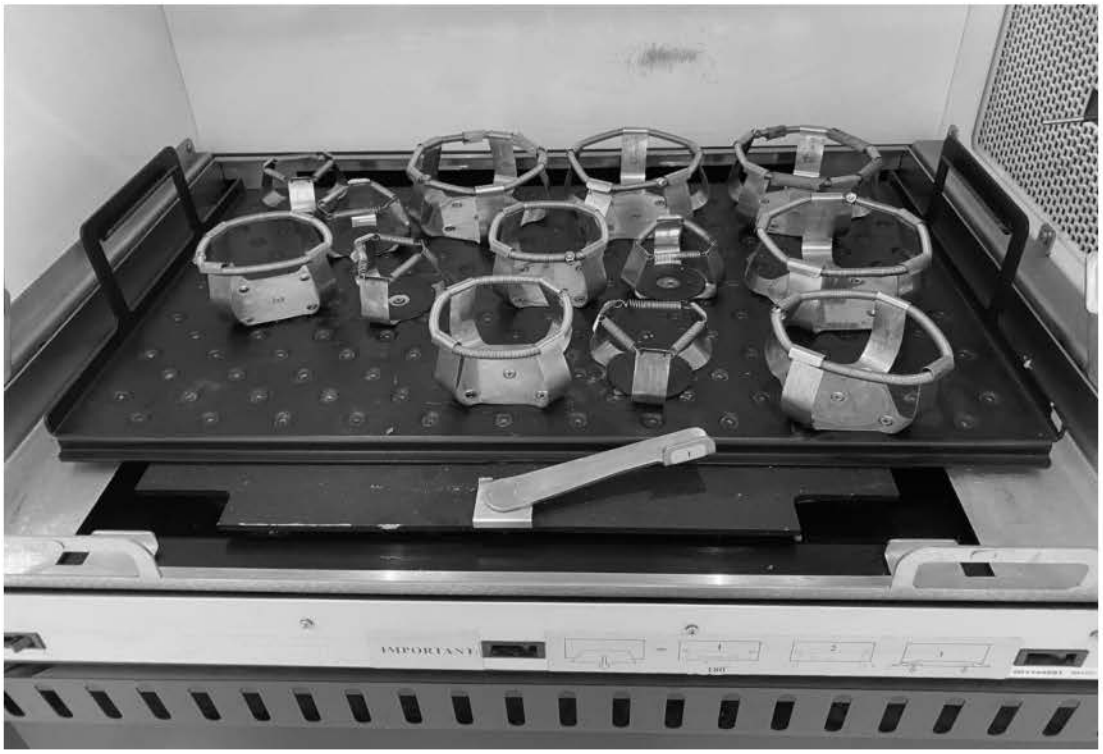
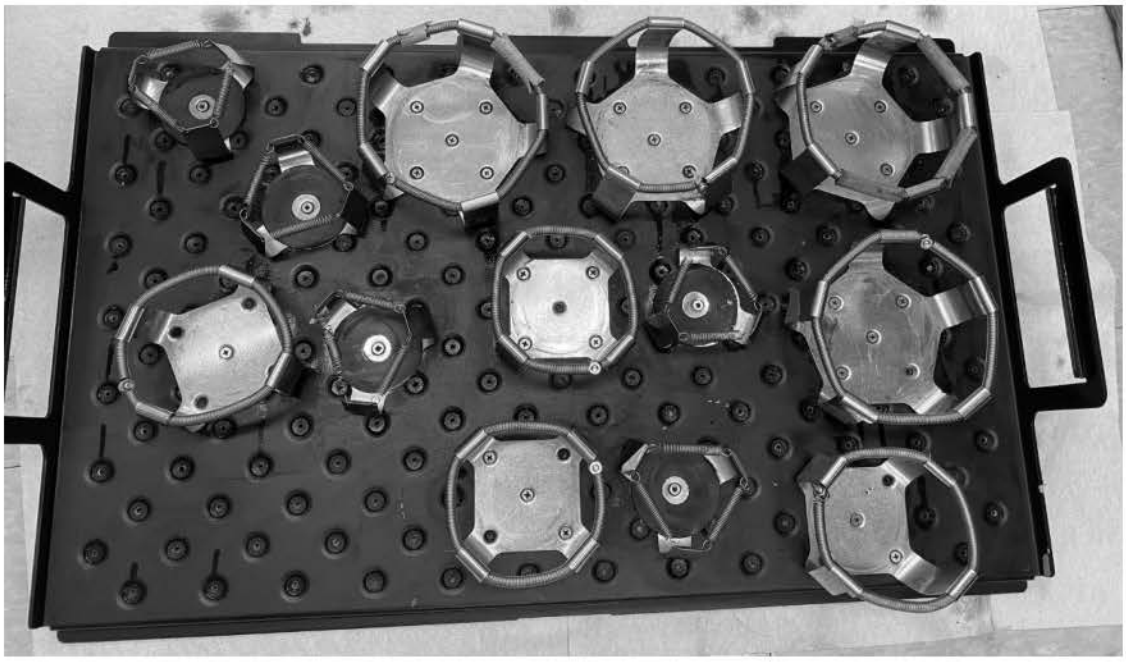
Obtained via FOIA by Judicial Watch Inc.

**Attachment 1:**

Arizona State University-Spill Incident Report September 2020

Photographs after successful spill-cleanup



Obtained via FOIA by Judicial Watch Inc.






Obtained via FOIA by Judicial Watch Inc.



# RELA (Homo sapiens) in pJFT7_nHalo_DC(r4)

Explanation of Terms

Clone: HsCD00832897 | Vector: pJFT7_nHalo_DC(r4) | Additional Annotations

| | |
|---|---|
| Gene: | Gene Symbol: RELA<br>Gene Name: "RELA proto-oncogene, NF-kB subunit"<br>Go to Sequence |
| Original Clone ID: | None |
| Keyword: | antibiotic resistance: Amp |
| Species: | Homo sapiens |
| Type: | cDNA |
| Vector Name: | pJFT7_nHalo_DC(r4) |
| **Format:** | FUSION |
| Source: | Center for Personalized Diagnostics |
| Description: | None |
| Comments: | None |
| Mutation / Discrepancy: | No / No |
| Publications: | None |
| Authors: | Center for Personalized Diagnostics |

**HsCD00832897**

Price: $35.00
AVAILABLE
CPD only
Special MTA: None

Add To Cart

Insert Sequence | Protein Sequence

**Insert sequence:** 1653nts
Open reading frame: 1 to 1653

Find Clones With this Sequence

```
ATGGACGAACTGTTCCCCCTCATCTTCCCGGCAGAGCCAGCCCAGGCCTCTGGCCCCTAT
GTGGAGATCATTGAGCAGCCCAAGCAGCGGGGCATGCGCTTCCGCTACAAGTGCGAGGGG
CGCTCCGCGGGCAGCATCCCAGGCGAGAGGAGCACAGATACCACCAAGACCCACCCCACC
ATCAAGATCAATGGCTACACAGGACCAGGGACAGTGCGCATCTCCCTGGTCACCAAGGAC
CCTCCTCACCGGCCTCACCCCCACGAGCTTGTAGGAAAGGACTGCCGGGATGGCTTCTAT
GAGGCTGAGCTCTGCCCGGACCGCTGCATCCACAGTTTCCAGAACCTGGGAATCCAGTGT
GTGAAGAAGCGGGACCTGGAGCAGGCTATCAGTCAGCGCATCCAGACCAACAACAACCCC
TTCCAAGTTCCTATAGAAGAGCAGCGTGGGGACTACGACCTGAATGCTGTGCGGCTCTGC
TTCCAGGTGACAGTGCGGGACCCATCAGGCAGGCCCCTCCGCCTGCCGCCTGTCCTTTCT
CATCCCATCTTTGACAATCGTGCCCCCAACACTGCCGAGCTCAAGATCTGCCGAGTGAAC
CGAAACTCTGGCAGCTGCCTCGGTGGGGATGAGATCTTCCTACTGTGTGACAAGGTGCAG
AAAGAGGACATTGAGGTGTATTTCACGGGACCAGGCTGGGAGGCCCGAGGCTCCTTTTCG
CAAGCTGATGTGCACCGACAAGTGGCCATTGTGTTCCGGACCCCTCCCTACGCAGACCCC
AGCCTGCAGGCTCCTGTGCGTGTCTCCATGCAGCTGCGGCGGCCTTCCGACCGGGAGCTC
AGTGAGCCCATGGAATTCCAGTACCTGCCAGATACAGACGATCGTCACCGGATTGAGGAG
AAACGTAAAAGGACATATGAGACCTTCAAGAGCATCATGAAGAAGAGTCCTTTCAGCGGA
CCCACCGACCCCCGGCCTCCACCTCGACGCATTGCTGTGCCTTCCCGCAGCTCAGCTTCT
GTCCCCAAGCCAGCACCCCAGCCCTATCCCTTTACGTCATCCCTGAGCACCATCAACTAT
GATGAGTTTCCCACCATGGTGTTTCCTTCTGGGCAGATCAGCCAGGCCTCGGCCTTGGCC
CCGGCCCCTCCCCAAGTCCTGCCCCAGGCTCCAGCCCCTGCCCCTGCTCCAGCCATGGTA
TCAGCTCTGGCCCAGGCCCCAGCCCCTGTCCCAGTCCTAGCCCCAGGCCCTCCTCAGGCT
GTGGCCCCACCTGCCCCCAAGCCCACCCAGGCTGGGGAAGGAACGCTGTCAGAGGCCCTG
CTGCAGCTGCAGTTTGATGATGAAGACCTGGGGGCCTTGCTTGGCAACAGCACAGACCCA
GCTGTGTTCACAGACCTGGCATCCGTCGACAACTCCGAGTTTCAGCAGCTGCTGAACCAG
GGCATACCTGTGGCCCCCCACACAACTGAGCCCATGCTGATGGAGTACCCTGAGGCTATA
ACTCGCCTAGTGACAGGGGCCCAGAGGCCCCCCGACCCAGCTCCTGCTCCACTGGGGGCC
CCGGGGCTCCCCAATGGCCTCCTTTCAGGAGATGAAGACTTCTCCTCCATTGCGGACATG
GACTTCTCAGCCCTGCTGAGTCAGATCAGCTCCTTG
```

## Coding Sequence Details

| | |
|---|---|
| **Insert Sequence Verified?:** | Y |
| **Verification Method:** | Sequence Verification |
| **Mutations:** | None |
| **Discrepancy:** | None |
| **5' Linker Sequence:** | None |
| **3' Linker Sequence:** | None |

## Recommended Growth Condition:

| | |
|---|---|
| **Distributed in bacterial strain:** | DH5-alpha T1 phage resistant |
| **Antibiotic Selection:** | Host Type: bacterial Marker: ampicillin<br>Bacterial Selection Condition:100 ug/mL ampicillin |

Growth Condition:Growth with the single antibiotic in LB at 37 degrees is recommended.
Obtained via FOIA by Judicial Watch Inc.
Comments:Commonly used conditions for ampicillin resistant plasmid clones.

**Protein Expression Results:** None

**Recommended expression in:** Not Applicable



**DNASU Plasmid Repository • PSI:Biology-Materials Repository**

The Biodesign Institute/Arizona State University

1001 S. McAllister Ave, Tempe, AZ 85287-6401 | Map

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Payment Questions - Phone: (480) 965-4544 • Email: DNASUPay@asu.edu

Page Contact: DNASU help | Biodesign Institute

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Obtained via FOIA by Judicial Watch Inc.



