2020. If you have any questions regarding this report please don't hesitate to contact me.

Best Regards and please stay safe,
Nancy

Nancy J. Henderson| Assistant Director
Research Operations | Office of Research Integrity & Assurance
Arizona State University | Knowledge Enterprise
t 480-965-6792| mobile Redacted by agreement
Nancy.J.Henderson@asu.edu|http://researchadmin.asu.edu
How am I doing? Email my supervisor

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This message may contain information that is privileged, confidential and exempt from disclosure under applicable law. Please do not copy or forward this message without permission. If you are not the intended recipient, please delete all copies and notify me immediately by reply e-mail or by telephone (480) 965-6792 so we may correct our records

Obtained via FOIA by Judicial Watch Inc.

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Arizona State University
Date of Report:	9/16/2020
Reporter name and position:	Nancy Henderson, Assistant Director Research Integrity & Assurance
Telephone number:	(480)965-6792
Email address:	Nancy.J.Henderson@asu.edu
Reporter mailing address:	660 S. Mill Ave, Suite 312 PO Box 876011 Tempe, AZ, 85287-6111
Date of incident:	8/20/2020
Name of Principal Investigator:	Joshua LaBaer
Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) NIH Grant Number: 5U01CA214201-05 NIH Funding Institute or Center: HHS: National Institute of Health, National Cancer Institute NIH Program Official: Christos F Patriotis (patriotisc@mail.nih.gov) NIH Grants Official: Tracie McGraw (mcgrawth@mail.nih.gov)

Obtained via FOIA by Judicial Watch Inc.

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☒Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 3/28/2018
What was the approved biosafety level of the research?	☐BL1 ☒BL2 ☐BL2+ ☐BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1 RG2, III-D-2 RG2 & RG3, III-F-1, and III-F-8 Appendix C-II
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA **N/A**
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	DH5-alpha, T1 phage Resistant *E. coli* transformed with pJFT7_nHalo_DC(r4) and expressing the gene v-rel avian reticuloendotheliosis viral oncogene homolog A.

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Description of the incident: Approximately 600 ml of bacterial culture was released when a culture flask in a shaker incubator broke during incubation overnight inside the BSL2 laboratory. Most of the volume was contained in the incubator, less than 20 ml of the material reached the floor.

Spill cleanup was performed as follows:

- A research specialist in Dr. LaBaer's laboratory discovered the spill, immediately alerted others and secured the area by taping off the affected area and posting a sign warning personnel not to enter the area.
- Allowed 30 minutes for aerosols to settle. During this time, the spill was reported to senior lab personnel and Environmental Health and Safety and materials for cleanup prepared.
- After 30 minutes, the research specialist donned a lab coat, safety glasses and gloves and re-entered the area to perform the spill cleanup. The research specialist had completed biosafety and bloodborne pathogen training including spill clean-up training on 2/4/2020. The spill clean-up was conducted as outlined in the approved Institutional Biosafety Committee Disclosure and lab-specific standard operating procedures (SOPs) described in the lab-specific biosafety manual. There was no deviation from these SOPs at the time of the incident.
- The spill cleanup was conducted following the steps below:
  - The spill was covered with paper towels. Microcide-SQ disinfectant was carefully poured onto the paper towels starting from the outer edge of the spill to the center and ensuring the paper towels were soaked with disinfectant. A 20-minute contact time was allowed for the Microcide-SQ disinfectant to inactivate the material.
  - Broken glass associated with the spill was removed with forceps and transferred to a biohazard sharps container.
  - After the 20 minutes contact time, the soaked paper towels were removed and transferred to a biohazard bag.
  - The area was wiped down with more paper towels to remove any spill residues. Used paper towels were placed in a biohazard bag.
  - The spill area was wiped a final time with paper towels sprayed with 70% EtOH and allowed to air dry.
  - After the area was successfully cleaned, the posted signed was removed and work resumed.

The shaker was decontaminated following the steps below:

Procedures for decontamination of shaker after a spill

Obtained via FOIA by Judicial Watch Inc.

1. Place a note that the shaker is currently being decontaminated.
2. Remove any glassware or plastic. Place glassware into the soaker bins. Place broken glassware in biohazard sharps containers. Place non-reusable plastic ware into biohazard waste.
3. Remove all metal holders that have been contaminated. Place into a bucket and soak in a 10% bleach solution for 20-30 minutes. Rinse with water and allow to completely dry.
4. In the shaker spray down the spilled liquid with 10% bleach allow to sit for 20-30 minutes.
5. Wipe down with paper wipes, disposing wipes in Biohazard waste container.
6. Once all standing liquid is taken care of, spray the shaker again and allow to sit for 20-30 minutes.
7. Wipe down the area one final time, making sure to dispose of the contaminated wipes or paper towels.
8. Reattach the metal holders after all surfaces are dry.

After the spill cleanup was conducted, lab personnel removed Personal Protective Equipment (PPE) and washed their hands with soap and water. There were no exposures to lab personnel before, during or after the spill, no medical surveillance was provided or recommended after this incident.

There were no deviations from the IBC approved containment level or IBC approval conditions at the time of the incident.

Please see Attachments 1 and 2 for supporting documentation.

Attachment 1. Laboratory pictures provided by the research specialist after the successful spill cleanup.

Attachment 2: Documentation: RELA (Homo sapiens) in pJFT7_nHalo_DC(r4)

Obtained via FOIA by Judicial Watch Inc.

Has the IBC reviewed this incident?	☒YES ☐NO
Please describe the root cause of this incident:	Culture flask in a shaker incubator broke during incubation overnight.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The IBC reviewed the incident with senior lab personnel during the IBC meeting on September 10, 2020. It was determined that lab personnel responded promptly and accurately to the incident following the IBC approved protocols and lab-specific SOPs. No further actions were recommended after the review of the incident.