# RELA (Homo sapiens) in pJFT7_nHalo_DC(r4)

Explanation of Terms

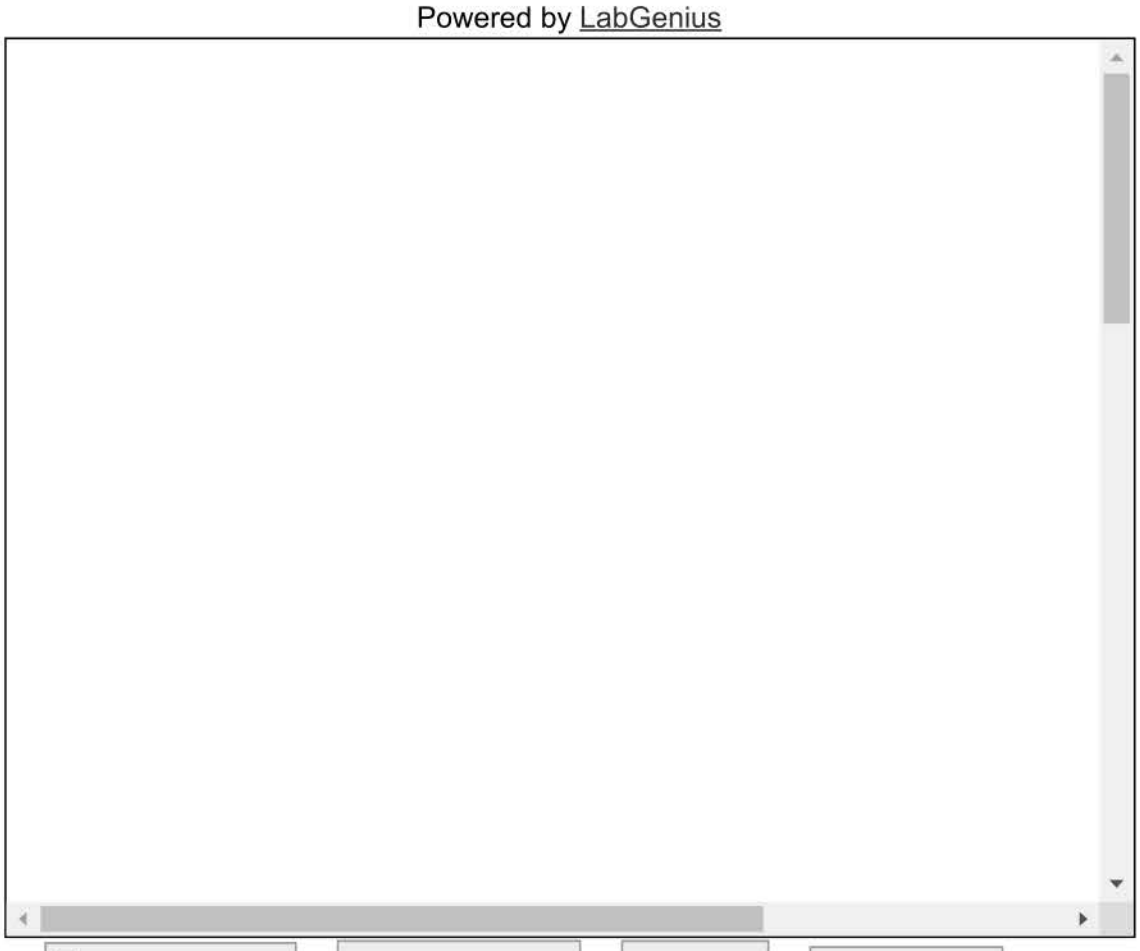
Clone: HsCD00832897 | Vector: pJFT7_nHalo_DC(r4) | Additional Annotations

**Vector Name:** pJFT7_nHalo_DC(r4)
**Synonyms:** "
**Sequencing Primer:**
Forward: HaloseqF
Reverse: pant1627r
**Description:** In vitro expression vector with a T7 promoter and N-terminal TEV-cleavable Halo tag; ampicillin resistance in bacteria; Gateway or Flexi cloning compatible
**Comments:** One in a series of pJFT7 vectors made by J. Saul for IVTT protein expression at CPD. This vector has been modified to improve sequencing the insert with a reverse primer.
**Size (bp):** 6140
**Parent Vector:** None
**Properties:** Gateway, acceptor (destination), in vitro transcription, recombinational cloning, with tag/fusion/marker
**Author Name:** Arizona State University
Joshua LaBaer
Ji Qiu
Justin Saul
Fernanda Festa
Andrea Throop
Center for Personalized Diagnostics
**Publications:** None
**Vector Map:**
**Vector Sequence:**
**Sequence:**

```
GGGCGAATTAATTCCGGTTATT
TTCCACCATATTGCCGTCTTTTG
GCAATGTGAGGGCCCGGAAAC
CTGGCCCTGTCTTCTTGACGA
GCATTCCTAGGGGTCTTTCCCC
TCTCGCCAAAGGAATGCAAGG
TCTGTTGAATGTCGTGAAGGAA
```

Find all Plasmids in pJFT7_nHalo_DC(r4)

DNA Vector Map
Powered by LabGenius



Show restriction sites | Download PDF of map | Enlarge Map | Advanced Viewer

Vector Features:

| Type | Name | Description | Start | End |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| bacterial origin | ColE | ColE1 origin | 3425 | 4107 |
| death cassette | ccdB | ccdB death cassette (removed in plasmids containing a gene insert) | 2785 | 2994 |
| enhancer | CITE | CITE enhancer | 17 | 515 |
| protease cleavage site | TEV | TEV protease cleavage site | 1422 | 1442 |
| recombination site | attR1 | attR1 recombination site | 1458 | 1474 |
| recombination site | attR2 | recombination site | 3145 | 3160 |
| selectable marker | AmpR | ampicillin resistance | 4205 | 4864 |
| selectable marker | CmR | chloramphenicol resistance (removed in clones containing a gene insert) | 1691 | 2347 |
| ssDNA origin | f1 | f1 origin | 5633 | 5939 |
| tag | HALO | N-terminal HALO tag | 522 | 1409 |

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The Biodesign Institute/Arizona State University

1001 S. McAllister Ave, Tempe, AZ 85287-6401 | Map

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Page Contact: DNASU help | Biodesign Institute

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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Nancy Henderson <Nancy.J.Henderson@asu.edu>
**Sent:** Wednesday, September 16, 2020 12:49 PM
**To:** NIH guidelines
**Cc:** Jacobs, Bertram; Debra Murphy; ibc@asu.edu
**Subject:** Arizona State University Incident Report 08.20.2020
**Attachments:** Arizona State University Incident Report 08202020.pdf

**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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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, October 15, 2020 2:45 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
**Sent:** Monday, September 21, 2020 11:34 AM
**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-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:** Wednesday, September 16, 2020 4:56 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 at BSL-2 involving a mouse bite from a mouse infected with recombinant murine parainfluenza "Sendai" virus expressing green fluorescent protein (GFP). The individual has reported the incident to the University Employee Occupational Health Clinic (UEOHC).

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of North Carolina at Chapel Hill |
| **Date of Report:** | 09/21/2020 |
| **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<br>1120 Estes drive<br>Campus Box 1650<br>Chapel Hill, NC 27599 |
| **Date of incident:** | 09/16/2020 |
| **Name of Principal Investigator:** | Dr. Carla Ribeiro |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 3/5/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Recombinant murine parainfluenza (Sendai) virus expressing green fluorescent protein (GFP). |

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## Description of the incident:

At approximately 11:00am on Wednesday, September 17, 2020 a Researcher was weighing and tail marking experimental mice within a biosafety cabinet (BSC) when the incident occurred. The Researcher was wearing the prescribed personal protective equipment (PPE) for work in that ABSL-2 room including disposable gloves, a gown, sleeve covers, hair bonnet, shoe covers, and a face shield. The Researcher has over 13 years of experience working in laboratory and animal facility environments and was compliant with all required EHS trainings.

The Researcher was weighing mice and marking their tails with a marker when a mouse being held by the tail turned and bit the Researcher on their right index finger. The mouse that was involved in the incident was a commercial C57BL/6N mouse that had previously been injected with a recombinant murine parainfluenza virus (Sendai virus) expressing green fluorescent protein (GFP) five days prior to the incident. After returning the mouse back to its cage, the Researcher immediately removed their gloves and exited the BSC. They noticed their wound was bleeding and sprayed their wound with a hypochlorite solution-based disinfectant. They then donned new gloves and returned to their work with the mice for approximately another hour.

After the Researcher finished their work, they returned to their main laboratory and notified their Supervisor and a co-Principal Investigator of the incident. Following instructions from their Supervisor, the Researcher then reported the incident to the University Employee Occupational Health Clinic (UEOHC) for medical assessment.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The IBC is aware of this incident and will review it at the next IBC meeting on 10/7/2020. |
| **Please describe the root cause of this incident:** | At the time of the incident, the Researcher was wearing all prescribed PPE and conducting the procedures according to their training and lab protocol. The root cause is likely attributed to insufficient restraint of the mouse during the procedure. |

**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 review of the Laboratory Safety Manual: Chapter 14 - Safe Handling of Laboratory Animals which describes animal-related hazards, common injuries associated with animal husbandry and care, and basic principles of safety regarding research animals. Furthermore, this Chapter also highlights the importance of immediately reporting incidents in the laboratory to their Supervisor and seeking prompt medical review by the University Employee Occupational Health Clinic (UEOHC).

This Chapter also covers methods for preventing bites and scratches from research animals, including handling techniques and the use of specialized PPE (e.g. bite and cut-resistant gloves) to prevent bites. The PI will be requested to review this Chapter and investigate potential alternative methods for handling mice that minimizes the risk for mouse bites. Such methods may include the use of restraining devices, use of bite-proof gloves, or the use of rubber-tipped forceps for handling the mouse to reduce physical interactions with the mouse using a gloved hand.

The PI will also be asked to discuss with their lab the importance of washing wounds and injuries with just soap and water and avoiding the use of chemical disinfectants (e.g. bleach) not expressly prescribed for treating personal injuries.

The expected date of completion for recommendations will be 09/30/2020.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
**Sent:** Monday, September 21, 2020 11:34 AM
**To:** NIH guidelines
**Cc:** Cyr, Douglas M.; Brennan, Catherine
**Subject:** RE: NIH Incident Report - Final
**Attachments:** NIH Incident Report_09212020.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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**Sent:** Wednesday, September 16, 2020 4:56 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)

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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:** Wednesday, September 16, 2020 4:56 PM
**To:** NIH guidelines
**Cc:** Cyr, Douglas M.; Brennan, Catherine
**Subject:** NIH Incident Report - Preliminary

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

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

Kind regards,
Garry
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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:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, October 15, 2020 2:10 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). 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:** Cook, Susan <shcook@wustl.edu>
**Sent:** Thursday, September 17, 2020 8:44 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident report

Attached, please find a report of a potential exposure to recombinant DNA. 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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Washington University in St. Louis |
| **Date of Report:** | 9/17/2020 |
| **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<br>Campus Box 8229<br>St. Louis, MO 63110 |
| **Date of incident:** | 7/25/2020 |
| **Name of Principal Investigator:** | Brian Van Tine |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☒ Personnel exposure<br>☒ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒ YES ☐ NO<br><br>If yes, date of approval:<br><br>Most recent approval 7/17/20 (originally approved 7/28/2017) |
| **What was the approved biosafety level of the research?** | ☒ BL1<br>☐ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-F-8, Appendix C-II (for the plasmid work in E. coli; downstream packaging of viral vectors would be under III-D) |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | pBABE plasmid carrying shRNA against ME1 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.**

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 research assistant was performing a plasmid DNA extraction using the E.Z.N.A maxiprep spin column kit on several bacterial samples. After adding the kit solutions to the column tubes provided, they attempted to tightly close the lid on all of the tubes to avoid aerosolization in the centrifuge. However, one of tubes provided in the kit had a slightly warped lid. When they applied pressure to tighten it, it slipped out of their hand and the fluid (~20mL total) splashed up into their face. Most of the fluid landed on their mask and lab coat, but some of the fluid splashed into their eyes. They immediately flushed their eyes in the nearby eye wash station. They then went to their desk to check the SDS for the kit components. The SDS indicated that immediate medical attention was necessary as one of the fluid components causes severe eye damage. They then called the emergency number and were escorted to the emergency department. They provided the treatment team with the SDS and received treatment accordingly.

The graduate research assistant had most recently completed the laboratory safety training on 7/1/2020. At the time of the incident, they were wearing a lab coat and gloves.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br>Graduate research assistant reported the incident on 9/15/2020 and the IBC chairs were notified on the same day. This will be discussed with the full committee at the next scheduled meeting. |
| **Please describe the root cause of this incident:** | The tube was warped and slipped from the graduate research assistant's hand when they attempted to close it. |

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):

Environmental Health & Safety is preparing a safety alert to distribute to the research community regarding the importance of wearing appropriate protective equipment, including eye 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:** Cook, Susan <shcook@wustl.edu>
**Sent:** Thursday, September 17, 2020 8:44 PM
**To:** NIH guidelines
**Subject:** Incident report
**Attachments:** Incident-Reporting-WUSTL-200725.pdf

Attached, please find a report of a potential exposure to recombinant DNA. 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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, November 3, 2020 2:13 PM
**To:** Kara Drolet; Sarah Byers; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: 09152020 Vir Bio initial report of potential exposure

Dear Dr. Kara Manning Drolet,

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

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**From:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Tuesday, October 20, 2020 6:23 PM
**To:** Sarah Byers <byerssa@ohsu.edu>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Subject:** RE: 09152020 Vir Bio initial report of potential exposure

Dear Dr. Harris,
Please find attached the detailed report in follow up to the initial report below.
Please 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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

**From:** Sarah Byers
**Sent:** Thursday, September 17, 2020 1:19 PM
**To:** 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** 09152020 Vir Bio initial report of potential exposure

Hello Dr. Harris,

This email serves as the initial notification of a potential exposure involving a risk group II recombinant agent that occurred on 9/15/2020 at Vir Biotechnology. As documented in the Vir Biotechnology IBC RMS registration, the OHSU IBC serves as the IBC for the Portland, OR based Vir Biotechnology laboratories.

While using a piece of equipment in a biosafety cabinet to concentrate an attenuated HCMV vaccine vector one of the tubes under pressure burst and virus sprayed out of the biosafety cabinet onto two researchers. Some of the spray got into the eye of one of the researchers who was taken to the emergency department after the initial washing of their eyes.

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 (*please leave voicemail, I am working remotely*)
byerssa@ohsu.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Tuesday, October 20, 2020 6:23 PM
**To:** Sarah Byers; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: 09152020 Vir Bio initial report of potential exposure
**Attachments:** Vir Bio Final Incident Report.pdf

Dear Dr. Harris,
Please find attached the detailed report in follow up to the initial report below.
Please 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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

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**From:** Sarah Byers
**Sent:** Thursday, September 17, 2020 1:19 PM
**To:** 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** 09152020 Vir Bio initial report of potential exposure

Hello Dr. Harris,

This email serves as the initial notification of a potential exposure involving a risk group II recombinant agent that occurred on 9/15/2020 at Vir Biotechnology. As documented in the Vir Biotechnology IBC RMS registration, the OHSU IBC serves as the IBC for the Portland, OR based Vir Biotechnology laboratories.

While using a piece of equipment in a biosafety cabinet to concentrate an attenuated HCMV vaccine vector one of the tubes under pressure burst and virus sprayed out of the biosafety cabinet onto two researchers. Some of the spray got into the eye of one of the researchers who was taken to the emergency department after the initial washing of their eyes.

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

Obtained via FOIA by Judicial Watch Inc.

503-494-9763 (*please leave voicemail, I am working remotely*)
byerssa@ohsu.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Thursday, September 17, 2020 4:19 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Kara Drolet
**Subject:** 09152020 Vir Bio initial report of potential exposure

Hello Dr. Harris,

This email serves as the initial notification of a potential exposure involving a risk group II recombinant agent that occurred on 9/15/2020 at Vir Biotechnology. As documented in the Vir Biotechnology IBC RMS registration, the OHSU IBC serves as the IBC for the Portland, OR based Vir Biotechnology laboratories.

While using a piece of equipment in a biosafety cabinet to concentrate an attenuated HCMV vaccine vector one of the tubes under pressure burst and virus sprayed out of the biosafety cabinet onto two researchers. Some of the spray got into the eye of one of the researchers who was taken to the emergency department after the initial washing of their eyes.

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 (*please leave voicemail, I am working remotely*)
byerssa@ohsu.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, October 15, 2020 1:44 PM
**To:** James, Mindy; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report

Dear Dr. Mindy James,

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

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**From:** James, Mindy <mindymc@okstate.edu>
**Sent:** Wednesday, September 23, 2020 3:29 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident Report

Good afternoon.

Please see the attached incident report for work conducted at Oklahoma State University.

Please contact me should you need additional information.

Regards,

*Mindy James, Ph.D.*
*Biological Safety Officer*

*University Research Compliance*
*223 Scott Hall*
*Stillwater, OK 74078*
*Phone: (405) 744-3203*
*Fax: (405) 744-4335*

Obtained via FOIA by Judicial Watch Inc.

Email: Mindymc@okstate.edu

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☑YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Oklahoma State University |
| **Date of Report:** | 09/23/2020 |
| **Reporter name and position:** | Mindy James, Ph.D.<br>Biosafety Officer |
| **Telephone number:** | (405) 744-3203 |
| **Email address:** | mindymc@okstate.edu |
| **Reporter mailing address:** | University Research Compliance<br>223 Scott Hall<br>Stillwater, OK 74078 |
| **Date of incident:** | 4/22/2018-5/8/2018 |
| **Name of Principal Investigator:** | Dingbo (Daniel) Lin, Ph.D. |
| **Is this an NIH-funded project?** | ☐ YES ☑NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☑ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ☑NO<br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4<br>N/A – The work was not reviewed by the IBC and thus, did not have an approved biosafety level. |
| **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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA<br>N/A – No other incident reports are required. |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Beta-Carotene Oxygenase 2 (BCO2) knock-out murine macrophage cells (RAW 264.7 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

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On September 15, 2020, the Oklahoma State University (OSU) Biosafety Officer (BSO) was reviewing a grant award package when she recognized the previous generation and use of recombinant mouse macrophage cells during preliminary studies for the proposed work. The BSO contacted the Principal Investigator (PI) and learned that the cells were used for a short time in 2018 (i.e., April 22, 2018 – May 8, 2018). No knockout cells remain from that study; however, they may be generated again for use in the upcoming study. The PI was instructed to not resume work with the cells until IBC approval has been obtained.

The cells were generated using a commercially available CRISPR/Cas9 knockout plasmid along with lipofectamine-mediated transfection. Transfected cells were then harvested and used for Western blotting. All work was carried out in an approved BSL-1 laboratory in accordance with practices detailed in the 5th edition of Biosafety in Microbiology and Biomedical Laboratories. The researcher wore a lab coat and gloves when handling the cells and all wastes were decontaminated by autoclaving prior to disposal. There were no risks to the health or safety of lab personnel or the environment as a result of this incident.

The PI has submitted a protocol detailing generation and use of the cells for review by the OSU Institutional Biosafety Committee (IBC). It will be reviewed at the next convened meeting of the IBC, which is currently scheduled for October 22, 2020. Work with the cells will on resume once the IBC has granted final approval.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ☑ NO<br>The incident will be reviewed during the OSU IBC's October meeting. |
| **Please describe the root cause of this incident:** | The PI believed that the work was exempt from the NIH Guidelines because he did not construct the plasmid vector himself and because he used lipofectamine-mediated transfection rather than lentivirus-mediated transfection. |

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 has been provided with information regarding the requirements of the NIH Guidelines and the need for IBC review and approval of research projects which involve recombinant or synthetic nucleic acid molecules. This information is also available on the OSU Office of University Research Compliance website.

Because the research was conducted in an approved BSL-1 laboratory and all wastes were appropriately decontaminated, no additional mitigation 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:** James, Mindy <mindymc@okstate.edu>
**Sent:** Wednesday, September 23, 2020 3:29 PM
**To:** NIH guidelines
**Subject:** Incident Report
**Attachments:** OSU Incident Report_09222020.pdf

Good afternoon.

Please see the attached incident report for work conducted at Oklahoma State University.

Please contact me should you need additional information.

Regards,

*Mindy James, Ph.D.*
*Biological Safety Officer*

*University Research Compliance*
*223 Scott Hall*
*Stillwater, OK 74078*
*Phone: (405) 744-3203*
*Fax: (405) 744-4335*
*Email: Mindymc@okstate.edu*

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, October 27, 2020 1:46 PM
**To:** ANDREA N LADD; NIH guidelines
**Cc:** Christopher Strang; Kristen Bernard; STEPHANIE G KUTZ; CARRIE A ENSRUD; 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) regarding the release of animals administered recombinant or synthetic nucleic acid molecules from containment without approval from a Federal agency as required under Section 1-A-1 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*).

As you may be aware, the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) has issued a statement regarding the release of certain client-owned animals. Please also see the notice on the NIH OSP website for further information:

https://osp.od.nih.gov/biotechnology/release-of-client-owned-animals/

If you have not already, we recommend advising the appropriate Federal agencies of the release. We understand that the investigator is working with FDA and USDA to obtain all necessary approvals. 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:** Wednesday, September 23, 2020 7:30 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Christopher Strang <christopher.strang@wisc.edu>; Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; CARRIE A ENSRUD <carrie.ensrud@wisc.edu>
**Subject:** Incident report attached

Dear Kathryn or Whom It May Concern,

Obtained via FOIA by Judicial Watch Inc.

Please find attached an incident report involving a potential failure to obtain approval to release animal research subjects from a federal agency under the *NIH Guidelines* (Section I-A-1) that was recently discovered. The Office of Biological Safety has carefully investigated the materials, cause, and follow-up.

Please let me know if you have any questions or need any additional information.

UW-Madison personnel included on this email:

- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety
- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Carrie Ensrud, Animal Research Safety Manager

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

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Wisconsin-Madison |
| **Date of Report:** | 09/23/20 |
| **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<br>30 East Campus Mall<br>Madison, WI 53715 |
| **Date of incident:** | Determined to be OSP-reportable: 08/24/20 |
| **Name of Principal Investigator:** | Ilene Kurzman |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other (please describe): potential failure to obtain approval for release of animal research subjects from a federal agency (Section I-A-1) |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 07/12/17 |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☒BL2 ☐BL2+ ☐BL1-N<br>☐BL3 ☐BL3+ ☐BL2-N<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-4-b, III-F-8 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA X Not applicable |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Irradiated 17CM98 canine melanoma cells that have been transfected with a plasmid expressing human GM-CSF |

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.

**Location:** University of Wisconsin Veterinary Care, Oncology Ward

**Persons involved:** UW-Madison employees

**Training received by individuals:** The PI and all laboratory employees have completed the UW-Madison Required Biosafety Training. All laboratory members receive lab-specific training initially and annually thereafter.

**Event description and follow-up:** A long-running study began at UW-Madison in the 1990s to evaluate a therapeutic vaccine for canine melanoma. The lab has investigated several vaccines since the late 90s; this report focuses on the vaccine that has been administered to dogs in recent years, which is composed of irradiated canine melanoma cells transfected with a plasmid expressing human GM-CSF (an immune stimulant). The original intent of the study was to investigate the efficacy of cell-based veterinary vaccines; UW-Madison does not plan to commercialize the vaccines studied. This study was reviewed by both the IBC and IACUC prior to initiation and has been continuously approved by both committees over the tenure of the study. In June 2020, the three-year renewal of the biosafety registration was reviewed by the IBC. The assessment of the IBC remains that this study is low risk to researchers, research subjects, and the environment. However, in light of announcements made by the FDA's Center for Veterinary Medicine and NIH-OSP on the release of client-owned animals in April 2020, the IBC called for a re-review of the documentation of approval to release client-owned animals enrolled in this study to ensure compliance with the *NIH Guidelines* Section I-A-1.

The PI received multiple approvals from USDA to ship the vaccine until being informed in 2008 by an employee at the USDA that she did not need to continue to reapply for approval to ship the vaccine if nothing had changed. In 2008, the USDA approval did not contain explicit information about disposition of animals. However, it was clear in the application materials the USDA would have reviewed that the vaccine would be administered to client-owned animals. The documents refer to owners' reports of dogs' lethargy for up to 24 hours post-vaccine, implying that the animals return home and are no longer being assessed by a veterinarian. Moreover, nothing in the consent form describes a dog being held at the facility for any length of time, which one would expect if not immediately released to the owner, as it would be likely to impact the decision of whether to enroll one's dog in the trial. There do not appear to have been any substantive changes to USDA's regulations related to experimental production, distribution, and evaluation of biological products between 2008 and now, though current application forms explicitly capture information on the disposition of the animals.

Vaccine administered at the UW Veterinary hospital does not require shipment, as it is produced in a UW laboratory. USDA regulations do not appear to contain a mechanism for authorizing

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release of client-owned animals that have been administered an experimental vaccine if the vaccine is not being shipped.

Although approval to release client-owned animals involved in this research seems implicit in the USDA's prior approval to ship the vaccine, documentation that explicitly approves release was not identified. Thus, it was decided to report this to NIH-OSP as a potential violation of Section I-A-1 of the *NIH Guidelines*.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The IBC discussed at the monthly meeting on June 3, 2020. The IBC Chair was included in subsequent discussions. The IBC will receive an update at the next meeting on October 7, 2020. |
| **Please describe the root cause of this incident:** | The root cause is the lack of a clear regulatory pathway for veterinary clinical trials involving recombinant materials in client-owned animals. |

**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 Biological Safety Officer will assist the PI in working with the FDA and USDA to obtain all necessary approvals. IBC approval of the renewal of this study has been suspended pending receipt of approval for release from a federal agency. The research team does not currently have any vaccine stocks and will not resume production of the vaccine until approval is secured; if such approval cannot be obtained, the study will be terminated.

The requirements under Section I-A-1 of the *NIH Guidelines* have been reviewed with the IBC. In addition, an internal review of other UW-Madison veterinary clinical trials involving the use of recombinant materials in client-owned animals was performed, and in each case the PI or study sponsor had documentation of approval for release by a federal agency.

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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:** ANDREA N LADD <andrea.ladd@wisc.edu>
**Sent:** Wednesday, September 23, 2020 7:30 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Christopher Strang; Kristen Bernard; STEPHANIE G KUTZ; CARRIE A ENSRUD
**Subject:** Incident report attached
**Attachments:** Kurzman_082420_OSP Reportable.docx

Dear Kathryn or Whom It May Concern,

Please find attached an incident report involving a potential failure to obtain approval to release animal research subjects from a federal agency under the *NIH Guidelines* (Section I-A-1) that was recently discovered. The Office of Biological Safety has carefully investigated the materials, cause, and follow-up.

Please let me know if you have any questions or need any additional information.

UW-Madison personnel included on this email:

- Chris Strang, Assistant Vice Chancellor for Environment, Health and Safety
- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Carrie Ensrud, Animal Research Safety Manager

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

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, November 20, 2020 3:18 PM
**To:** Antony Schwartz, PhD; NIH guidelines
**Cc:** Wayne Thomann; Frothingham, Richard; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Final Report: splash exposure to lentiviral vector, September 25, 2020

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.

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:** Monday, October 26, 2020 5:27 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Wayne Thomann <wayne.thomann@duke.edu>; Frothingham, Richard <richard.frothingham@duke.edu>
**Subject:** Final Report: splash exposure to lentiviral vector, September 25, 2020

Dear Dr. Harris,

I am writing to provide a final report on the splash exposure to a Duke researcher to lentiviral vector with the genetic sequence for Cas9 and gRNAs. The event occurred on September 25, 2020 at approximately mid-day. I sent you a preliminary report on September 29, 2020 via email.

**Event:** A Duke researcher (graduate student) was working at the biosafety cabinet with 1.5ml vials containing 1ml lentiviral vector with genetic sequence for Cas9 and gRNA for NR3C1, SMARCA2 and two non-targeting gRNAs. The researcher accidentally knocked the tube rack causing most of the vials' contents to spill inside the BSC. The researcher was wearing a lab coat and gloves. A small volume of the vials' contents splashed on the researcher's forearm in the gap between the lab coat and the gloves.

**First aid and employee health response:** The researcher immediately removed the gloves and lab coat and washed the area thoroughly with soap and water. The researcher notified lab safety personnel, completed a worker injury report, and was evaluated by Duke Student Health and Duke Employee Health. It was determined that no additional treatment was required for this exposure to intact skin.

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**Material description and risk assessment:** The IBC conducted a comprehensive risk assessment including features of the material and the circumstances of the exposure event.

- **Lentiviral vector:** Each lentiviral vector expressed Cas9 and a guide RNA. Guide RNAs either targeted NR3C1 or SMARCA2 or were non-targeting gRNA controls. The IBC had reviewed and approved the rDNA registration and Standard Operating Procedure (SOP) document at the time of registration for this project. However, the PI had not updated the registration with an amendment to include these particular target genes. The PI has been reminded of their responsibility to submit to the IBC any changes to the protocol for the IBC review and approval. The SOP called for BL2 containment with enhancements, including confining all open container work to a BSC. These procedures were followed by the researcher at the time of the incident.
- **Clinical evaluation and management:** The researcher had consultations with both Duke Student Health and Duke Employee Occupational Health and Wellness. No laboratory tests or treatment were recommended. The researcher was advised to contact employee health if any symptoms or signs arise related to this exposure, or if the researcher had further questions.
- **Risk assessment**: In the laboratory, the majority of exposures to lentiviral vectors occur by direct contact with intact skin. Exposure to intact skin is not clinically relevant and does not pose a significant risk. The preferred method to respond to this exposure is copious washing of the affected area with running water to dilute, cleanse, and flush the lentiviral vector from intact skin, as was done in this case. There is no indication for post-exposure chemoprophylaxis for an intact skin exposure. Based on these factors, the IBC considered this event to pose very minimal risk to the researcher.

**Safety evaluation:** The exposure is not expected to cause significant adverse effects. The PI had an approved registration and SOP for work with lentiviral vectors and these approvals/procedures were appropriate for the risks associated with the material involved in the exposure; however, the PI was reminded of the his responsibility to submit amendments whenever there is a change in the recombinant research materials.

**Corrective action:** The researcher was advised to work in the middle of the biosafety cabinet and keep BSC free of any obstructions/clutter that could cause the tube racks to be knocked over (although this was not the reason for this incident). PI has been advised that cuffed laboratory coats must be worn when working with infectious material with splash potential.

**IBC review:** The Duke IBC reviewed this event at the October 21, 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

Obtained via FOIA by Judicial Watch Inc.

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

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## Hunter, Renee (NIH/OD) [C]

**From:** Antony Schwartz, PhD <antony.schwartz@duke.edu>
**Sent:** Monday, October 26, 2020 5:27 PM
**To:** NIH guidelines; Harris, Kathryn (NIH/OD) [C]
**Cc:** Wayne Thomann; Frothingham, Richard
**Subject:** Final Report: splash exposure to lentiviral vector, September 25, 2020

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**Event:** A Duke researcher (graduate student) was working at the biosafety cabinet with 1.5ml vials containing 1ml lentiviral vector with genetic sequence for Cas9 and gRNA for NR3C1, SMARCA2 and two non-targeting gRNAs. The researcher accidentally knocked the tube rack causing most of the vials' contents to spill inside the BSC. The researcher was wearing a lab coat and gloves. A small volume of the vials' contents splashed on the researcher's forearm in the gap between the lab coat and the gloves.

**First aid and employee health response:** The researcher immediately removed the gloves and lab coat and washed the area thoroughly with soap and water. The researcher notified lab safety personnel, completed a worker injury report, and was evaluated by Duke Student Health and Duke Employee Health. It was determined that no additional treatment was required for this exposure to intact skin.

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- **Lentiviral vector:** Each lentiviral vector expressed Cas9 and a guide RNA. Guide RNAs either targeted NR3C1 or SMARCA2 or were non-targeting gRNA controls. The IBC had reviewed and approved the rDNA registration and Standard Operating Procedure (SOP) document at the time of registration for this project. However, the PI had not updated the registration with an amendment to include these particular target genes. The PI has been reminded of their responsibility to submit to the IBC any changes to the protocol for the IBC review and approval. The SOP called for BL2 containment with enhancements, including confining all open container work to a BSC. These procedures were followed by the researcher at the time of the incident.
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**Corrective action:** The researcher was advised to work in the middle of the biosafety cabinet and keep BSC free of any obstructions/clutter that could cause the tube racks to be knocked over (although this was not the reason for this incident). PI has been advised that cuffed laboratory coats must be worn when working with infectious material with splash potential.

**IBC review:** The Duke IBC reviewed this event at the October 21, 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:** Tuesday, September 29, 2020 9:24 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Wayne Thomann; Frothingham, Richard
**Subject:** Preliminary report: splash exposure to lentiviral vector, September 25, 2020

Dear Dr. Harris,
I have received a report of a splash exposure to lentiviral vector with the genetic sequence for Cas9 and a gRNA. The event occurred on September 25, 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

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, October 15, 2020 3:06 PM
**To:** Karen McCulloch; NIH guidelines
**Cc:** Chris Doyle (cdoyle@wirb.com); mindermaur@womenscarefl.com; awhitaker@womenscarefl.com; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: IBC Incident Report - Women's Care Florida

Dear Karen McCulloch,

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
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:** Wednesday, September 30, 2020 3:24 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Chris Doyle (cdoyle@wirb.com) <cdoyle@wirb.com>; mindermaur@womenscarefl.com; awhitaker@womenscarefl.com
**Subject:** IBC Incident Report - Women's Care Florida

To Whom it May Concern,

Please see the attached incident report, related to the use of facilities prior to IBC approval. The IBC convened a meeting on September 29, 2020 and approved use of the facility. Please feel free to reach out with any questions or if I can provide any additional details.

Best,
Karen

**Karen A. McCulloch | IBC Chair**

Obtained via FOIA by Judicial Watch Inc.

**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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# 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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## 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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Women's Care Florida<br>2191 9th Ave North<br>St. Petersburg, FL 33713 |
| **Date of Report:** | 09-30-2020 |
| **Reporter name and position:** | Karen McCulloch, BS<br>IBC Chair, Women's Care Florida |
| **Telephone number:** | 651-429-1058 |
| **Email address:** | kmcculloch@wcgclinical.com |
| **Reporter mailing address:** | 1019 39th Ave SE, Suite 120<br>Puyallup, WA 98374 |
| **Date of incident:** | 09-09-2020 |
| **Name of Principal Investigator:** | Megan D. Indermaur, MD |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other (please describe): Use of new facilities prior to IBC approval. |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval:<br>Initial: 08-06-2019<br>Continuing: 09-29-2020 |
| **What was the approved biosafety level of the research?** | ☒BL1+<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation,** | Lipolymer-encased IL-12 plasmid |

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| | |
|---|---|
| **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)
- 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:**

Women's Care Florida informed IBC Services of a change in address location in June, 2020 and an IBC Review meeting was not held in time prior to subject dosing which occurred on September 9, 2020. The new site physical areas (rooms, equipment, etc.) where study agent was handled is like-for-like compared to the physical areas at the IBC-approved previous address location. Handling activities as outlined in the IBC-approved Biosafety SOP were followed by study staff members during preparation of the study agent and dosing of the subject on September 9, 2020.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | Failure to conduct an IBC Review meeting to review the new facility prior to subject dosing. |

**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 convened a meeting on September 29, 2020 and approved research at the new facility. Any future changes to the institution's facilities or practices will be reviewed by the IBC prior to implementation.

- **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:** Karen McCulloch <KMcCulloch@wcgclinical.com>
**Sent:** Wednesday, September 30, 2020 3:24 PM
**To:** NIH guidelines
**Cc:** Chris Doyle (cdoyle@wirb.com); mindermaur@womenscarefl.com; awhitaker@womenscarefl.com
**Subject:** IBC Incident Report - Women's Care Florida
**Attachments:** OSP Incident Report, Dr. Indermaur, 201-17-201.pdf

**Categories:** Green Category

To Whom it May Concern,

Please see the attached incident report, related to the use of facilities prior to IBC approval. The IBC convened a meeting on September 29, 2020 and approved use of the facility. 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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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, November 3, 2020 2:17 PM
**To:** NIH guidelines; Driskill, Colleen; NIH guidelines
**Cc:** Lebetkin, Kenneth; Greenough, Thomas; Moran, Casey; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Trying to Notify NIH OSP of Incident but received Bounce Back Email

Dear Colleen Driskill,

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:** NIH guidelines <NIHguidelines@od.nih.gov>
**Sent:** Thursday, October 1, 2020 6:02 PM
**To:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Lebetkin, Kenneth <Kenneth.Lebetkin@umassmemorial.org>; Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>; O'Reilly, Marina (NIH/OD) [E] <OReillyM@OD.NIH.GOV>; Broomfield, Violet (NIH/OD) [C] <BroomfiV@OD.NIH.GOV>
**Subject:** RE: Trying to Notify NIH OSP of Incident but received Bounce Back Email

Dear Ms. Driskill,

The attached incident notification has been received by the NIH Office of Science Policy.

Please let us know if you have any additional questions.

Sincerely,
Eugene Rosenthal, Ph.D.
Biotechnology Program Advisor
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy (OSP)
Office of the Director
National Institutes of Health

Obtained via FOIA by Judicial Watch Inc.

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Thursday, October 1, 2020 10:07 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** SciencePolicy <SciencePolicy@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmemorial.org>; Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>
**Subject:** Trying to Notify NIH OSP of Incident but received Bounce Back Email

Attached are relevant emails. Please contact me if you have any questions.

Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** NIH guidelines
**Sent:** Thursday, October 1, 2020 6:02 PM
**To:** Driskill, Colleen; NIH guidelines
**Cc:** Lebetkin, Kenneth; Greenough, Thomas; Moran, Casey; O'Reilly, Marina (NIH/OD) [E]; Broomfield, Violet (NIH/OD) [C]
**Subject:** RE: Trying to Notify NIH OSP of Incident but received Bounce Back Email
**Attachments:** UMMS 091520 Incident Notification; Undeliverable: UMMS 091520 Incident Notification

Dear Ms. Driskill,

The attached incident notification has been received by the NIH Office of Science Policy.

Please let us know if you have any additional questions.

Sincerely,
Eugene Rosenthal, Ph.D.
Biotechnology Program Advisor
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy (OSP)
Office of the Director
National Institutes of Health

---

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Thursday, October 1, 2020 10:07 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** SciencePolicy <SciencePolicy@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmemorial.org>; Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>
**Subject:** Trying to Notify NIH OSP of Incident but received Bounce Back Email

Attached are relevant emails. Please contact me if you have any questions.

Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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## Hunter, Renee (NIH/OD) [C]

**From:** NIH guidelines
**Sent:** Thursday, October 1, 2020 6:02 PM
**To:** Driskill, Colleen; NIH guidelines
**Cc:** Lebetkin, Kenneth; Greenough, Thomas; Moran, Casey; O'Reilly, Marina (NIH/OD) [E]; Broomfield, Violet (NIH/OD) [C]
**Subject:** RE: Trying to Notify NIH OSP of Incident but received Bounce Back Email
**Attachments:** UMMS 091520 Incident Notification; Undeliverable: UMMS 091520 Incident Notification

Dear Ms. Driskill,

The attached incident notification has been received by the NIH Office of Science Policy.

Please let us know if you have any additional questions.

Sincerely,
Eugene Rosenthal, Ph.D.
Biotechnology Program Advisor
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy (OSP)
Office of the Director
National Institutes of Health

---

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Thursday, October 1, 2020 10:07 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** SciencePolicy <SciencePolicy@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmemorial.org>; Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>
**Subject:** Trying to Notify NIH OSP of Incident but received Bounce Back Email

Attached are relevant emails. Please contact me if you have any questions.

Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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## Hunter, Renee (NIH/OD) [C]

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Wednesday, September 30, 2020 5:27 PM
**To:** 'NIHGuidelines@od.nih.gov.'
**Cc:** DuenasDecamp, Maria Jose; Greenough, Thomas; Moran, Casey; Lebetkin, Kenneth; Schrader, Carol; Giaya, Kris; Pustis, Daniel
**Subject:** UMMS 091520 Incident Notification

To Whom it May Concern at the Office of Science Policy, NIH,

On September 15, an incident occurred in a BSL-2 laboratory with BSL-2 enhanced practices. A researcher was conducting neutralization assays and had taken a rack out of a liquid nitrogen Dewar. She then removed a box from the rack and was in the process of transferring a cryotube to a separate rack, when a cap from a different tube within the box shattered, causing the center of the cap to completely disappear. The liquid was frozen inside the 2 ml cryotube at the time of the incident and remained in the tube after. The very center of the cap was expelled (there was a hole in the very center of the cap), not the entire cap itself, and the researcher and the other lab worker in the room did not believe any material was released and did not believe that the researcher was exposed. It seems that the tube may have been defective.

The researcher involved was wearing double gloves, a surgical mask, disposable gown, and goggles. The tube contained a pseudovirus made by cotransfecting pSVIII and carries a LN40 envelope and pNL4.3 that has a stop codon at the beginning of the HIV envelope (called L4-1-1 by their lab), in 293T cells.

The researcher washed her face and used the eyewash as a precaution and with a coworker, contacted Employee Health Services. No follow up or treatment was provided as it was deemed there was no exposure. The researchers disinfected the work area, the tube and its' contents, and autoclaved and disposed of the PPE and tube. Internally we have discussed and closed out actions to prevent future recurrences.

I am sending a notification regarding this incident however, since it was not considered an exposure or release, it seems that filing a full report may not be necessary. Please let me know if you have any questions or concerns, or find that this incident is severe enough to warrant a full report.

Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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## Hunter, Renee (NIH/OD) [C]

**From:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Tuesday, November 17, 2020 3:55 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Initial report of incident at BL2 involving rDNA - Harvard University

Hi Kathryn,

I sincerely apologize for the delay in following up on this e-mail. In our subsequent investigation we determined that the material that the researcher was exposed to did NOT contain rabies viral vector and furthermore was completely fixed with paraformaldehyde so as to renter the tissue completely non-viable.

Therefore, any recombinant material that may be have been present due to the AAV vector, would not be contained within a living system and would likely be somewhat degraded. Therefore, this would be exempt from the NIH guidelines (III-F-2).

Harvard EH&S has fully reviewed the injury, helped the lab develop a safety SOP, and discussed prevention techniques with the PI and lab members.

Please let me know if you have any further questions.

Regards,
Marissa

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, November 12, 2020 10:59 AM
**To:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Subject:** RE: Initial report of incident at BL2 involving rDNA - Harvard University

Hi Marissa:

Just following up on this email the event I missed the final report coming in?

Thanks,

Kathryn

---

**From:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Thursday, October 1, 2020 10:09 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**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 replication incompetent rabies viral vector (BL2) and adeno-associated viral vector (BL1). The vectors were administered

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to a mouse intracranially. Subsequent harvesting of the brain tissue and processing via cryostat led to a sharps injury.

We are investigating the details of the incident and will follow with a formal report 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

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## Hunter, Renee (NIH/OD) [C]

**From:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Wednesday, November 18, 2020 8:11 AM
**To:** Cardwell, Marissa M
**Subject:** RE: Initial report of incident at BL2 involving rDNA - Harvard University

Hi Marissa:

Thanks for letting us know. We will close out this incident.

Regards,

Kathryn

---

**From:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Tuesday, November 17, 2020 3:55 PM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Subject:** RE: Initial report of incident at BL2 involving rDNA - Harvard University

Hi Kathryn,

I sincerely apologize for the delay in following up on this e-mail. In our subsequent investigation we determined that the material that the researcher was exposed to did NOT contain rabies viral vector and furthermore was completely fixed with paraformaldehyde so as to renter the tissue completely non-viable.

Therefore, any recombinant material that may be have been present due to the AAV vector, would not be contained within a living system and would likely be somewhat degraded. Therefore, this would be exempt from the NIH guidelines (III-F-2).

Harvard EH&S has fully reviewed the injury, helped the lab develop a safety SOP, and discussed prevention techniques with the PI and lab members.

Please let me know if you have any further questions.

Regards,
Marissa

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, November 12, 2020 10:59 AM
**To:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Subject:** RE: Initial report of incident at BL2 involving rDNA - Harvard University

Hi Marissa:

Just following up on this email the event I missed the final report coming in?

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Thanks,

Kathryn

---

**From:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Thursday, October 1, 2020 10:09 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**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 replication incompetent rabies viral vector (BL2) and adeno-associated viral vector (BL1). The vectors were administered to a mouse intracranially. Subsequent harvesting of the brain tissue and processing via cryostat led to a sharps injury.

We are investigating the details of the incident and will follow with a formal report 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

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## Hunter, Renee (NIH/OD) [C]

**From:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Thursday, October 1, 2020 10:09 PM
**To:** NIH guidelines
**Subject:** Initial report of incident at BL2 involving rDNA - Harvard University

**Categories:** Green Category

To OSP:

I would like to make an initial report of an incident that occurred at Harvard University involving replication incompetent rabies viral vector (BL2) and adeno-associated viral vector (BL1). The vectors were administered to a mouse intracranially. Subsequent harvesting of the brain tissue and processing via cryostat led to a sharps injury.

We are investigating the details of the incident and will follow with a formal report 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

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, November 20, 2020 3:40 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
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:** ANDREA N LADD <andrea.ladd@wisc.edu>
**Sent:** Thursday, November 5, 2020 1:41 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:** Incident report attached

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the exposure initially reported on 10/06/20 (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

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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
**Sent:** Tuesday, October 6, 2020 2:41 PM
**To:** 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 an exposure involving recombinant materials in one of our BSL2 laboratories. The employee went 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
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

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

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## 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

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☒YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Wisconsin-Madison |
| **Date of Report:** | 10/06/20 (initial email to OSP)<br>11/05/20 (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<br>30 East Campus Mall<br>Madison, WI 53715 |
| **Date of incident:** | 10/06/20 |
| **Name of Principal Investigator:** | David Evans |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 02/22/19 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA<br><br>Not applicable |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Non-conjugative bacterial plasmid containing SHIV-AD8 EO (molecular clone of SHIV-AD8, a strain of chimeric SIV engineered to have the envelope of HIV) |

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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.**

**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, face covering

**Event description:** The employee was learning how to perform a plasmid maxi prep from Stbl2 *E. coli* (a K12 derivative). At the final step, the Eppendorf tube was placed in a mini-tabletop centrifuge for a quick pulse spin. The centrifuge rotor broke and the tube cracked, spraying some of the liquid from the tube in the employee's face. None of the liquid got in the employee's eyes.

It should be noted that exposure to this material is deemed to be low risk. Although used to generate virus, the plasmid itself is not infectious. In addition, no hazardous chemicals are used in this step of the plasmid prep.

**Immediate follow-up and medical follow-up:** The employee immediately washed their face for 15 minutes using a chlorhexidine sponge in accordance with the laboratory's SOP for exposures. The employee informed the PI and then went to University Health Services for medical follow-up. The incident was reported to the Office of Biological Safety and an initial report was submitted to OSP.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br>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 November 4, 2020. |
| **Please describe the root cause of this incident:** | Root cause was misuse of the mini centrifuge. After the incident it was determined that unbeknownst to the employee or the PI the centrifuge rotor had previously been broken and improperly repaired. In addition, the centrifuge was run without closing the lid so there was no containment when the rotor broke again. |

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| | |
|---|---|

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 employee followed the laboratory's emergency procedures. The PI had reviewed the incident with the employee and at an all-hands lab meeting. To prevent future occurrences, the laboratory is instituting the following changes:

- Discontinue use of the broken mini-centrifuge
- Ensure all lab members know never to operate a centrifuge without securing the lid (other centrifuges in the lab will not operate without locking the lid)
- Use cryovials with screw caps instead of Eppendorf tubes, as these are sturdier and less prone to breakage or leakage
- Perform plasmid preps in a biosafety cabinet

It was additionally noted that eye protection should be worn when working 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:** Thursday, November 5, 2020 1:41 PM
**To:** NIH guidelines; Harris, Kathryn (NIH/OD) [C]
**Cc:** Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
**Subject:** Incident report attached
**Attachments:** Evans_100620_OSP Reportable.docx

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the exposure initially reported on 10/06/20 (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

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**From:** ANDREA N LADD
**Sent:** Tuesday, October 6, 2020 2:41 PM
**To:** 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 an exposure involving recombinant materials in one of our BSL2 laboratories. The employee went 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.*
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

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** ANDREA N LADD <andrea.ladd@wisc.edu>
**Sent:** Tuesday, October 6, 2020 3:41 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 an exposure involving recombinant materials in one of our BSL2 laboratories. The employee went 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
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

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, November 3, 2020 1:54 PM
**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 09.17.2020

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:** Monday, October 12, 2020 2:33 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 09.17.2020
**Importance:** High

Good Morning,

Attached is ASU's report of an incident that occurred on September 17, 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

Obtained via FOIA by Judicial Watch Inc.

*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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Arizona State University |
| **Date of Report:** | 10/12/2020 |
| **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<br>PO Box 876011<br>Tempe, AZ 85287-6111 |
| **Date of incident:** | 9/17/2020 |
| **Name of Principal Investigator:** | Barbara Smith |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number: NIH funding institute or center:*<br>NOTE: Project funded by National Science Foundation under Grant No. 1944846 |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 11/26/2018 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-4 RG 2<br>III-E<br>III-E-1<br>III-E-3<br>III-F-8, Appendices C-I, C-II, and C-VII |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA<br>N/A |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Transgenic Mouse: Strain B6; 129P2-Pvalb<tn1(cre)Arbr>J<br>Mouse had been IC injected with AAV 12 hours prior to the bite (injected with AAV1-EF1a-DiO-Nuc-IRFP)<br>Buprenorphine was being injected SQ for pain management, between the shoulder blades. |

Obtained via FOIA by Judicial Watch Inc.

A graduate research associate was giving a mouse a subcutaneous injection in the vivarium on 9/17/2020, when the mouse got free and bit the research associates right thumb. He immediately washed the bite with soap and water, wiped it with alcohol, and applied antibacterial ointment and a band-aid. The research associate notified his PI of the bite and reported to ASU Health Services. Following his visit, he was directed to go to Urgent Care where he received a tetanus booster on 9/17/2020 and antibiotics. The research associate had a follow up appointment with Urgent Care on 9/22/2020 and did not experience any additional problems from the mouse bite.

The Research Associate completed the following trainings:

OHSP: 12/2018
Biosafety and Bloodborne Pathogen Training: 4/27/2020
Laboratory Safety: 4/27/2020

The Research Associate was wearing gloves, a disposable gown, and a mask during the time of the incident.

There were no deviations from the SOP's at the time of the incident.

There were no equipment failures at the time of the incident.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The incident was reviewed at the October 8, 2020 IBC Meeting. |
| **Please describe the root cause of this incident:** | A mouse became free during an injection. |

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 lab will provide Kevlar gloves for employees to use during injections.

The lab will replace buprenorphine and modify the existing protocol for extended release analgesic or an alternative with a longer half-life to prevent middle of the night injections.

This incident was reviewed at the IBC meeting on October 8, 2020 to determine if additional measures were needed. No further actions were recommended after review.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Nancy Henderson <Nancy.J.Henderson@asu.edu>
**Sent:** Monday, October 12, 2020 2:33 PM
**To:** NIH guidelines
**Cc:** Jacobs, Bertram; Debra Murphy; ibc@asu.edu
**Subject:** Arizona State University Incident Report 09.17.2020
**Attachments:** Arizona State University Incident Report Bite (Smith) 10122020.pdf

**Importance:** High

Good Morning,

Attached is ASU's report of an incident that occurred on September 17, 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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, November 3, 2020 2:19 PM
**To:** Major, Sheryl; NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; Bier, Ethan; 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). 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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Tuesday, October 13, 2020 4:51 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** McMahill, Angela <amcmahill@ucsd.edu>; Scott, Lance <lscott@ucsd.edu>; Bier, Ethan <ebier@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 loss of a transgenic animal from Arthropod Containment Level 2. A transgenic *Drosophila melanogaster* was found on a trap located in the hallway outside the ACL-2 facility. This incident was reported to the Biosafety Officer on 09/16/2020 and the Institutional Biosafety Committee on 09/25/2020.

The investigation into this breach of containment found the facility containment features to be sound, and the incident likely resulted due to a deviation from the entry/exit procedures. Retraining of these procedures and additional site inspection have been implemented.

Please let me know if you have any questions regarding this report.
Best,

Sheryl Major

Obtained via FOIA by Judicial Watch Inc.

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

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | X YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, San Diego |
| **Date of Report:** | 10/13/2020 |
| **Reporter name and position:** | Sheryl Major, Biosafety Officer |
| **Telephone number:** | (858) 822-2493 |
| **Email address:** | smajor@ucsd.edu |
| **Reporter mailing address:** | 9500 Gilman Drive #0090<br>La Jolla, CA 92093 |
| **Date of incident:** | 09/16/2020 |
| **Name of Principal Investigator:** | Ethan Bier |
| **Is this an NIH-funded project?** | ☐YES X NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>X Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br><br>If yes, date of approval: 04/10/2015 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 [Arthropod Containment Level 2 (ACL-2)]<br>☐BL2+ (describe specific enhancement in report)<br>☐ BL3<br>☐ ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA<br>☐ FDA<br>☐ EPA<br>☐ OSHA<br>☐Funding agency/sponsor<br>☐State or local Public Health<br>☐Law enforcement<br>☐Other (please describe): |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Transgenic *Drosophila melanogaster* balancer fly (BASC). No florescence noted, based on eye pigment estimated phenotype is yellow+/white+. |

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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 September 16th, 2020, a researcher in a UC San Diego Arthropod Containment Level 2 (ACL-2) insectary facility notified the BSO that a fruit fly had been found on a sticky trap located in the hallway outside the facility. Further investigation and evaluation of the carcass determined the fly was likely a transgenic *Drosophila melanogaster* balancer fly (BASC). This fly would not have been created by the laboratory but rather ordered from a stock center for isolating and maintaining isogenized Drosophila lines/stocks. No florescence was noted, and based on eye pigment the estimated phenotype of the fly was yellow+/white+. It was determined that the fly may have originated from the ACL-2 facility.

All ACL-2 facility users are required to have general and site-specific ACL-2 training prior to being granted access, which includes entry and exit procedures. These entry/exit procedures include the requirement of users to conduct a manual self-brushdown prior to moving both from the main facility into the antechamber, during doffing PPE, and from the antechamber to exit. Prior to each stage, users are required to sweep the room for escapees and kill any found.

Immediate actions following the incident were a sweep of the facility by the lab manager and then the biosafety staff, retraining of users on entry/exit procedures and escapee management, and consultation with the insectary manager to re-evaluate insectary work practices. The lab installed two additional traps to the existing four traps, and additional signage was posted reiterating entry/exit procedures and reporting requirements.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO |
| **Please describe the root cause of this incident:** | Deviation from entry/exit procedures. |

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 Biosafety Program and the lab manager investigated as to how the Drosophila may have exited the facility. Findings from the investigation lead to the conclusion that this was occurred during an entry/exit and consider this an isolated incident. The hallway and surrounding laboratories and offices have not experienced fruit fly infestations. The investigation results was presented to the IBC on 09/25/2020.

The insectary manager and biosafety officers conducted a facility evaluation on 9/17/2020 with a follow up on 9/23/2020, assessing if containment features of the facility are sufficient. During both site visits, no deviations from the NIH Guidelines or Arthropod Containment Guidelines were found. The ACL-2 facility meets NIH Guidelines for BSL-2 facilities, and the Arthropod Containment Guidelines for ACL-2. Containment methods for this facility are interlocked anteroom doors, air curtain, negative directional airflow into the facility, sealed penetrations, screened vents, and traps. All primary containment of arthropods is enclosed in secondary containment in the form of either standing incubators or locked cabinets.

Mitigation measures implemented immediately including retraining of users on entry/exit procedures, installation of additional traps. Additional signage reiterating entry/exit procedures and reporting requirements was posted on 9/23/2020.

On 9/23/2020 placement of the additional traps was confirmed. From the 9/17/2020 site visit, it was determined that trap placement could be increased adjacent to work areas to increase the likelihood of escapee capture.

While a specific incident of deviation from the entry/exit procedures was not identified, it is believed that it was during entry or exit of the facility that the fly may have escaped. The lab manager and the biosafety officer are taking this opportunity to reevaluate work practices in the facility to ensure adherence to containment practices. We do not believe that modifications to entry/exit procedures would improve containment at this juncture. The biosafety and lab manager will continue to conduct frequent inspections.

Retraining of all users on entry/exit procedures and escapee management was completed by 09/24/2020. Additional biosafety retraining is scheduled for later this month and will focus on work practices and regulatory oversight.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Tuesday, October 13, 2020 4:51 PM
**To:** NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; Bier, Ethan
**Subject:** UCSD Report to the NIH
**Attachments:** 2020_NIH_Incident_Report_Bier.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 loss of a transgenic animal from Arthropod Containment Level 2. A transgenic *Drosophila melanogaster* was found on a trap located in the hallway outside the ACL-2 facility. This incident was reported to the Biosafety Officer on 09/16/2020 and the Institutional Biosafety Committee on 09/25/2020.

The investigation into this breach of containment found the facility containment features to be sound, and the incident likely resulted due to a deviation from the entry/exit procedures. Retraining of these procedures and additional site inspection have been implemented.

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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, November 3, 2020 2:40 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 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:** Wednesday, October 14, 2020 4:46 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 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

*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.*

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of North Carolina at Chapel Hill |
| **Date of Report:** | 10/14/2020 |
| **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<br>1120 Estes drive<br>Campus Box 1650<br>Chapel Hill, NC 27599 |
| **Date of incident:** | 08/18/2020 |
| **Name of Principal Investigator:** | Dr. Lishan Su |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* 5-R01-DK119937<br>*NIH funding institute or center:* NIDDK<br>*NIH program officer (name, email address): Edward Doo, M.D.* dooe@niddk.nih.gov |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐YES ☒NO<br>If yes, date of approval:<br><br>The PI had long-standing approvals for work with HIV. However, the PI had no active IBC approvals for use of the particular molecular HIV infectious clone involved in this incident. |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☐BL2 ☒BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | HIV-1 JR-CSF Infectious Molecular Clone (pYK-JRCSF). A full-length replication competent, infectious HIV-1 JR-CSF molecular clone derived from a primary isolate obtained from an AIDS patient. The virus produced by this molecular clone utilizes the co-receptor CCR5. |

Obtained via FOIA by Judicial Watch Inc.

## Description of the incident:

At approximately 3:30 pm on Tuesday, August 18, 2020 the Researcher was isolating bone marrow cells from a mouse femur from a NOD-Rag1-/-IL2RgammaC-null (NRG) Fumarylacetoacetate Hydrolase (Fah) Knockout Mice that had been experimentally infected with a HIV-1 JR-CSF Infectious Molecular Clone (pYK-JRCSF). This work was being performed inside a biosafety cabinet (BSC) within a BSL-2+ tissue culture room when the incident occurred. For personal protective equipment (PPE), the Researcher was wearing a Tyvek gown, two pairs of nitrile gloves and a surgical maske.but not safety glasses. The Researcher was compliant with all their required laboratory safety, bloodborne pathogen (BBP) safety and BSL-2+ safety training. The Researcher indicated that they had significant laboratory experience, including performance of this specific procedure in the lab.

Following the procedure for bone marrow isolation, the Researcher was holding the mouse femur with forceps in their right hand and an insulin needle containing RPMI 1640 medium in their left hand for flushing the cells out of the femur. The mouse femur was being held over a 15ml conical tube to collect the isolated cells. When the Researcher attempted to insert the tip of the needle into the end of the femur, the needle slipped and pricked into their right thumb. The needle had previously been used to isolate bone marrow cells form another femur.

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 10 minutes. The Researcher then exited the tissue culture room, went into the main lab space, and reported the incident to the Laboratory Manager. The Laboratory Manager advised the Researcher to go to the University Employee Occupational Health Clinic (UEOHC) to report the incident. The Researcher went to the UEOHC where they were examined by medical personnel. Post-exposure prophylaxis (PEP) was prescribed as was a baseline diagnostic test. The Researchers' test result was negative for HIV after the 6-week follow up test.

*** Due to an administrative oversight by the Workers Compensation Administrator, the incident notification was not entered into the incident tracking system. As a consequence, the Biosafety Office was not notified of the incident, as is standard procedure for any incidents involving research in biosafety laboratories, and therefore the IBC was not able to immediately report the incident to NIH OSP as required under the NIH Guidelines..

On Monday, October 12, 2020 a review of the incident tracking system by the Workers Compensation Administrator identified the accidental omission and the Biosafety Office was notified of the incident by the Administrator. Once notified, the Biosafety Office immediately initiated their investigation into the incident and compiled this incident report.

It should be noted that at the time of the incident investigation by the Biosafety Office, the PI and the Researcher were no longer employees at UNC and had moved to another institution ***

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The IBC is aware of the incident and will review it at the next IBC meeting on 11/4/2020. |
| **Please describe the root cause of this incident:** | The root cause of the incident appears to be related to the inherent risk of the procedure that involves the use of a sharp needle in close proximity to the users' hand. Additional PPE or procedures can be employed to minimize the risk. |

**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 filed with the Department of Environment, Health and Safety (EHS) that details the incident and includes recommendations to mitigate future reoccurrence of the incident. Normally this incident report would be submitted to the PI for completion. However, since the PI is no longer with the Institution, the recommendations will be applied to the general biosafety program by the Biosafety Office.

To reduce the likelihood of similar incidents, the Biosafety Office will update online BSL-2+ trainings, and also emphasize during in-person BSL-2+ trainings, that laboratories must use safer sharps practices when working in BSL-2+ laboratory spaces. Where possible, the sharps should be eliminated or substituted with safer options or practices. Where not feasible, given experimental needs and constraints, risk from sharps should be minimized through the use of puncture-resistant gloves, single-use needles, and defined procedures that employ best practices with regards sharps usage. Relevant to isolation of bone marrow cells from mice infected with infectious agents, it will be recommended that experimental SOP's specifically detail the need for i) using forceps long enough to physically distance the users hand as far away from the needle as possible, and ii) inserting the needle into the bone (e.g. femur) in a direction moving away from the hand holding the bone so that any slips would not move the needle towards the users' hand.

The BSL-2+ training materials will also be updated to expressly clarify that safety glasses are mandatory PPE, and that conducting research in a BSC does not replace the need for a researcher to wear safety glasses.

Additionally, the BSL-2+ trainings will be updated to include a section on the use of recombinant materials, commonly used in these labs, to ensure the labs understand the requirements for registering the work with the IBC prior to initiation of experiments.

The expected date of completion for recommendations will be 10/23/2020.

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Lastly, to prevent a repeat of the observed notification failure, relevant groups within EHS will perform a comprehensive review of the existing notification procedure, identify the gaps in the current process, and develop appropriate processes and procedures to ensure the Biosafety Office is notified of incidents in a timely manner .

The expected date of completion for recommendations will be 10/23/2020.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
**Sent:** Wednesday, October 14, 2020 4:46 PM
**To:** NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.
**Subject:** NIH Incident Report
**Attachments:** NIH_Incident_Report_10142020_.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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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, November 3, 2020 2:31 PM
**To:** Arnaboldi, Paul; NIH guidelines
**Cc:** Razukiewicz, Amy; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report - New York Medical College

Dear Dr. Paul Arnaboldi,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information provided and acknowledge the explanation for the lateness of the report. 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:** Arnaboldi, Paul <Paul_Arnaboldi@NYMC.EDU>
**Sent:** Friday, October 16, 2020 3:15 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Razukiewicz, Amy <Amy_Razukiewicz@nymc.edu>
**Subject:** Incident Report - New York Medical College

Hi,
In accordance with NIH guidelines we are reporting the attached incident (violation of NIH guidelines) to OSP. Let me know if you have any questions.
Regards,
Paul

Paul M. Arnaboldi, PhD
Assistant Professor
Chair, Institutional Biosafety Committee
Department of Microbiology and Immunology
School of Medicine
New York Medical College
40 Sunshine Cottage Rd, Room C30
Valhalla, NY 10595
P-914-594-4920
F-914-594-4922

Obtained via FOIA by Judicial Watch Inc.

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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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | New York Medical College |
| **Date of Report:** | October 16th, 2020 |
| **Reporter name and position:** | Paul M. Arnaboldi, PhD, IBC Chair |
| **Telephone number:** | 914-594-4920 |
| **Email address:** | paul_arnaboldi@nymc.edu |
| **Reporter mailing address:** | New York Medical College<br>Department of Microbiology and Immunology<br>40 Sunshine Cottage Rd.<br>Valhalla, NY 10595 |
| **Date of incident:** | April 2014, September 2017 |
| **Name of Principal Investigator:** | Petra Rocic |
| **Is this an NIH-funded project?** | ☒YES NO<br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* R01HL093052<br>*NIH funding institute or center:* NHLBI<br>*NIH program officer (name, email address):*Hasan, Ahmed A K |

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| | |
|---|---|
| **What was the nature of the incident?** | ☒Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other (please describe): inaccurate reporting |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO If yes, date of approval: January, 2014 (Adenovirus)<br>October, 2015 (Lentivirus) |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒ BL2 ☐BL2+ (describe specific enhancement in report)<br>☐BL3 ☐BL3+ (describe specific enhancement in report)<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Adenoviral vector containing EGFP.<br>Lentiviral vector containing GPR75-shRNA |

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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 violations occurred in the vivarium.**

- Who was involved in the incident/violation, including others present at the incident location? **The investigation states that the only individual involved was the PI.**

  **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 event was not identified at the time it occurred, but rather several years later during the course of an unrelated investigation. Therefore, no actions were taken at the time related to these violations.**

- The training received by the individual(s) involved and the date(s) the training was conducted: **As the incidents occurred over ~3 and ~6 years ago and was only recently reported, no training was provided at the time it was discovered. The PI has completed NIH guidelines training and taken annual safety training. The PI is no longer employed at the institution so further** training was not provided.

- 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: **Animals injected with adenoviral vectors were supposed to be housed at ABSL-2 for a minimum of 48hrs post injection according to the approved protocol, the animals were immediately placed back in ABSL1 housing. Animals injected with the lentiviral vectors were supposed to be maintained at ABSL2 for at least 48hrs according to the approved protocol; the animals were immediately placed back at ABSL1 housing. Furthermore, the animal husbandry staff were not notified that the experiments were being conducted, and when the continuation protocol for the Adenoviral vector work was submitted, the PI indicated that the project was not yet initiated.**

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation. **Animals were housed at ABSL1 immediately following injection of the adenovirus and lentivirus vectors instead of at ABSL2 as directed by the approved protocols.**

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

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**disposable gown, facemask, booties, and gloves are standard PPE worn in the vivarium**.

- The occupational health requirements for laboratory personnel involved in the research. **Clearance to work in the animal facility. HBV/Tdap vaccines, allergy and exposure risk assessments**

- Any medical surveillance provided or recommended after the incident: **The incidents occurred ~3 and 6 years ago, but were not reported until recently. Thus, no actions were taken.**

- Any injury or illness associated with the incident: **Unknown/none reported**

- Equipment failures**: N/A**

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

**The PI had two IBC protocols that were approved for the use of 1) Adenoviral vectors containing EGFP, adenoviral vectors containing microRNA-145, and 2) lentiviral vectors containing GPR-shRNA. These were to be injected into rats. The protocols were reviewed and approved by the IBC committee. According to the both approved protocols, injected rats were to be maintained at ABSL2 following injection for a minimum of 48hrs due to the risk of shedding. The adenoviral experiment occurred in April of 2014. The rats that were injected were returned to ABSL1 containment immediately after injection. In January of 2015, the PI submitted an annual IBC update falsely stating that the work had not taken place and that it was anticipated to begin in April of 2015. The lentiviral experiments took place in September of 2017. The PI admitted to injecting 3 rats with a lentiviral construct containing GPR75-shRNA. These rats were to be maintained at ABSL2 following injection for a minimum of 48hrs. due to the risk of shedding. However, the rats were returned to ABSL1 housing immediately after injection. These incidents were uncovered during an unrelated compliance investigation that commenced in April of 2019. Following the completion of the compliance investigation, the details of the infractions were reported to the IBC chair by the Vice President of Research for New York Medical College, in the form of a report assembled by the compliance committee. As chair of the IBC, in accordance with NIH guidelines, I am reporting the incident as presented in the report. The investigator in question is no longer employed at the institution**.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | The root cause of the incidents is unclear. The PI stated in an interview with the compliance committee that they "did not believe the virus had the capacity to shed and therefore did not use separate containment," and "that animals were moved out of containment minutes after the injection was completed because her procedure used equipment that was too cumbersome to be kept in ABSL2." A possible cause is that information on the use of viral vectors was not clearly presented in training materials, so that the investigator was unaware of the correct procedures, though it is unclear why then the correct procedure was present in the PI's submitted and approved protocols. The investigator is no longer employed at the institution. |

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(s) described here were reported to the IBC in a report from a compliance committee formed due to a separate incident. They incidents took place in 2014 and 2017 respectively. Since that time, we have implemented several new procedures to maintain investigator awareness of correct procedures in the use of viral vectors. The NYMC Department of Energy, Environment, Health & Safety working under guidance from the IBC assembled a document called 'Guidance for working with Viral Vectors.' This organizes information on all of the viral vectors used at our institution in one concise source so that investigators have a single source to refer to for guidance on all viral vector usage. In addition, we have also instituted a policy where all lab members in a PIs lab must read the IBC protocols and sign an acknowledgement form from indicating that they have read and understood the protocol. In this manner everyone in the lab knows the requirements of each protocol. Yearly refresher courses have also been updated. In addition, for the use of both adenoviral vectors and lentiviral vectors the required minimum time for containment has been increased to 7 days. All of the above changes have already been implemented.**

- **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:** Arnaboldi, Paul <Paul_Arnaboldi@NYMC.EDU>
**Sent:** Friday, October 16, 2020 3:15 PM
**To:** NIH guidelines
**Cc:** Razukiewicz, Amy
**Subject:** Incident Report - New York Medical College
**Attachments:** Incident-Reporting-NYMC 10-16-20.pdf

Hi,
In accordance with NIH guidelines we are reporting the attached incident (violation of NIH guidelines) to OSP. Let me know if you have any questions.
Regards,
Paul

Paul M. Arnaboldi, PhD
Assistant Professor
Chair, Institutional Biosafety Committee
Department of Microbiology and Immunology
School of Medicine
New York Medical College
40 Sunshine Cottage Rd, Room C30
Valhalla, NY 10595
P-914-594-4920
F-914-594-4922

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, November 3, 2020 2:14 PM
**To:** Kara Drolet; NIH guidelines
**Cc:** Sarah Byers; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: OHSU incident report

Dear Dr. Kara Manning Drolet,

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:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Tuesday, October 20, 2020 6:32 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Sarah Byers <byerssa@ohsu.edu>
**Subject:** OHSU incident report

Dear Dr. Harris,
Please find attached a report of an incident involving failure to follow IBC PPE requirements.
Please 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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

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## Hunter, Renee (NIH/OD) [C]

**From:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Tuesday, October 20, 2020 6:32 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Sarah Byers
**Subject:** OHSU incident report
**Attachments:** OHSU Incident Report PPE deviation.pdf

Dear Dr. Harris,
Please find attached a report of an incident involving failure to follow IBC PPE requirements.
Please 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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, November 20, 2020 3:35 PM
**To:** Don Sibley; NIH guidelines
**Cc:** Laurence Vonkalm; Renee Michel; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident report filing

Dear Dr. Don Sibley,

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
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:** Don Sibley <Don.Sibley@ucf.edu>
**Sent:** Friday, October 23, 2020 2:52 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Laurence Vonkalm <lvonkalm@ucf.edu>; Renee Michel <Renee.Michel@ucf.edu>
**Subject:** Incident report filing

Good afternoon,

Please find attached an incident report concerning non-exempt research involving recombinant nucleic acid molecules conducted by Hao Yu, Ph.D. without obtaining IBC approval. Dr. Yu is the President and CEO of OncoTroy Inc., which is conducting research is a private concern leasing space operated by the UCF Business Incubator Program. The UCF IBC and the Department of Environmental Health and Safety provide research compliance and occupational health and safety oversight for research conducted within the UCF business incubator.

If you have any questions concerning this incident report or the UCF response to the incident please contact me.

Sincerely,

Obtained via FOIA by Judicial Watch Inc.

Don Sibley

Don Sibley, Ph.D., RBP
Biological Safety Officer
University of Central Florida
P 407-823-1526
C Redacted by agreement
F 407-823-1219
Don.Sibley@ucf.edu
3512 Perseus Loop Bldg 48, Office 132
Laboratory and Environmental Support
Orlando, FL 32816-3500

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Central Florida |
| **Date of Report:** | 10/20/20 |
| **Reporter name and position:** | Don Sibley, Biological Safety Officer |
| **Telephone number:** | 407-823-1526 |
| **Email address:** | Don.Sibley@ucf.edu |
| **Reporter mailing address:** | 3512 Perseus Loop Bldg 48, Office 132<br>Laboratory and Environmental Support<br>Orlando, FL 32816-3500 |
| **Date of incident:** | 9/17/2018 – 9/23/2020 |
| **Name of Principal Investigator:** | Hao Yu |
| **Is this an NIH-funded project?** | ☐YES X NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>X Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES X NO<br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Experiments involving the use of infectious DNA/RNA Viruses **OR** Defective DNA/RNA viruses in the presence of helper virus in tissue culture systems. **(III-D-3)** |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | PI was modifying Vesticular Stomatitis virus to be used for targeting human tumor cells for lysis by the recombinant VSV. E. coli K-12 strains were used as expression vectors for plasmids containing the tumor receptor protein sequence. The VSV used was replication incompetent virus which was propagated using BHK cells co-infected with MVA as a helper virus and co-transfected with the tumor target plasmid using a lipofectamine system. All studies were conducted in vitro using a certified BSC and BSL-2 containment practices. |

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)

This case was uncovered in an UCF incubator facility involving a tenant operating a private lab under the corporate name of OncoTroy Inc. Dr. Yu, President/CEO, Oncotroy was unaware of the IBC registration requirements by NIH guidelines for research involving recombinant or synthetic nucleic acid molecules. Once the research involving human tumor cell lines was identified in conjunction with the review of a biological permit with EHS, the PI was asked to register the work with the IBC. During the follow up inspection of his laboratory associated with the registration process it was determined that Dr. Yu had been conducting non-exempt recombinant DNA studies since the fall of 2018. It was later determined that Dr. Yu sent a protocol describing this work to the IBC on September 17,2018. The original protocol was not presented to the IBC or acted upon at that time. During this time, the IBC chair and the BSO had resigned and the positions were being filled. Dr. Von Kalm was named IBC chair during this time period and Dr. Sibley was hired as BSO on November 30 2018. Dr. Yu admitted that he had not heard back from the IBC concerning the protocol but failed to follow up on its approval. On September 23, 2020 the IBC met to consider Dr. Yu's case and ordered Dr. Yu's research to be suspended and his lab to cease all work. Dr. Yu complied with the IBC and immediately ceased all work on September 23. Dr. Sibley met with Dr. Yu on September 25 to explain the reasons his lab was shut down and what actions were required to reopen his laboratory. Dr. Yu was required to complete the UCF training course covering the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, and the bloodborne pathogens training for laboratory personnel. He completed both courses on September 29. Since this time Dr. Sibley has worked with Dr. Yu to draft an exempt registration protocol to allow him to begin working with his K-12 E. coli strains and plasmids. This exempt protocol was reviewed and approved by the BSO and IBC chair as a step toward reopening his laboratory in a manner fully compliant with the NIH guidelines and UCF policy. Dr. Yu has agreed to work closely with Dr. Sibley and the IBC to make certain he remains in full compliance with all regulations concerning research safety in the future.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO |
| **Please describe the root cause of this incident:** | The Pi was not knowledgeable of the NIH guidelines and the requirements for IBC approval for non-exempt work. In addition, the University has stepped up its oversight of these incubator facilities and the operations of the organizations leasing these spaces. |

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 University is evaluating the lease agreements to assure UCF authority over the approval process for use of these spaces and the onboarding process for tenants leasing these spaces. In conjunction with these processes the University is stepping up the oversight and inspection processes for tenants in these incubator laboratories. Since this incident, the EHS Director implemented a requirement for all tenants to follow the same onboarding process as used for new faculty, requiring a detailed hazard assessment and the appropriate laboratory safety training for all personnel working in these spaces. It is also likely additional changes may be implemented by UCF administration once a full review and evaluation of the leasing program for these incubator laboratories has been completed.

- **Additional information may be requested by NIH OSP after review of this report**

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**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:** Don Sibley <Don.Sibley@ucf.edu>
**Sent:** Friday, October 23, 2020 2:52 PM
**To:** NIH guidelines
**Cc:** Laurence Vonkalm; Renee Michel
**Subject:** Incident report filing
**Attachments:** NIH Incident report_Yu_201020.docx

Good afternoon,

Please find attached an incident report concerning non-exempt research involving recombinant nucleic acid molecules conducted by Hao Yu, Ph.D. without obtaining IBC approval. Dr. Yu is the President and CEO of OncoTroy Inc., which is conducting research is a private concern leasing space operated by the UCF Business Incubator Program. The UCF IBC and the Department of Environmental Health and Safety provide research compliance and occupational health and safety oversight for research conducted within the UCF business incubator.

If you have any questions concerning this incident report or the UCF response to the incident please contact me.

Sincerely,

Don Sibley

Don Sibley, Ph.D., RBP
Biological Safety Officer
University of Central Florida
P 407-823-1526
C Redacted by agreement
F 407-823-1219
Don.Sibley@ucf.edu
3512 Perseus Loop Bldg 48, Office 132
Laboratory and Environmental Support
Orlando, FL 32816-3500

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 11:14 AM
**To:** Kara Drolet; Sarah Byers; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: OHSU 10/23/2020 Initial report of potential exposure

Dear Dr. Kara Manning Drolet,

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

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**From:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Thursday, December 10, 2020 6:44 PM
**To:** Sarah Byers <byerssa@ohsu.edu>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Subject:** RE: OHSU 10/23/2020 Initial report of potential exposure

Dear Dr. Harris,
Please find the final report for this incident attached 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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

**From:** Sarah Byers
**Sent:** Friday, October 23, 2020 4:33 PM
**To:** 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** OHSU 10/23/2020 Initial report of potential exposure

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 10/23/2020 at Oregon Health & Science University. While administering antiretroviral therapy to a non-human primate infected with SHIV a staff member sustained 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.

OREGON HEALTH & SCIENCE UNIVERSITY

**Institutional Biosafety Committee**

Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
fax 503 346-6808
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

December 10, 2020

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

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 10/23/2020.

| | |
|---|---|
| OHSU IBC registration number | IBC-11-15 |
| OHSU project title | Novel approaches to overcome retrovirus diversity for vaccine development |
| Nature of the material | Non-human primate infected SHIV AD8 (using the envelope from HIV strain AD8) with wild type pathogenicity. Viral load not detectable in the animal. |
| Risk Group | III |
| Containment level | ABSL-2+, enhancement is through PPE and work practices |
| Nature of the incident | Personnel Exposure |
| PPE in use | Dedicated footwear or boot covers, scrubs, disposable gown, hair bonnet, double gloves, face shield, and fiber mask |

**Description of incident:**

A clinical technician was attempting to give a subcutaneous injection of anti-retroviral therapy cage side to a non-human primate that was on a tether system and in a jacket. Injections in animals in tether systems are more complicated and less frequently conducted. The animal moved while technician was trying to get the needle into position for the injection and the needle poked the technician. The technician secured the animal, washed the exposure site for 20 minutes and reported to the occupational health nurse for evaluation of the exposure.

**Actions taken:**

The incident was reviewed by the IBC administrative group and by the West Campus incident review committee. The root cause of the needle stick was due to unanticipated animal movement. When conducting this more complicated injection in the future, the clinical work unit will try to use a Kevlar glove or forceps as an engineering control to provide projection for the hand that needs to be positioned near the injection site on the animal.

The IBC has determined that this incident has now been resolved with the submission of this report to OSP. If the individual develops symptoms related to this exposure the OHSU IBC will notify NIH-OSP.

Sincerely,

Kara Drolet
Digitally signed by Kara Drolet
Date: 2020.12.10 15:38:24 -08'00'

Kara Manning Drolet, PhD
Associate Vice President, Research Integrity

Cc: 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:** Thursday, December 10, 2020 6:44 PM
**To:** Sarah Byers; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: OHSU 10/23/2020 Initial report of potential exposure
**Attachments:** 10232020 OHSU SHIV needle stick final report.pdf

Dear Dr. Harris,
Please find the final report for this incident attached 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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

---

**From:** Sarah Byers
**Sent:** Friday, October 23, 2020 4:33 PM
**To:** 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** OHSU 10/23/2020 Initial report of potential exposure

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 10/23/2020 at Oregon Health & Science University. While administering antiretroviral therapy to a non-human primate infected with SHIV a staff member sustained 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:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Friday, October 23, 2020 7:33 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Kara Drolet
**Subject:** OHSU 10/23/2020 Initial report of potential exposure

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 10/23/2020 at Oregon Health & Science University. While administering antiretroviral therapy to a non-human primate infected with SHIV a staff member sustained 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, November 20, 2020 3:26 PM
**To:** Ryan C. McAllister; NIH guidelines
**Cc:** Dr. Ellyn D Segal PhD; Mark Holodniy; Yvonne A Maldonado; Kathy McClelland; Kathryn Ann Moler; Ruth O'hara; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Report from Stanford University

Dear Dr. Ryan McAllister,

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:** Ryan C. McAllister <rcmcalli@stanford.edu>
**Sent:** Tuesday, October 27, 2020 1:17 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Dr. Ellyn D Segal PhD <esegal@stanford.edu>; Mark Holodniy <holodniy@stanford.edu>; Yvonne A Maldonado <bonniem@stanford.edu>; Kathy McClelland <kathymcc@stanford.edu>; Kathryn Ann Moler <kmoler@stanford.edu>; Ruth O'hara <roh@stanford.edu>
**Subject:** Report from Stanford University
**Importance:** High

To Whom it May Concern,

Please find the attached document reporting an event of NIH Guideline non-compliance.

Please do not hesitate to reach out Dr. Ellyn Segal or myself at any time regarding any concern or question that arises during the NIH OSP review process.

Best,

Ryan

Ryan C. McAllister Ph.D.
Assistant Biosafety Officer

Obtained via FOIA by Judicial Watch Inc.

Stanford University
Environmental Health & Safety
480 Oak Road
Stanford, CA 94305
RyanMcAllister@Stanford.edu
T 650.723.3635

Ellyn Segal, Ph.D.
Assistant Director, EH&S
Biosafety & Biosecurity Manager
Stanford University
Ph: 650.725.1473
esegal@stanford.edu

Obtained via FOIA by Judicial Watch Inc.

Stanford | Environmental Health & Safety

ELLYN SEGAL, PH.D.
BIOSAFETY & BIOSECURITY MANAGER

NIH Office of Biotechnology Activities
6705 Rockledge Drive
Bethesda, MD
20892-7985

Re: Report of non-compliance with Clinical Research Protocol

To Whom It May Concern: October 27, 2020

This report is to notify NIH of a Stanford lead clinical research study being in non-compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines, April 2019). Specifically, the Principle Investigator did not submit a clinical protocol involving rDNA to the Stanford University IBC (at Stanford this is the Administrative Panel on Biosafety (APB)) for review and approval prior to conducting the study.

The following is a summary of events related to this report:

Upon receipt and review by the APB (Sept. 2020) of a protocol entitled "A Randomized, Sham Controlled, Masked Phase II Study to Evaluate the Safety and Efficacy of Dual Intravitreal Implantation of NT-501 Encapsulated Cell Therapy for the Treatment of Glaucoma (Gene Transfer)" it was discovered that apparent non-compliance has occurred regarding this study up to this point in time.

Per the Stanford University Research Compliance Office (RCO), the Investigative Product (IP) for this study has been used at Stanford since 2016 (5/11/2016) and 55 subjects have been treated at Stanford.

The Investigator Brochure (IB, 2015) states the following regarding the Investigational Product (IP):

> ***1.3.1. T*** *The Renexus NT-501 ECT investigational product is a unique platform for the intraocular delivery of neurotrophic factors for the treatment of retinal degeneration diseases.* ***The ECT implants consist of genetically modified human retinal pigment epithelium (RPE) cells encapsulated in a section of semipermeable hollow fiber membrane (HFM).*** *The cells are loaded into the interior volume of the HFM and attach to a supportive matrix within this space and the ends are integrally sealed. The ECT implants are surgically placed in the vitreous body, yet outside of the*

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*visual axis so that visual function is not adversely affected. The implant is sutured in a manner that allows for its retrieval when desired.*

The IB submitted to the APB (NT-501 17 June 2020, Edition 5.4) states the following:

***3.2.4. Cell Lines***
*The cells encapsulated in the NT-501 investigational product constitutively express human ciliary neurotrophic factor (hCNTF) and are termed NTC-201 cells. They are derived from a human RPE continuous cell line, ARPE-19 (ATCC # CRL-2302). Neurotech established a parental master stock of ARPE-19 cells and designated them as NTC-200.* ***Transfection of NTC-200 cells with a plasmid vector produced the NTC-201 cell lines, which constitutively secrete CNTF.***
*The transfection of the NTC-200 cell line to produce the 2 NTC-201 cell lines was accomplished with the mammalian expression vector pNUT-IgSP-hCNTF. The entire vector has been sequenced and is well characterized. Secretory hCNTF expression is driven by the mouse metallothionein promoter and contains the human growth hormone polyadenylation signal. To target CNTF for secretion the genomic murine immunoglobulin signal peptide gene is fused in frame to the 5' genomic hCNTF gene, which lacks the codon for the initial methionine. As part of the constitutive secretory pathway processing, the signal sequence is cleaved from the Hcntf N-terminus, resulting in release of mature hCNTF from the cell.*

A review of Adverse Events/Serious Adverse Events (AEs/SAEs, provided in the Annual Report to the FDA (March 5, 2020)) from the initial study of 55 treated subjects shows that there have not been any SAEs, either related or not-related to the IP.

Causes and Moving Forward:

The PI was made aware of this oversight, as was the Stanford University IRB and Office of Research Compliance. At Stanford it is the policy that the PI has the responsibility for all oversight of research. The IRB assists in vetting clinical protocols for APB requirements along with the APB providing regulatory information to researchers.

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Stanford | Environmental Health & Safety

ELLYN SEGAL, PH.D.
BIOSAFETY & BIOSECURITY MANAGER

In response to how this mishap occurred the PI stated that per the regulatory consultant for Neurotech (the company that makes the IP) this project was not considered gene therapy. Upon continued discussion the PI assured that they will work to be responsive to NIH Guidelines, including early discussions in cases that may involve recombinant or synthetic DNA and gene therapy.

Sincerely,

Redacted by agreement

Ryan McAllister Ph.D.
Assistant Biosafety Officer
Stanford University

Signing on Behalf of

Ellyn Segal, Ph.D.
Assistant Director, EH&S
Manager, Biosafety & Biosecurity
Stanford University

Cc: Kathryn Moler, Ph.D., Vice Provost and Dean of Research, Stanford University
Ruth O'Hara, Ph.D., Sr. Associate Dean of Research, Stanford University School of Medicine
Kathy McClelland, Research Compliance Office Director, Stanford University
Mark Holodniy, M.D., Professor of Medicine (infectious Diseases), Stanford University
Yvonne Maldonado, Sr. Associate Dean, Professor of Pediatrics (Infectious Diseases), Epidemiology and Population Health, Stanford University

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Ryan C. McAllister <rcmcalli@stanford.edu>
**Sent:** Tuesday, October 27, 2020 1:17 PM
**To:** NIH guidelines
**Cc:** Dr. Ellyn D Segal PhD; Mark Holodniy; Yvonne A Maldonado; Kathy McClelland; Kathryn Ann Moler; Ruth O'hara
**Subject:** Report from Stanford University
**Attachments:** Stanford APB Letter to NIH OSP October 2020.pdf

**Importance:** High

To Whom it May Concern,

Please find the attached document reporting an event of NIH Guideline non-compliance.

Please do not hesitate to reach out Dr. Ellyn Segal or myself at any time regarding any concern or question that arises during the NIH OSP review process.

Best,

Ryan

Ryan C. McAllister Ph.D.
Assistant Biosafety Officer
Stanford University
Environmental Health & Safety
480 Oak Road
Stanford, CA 94305
RyanMcAllister@Stanford.edu
T 650.723.3635

Ellyn Segal, Ph.D.
Assistant Director, EH&S
Biosafety & Biosecurity Manager
Stanford University
Ph: 650.725.1473
esegal@stanford.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, November 20, 2020 3:28 PM
**To:** Major, Sheryl; NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; Gustafsson, Asa; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: UCSD Injury 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). 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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Tuesday, October 27, 2020 2:41 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** McMahill, Angela <amcmahill@ucsd.edu>; Scott, Lance <lscott@ucsd.edu>; Gustafsson, Asa <abgustafsson@UCSD.EDU>
**Subject:** UCSD Injury 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 an animal bite from a mouse that had been infected with AAV-GFP viral vector 4 weeks earlier. This incident was reported to the Biosafety Program on 10/06/2020 and the Institutional Biosafety Committee on 10/23/2020.

Please let me know if you have any questions regarding this report.
Best,

Sheryl Major
Biosafety Officer (BSO)
High Containment Officer (HCO)

Obtained via FOIA by Judicial Watch Inc.

UC San Diego
Environment, Health and Safety
CRSF 241
Ph: 858-822-2493
Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | XYES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, San Diego |
| **Date of Report:** | October 22, 2020 |
| **Reporter name and position:** | Sheryl Major, Biosafety Officer |
| **Telephone number:** | (858) 822-2493 |
| **Email address:** | smajor@ucsd.edu |
| **Reporter mailing address:** | 9500 Gilman Drive<br>m/c 0090<br>UCSD<br>La Jolla, California 92093-0090 |
| | |
| **Name of Principal Investigator:** | Asa Gustafsson |
| **Is this an NIH-funded project?** | XYES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* 5R01HL132300<br>*NIH funding institute or center: NHLBI*<br>*NIH program officer (name, email address):*<br>*Renee Wong, wongr2@nhlbi.nih.gov* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>Other (please describe): Researcher bitten by a mouse that had been infected with AAV-GFP viral vector 4 weeks earlier. |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO If<br>yes, date of approval:<br>5/11/2018 |
| **What was the approved biosafety level of the research?** | X BL1<br>☐BL2 ☐BL2+ (describe specific enhancement in report)<br>☐BL3 ☐BL3+ (describe specific enhancement in report)<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Adeno-associated virus (AAV) is a Risk Group 1 virus not associated with disease in healthy adult humans. The serotype used in this case was AAV Serotype 9. Green fluorescent protein is a widely used marker gene and is not expected to increase the hazard. |

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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)

On October 6, 2020, a male post-doctoral fellow was working in laboratory space at Biosafety Level 1. He was trying to scruff the mouse for euthanasia according to the lab's IACUC approved protocol. The mice are placed under deep anesthesia using sodium pentobarbital prior to being euthanized by exsanguination. It was during administration of the sodium pentobarbital when the mouse twisted and bit the researcher's index finger. The researcher returned the mouse to the cage and washed his finger with antibacterial soap and water for 10 minutes. Further medical attention has been offered. There was no deviation from IBC conditions of approval or laboratory standard operating procedures.

The researcher was wearing single use nitrile gloves, laboratory coat, and safety glasses. The researcher had taken the training class "Biosafety: Recombinant and Synthetic Nucleic Acids" on June 25, 2019 and was approved by Institutional Animal Care and Use Committee for this procedure.

The researcher will attend one-on-one training in small animal handling provided by the Animal Care Program to evaluate his technique and provide recommendations.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO<br>10/23/2020 |
| **Please describe the root cause of this incident:** | To avoid animal bites, researchers must be proficient in good animal handling 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):

The researcher will undergo required training in small animal handling. Due to the nature of the research an alternate euthanasia procedure cannot be used.

This injury was discussed by the Institutional Biosafety Committee on October 23, 2020. The campus veterinarians were present at the meeting. Different euthanasia methods, restraint methods, and hand protections were reviewed. Based on the research protocol, the euthanasia method cannot be modified. The Committee agreed that retraining on the restraint method and use of double gloving is suitable. The lab is evaluating the use of double gloves for this procedure.

- **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.

## Hunter, Renee (NIH/OD) [C]

**From:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Tuesday, October 27, 2020 2:41 PM
**To:** NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; Gustafsson, Asa
**Subject:** UCSD Injury Report to the NIH
**Attachments:** NIH Report - Gustafsson 10-19-20.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 an animal bite from a mouse that had been infected with AAV-GFP viral vector 4 weeks earlier. This incident was reported to the Biosafety Program on 10/06/2020 and the Institutional Biosafety Committee on 10/23/2020.

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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, November 20, 2020 3:38 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 Incident Report

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:** Wednesday, October 28, 2020 5:33 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:** NIH Incident Report

Dear OPS,
On behalf of our IBC co-chairs, please find the attached report to document an incident for failure to register an experiment falling under section III E no sub-section prior to initiation. The PI has since registered the experiment and the incident will be discussed at our next monthly IBC meeting on November 10, 2020.

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

Obtained via FOIA by Judicial Watch Inc.

Urbana, IL 61801
217.244.1939 | lmarsene@illinois.edu
www.drs.illinois.edu

ILLINOIS

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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Illinois Urbana Champaign |
| **Date of Report:** | 10/28/20 |
| **Reporter name and position:** | Mary Kraft, IBC Co-Chair and Associate Professor of Chemical and Biomolecular Engineering |
| **Telephone number:** | 217.333.2228 |
| **Email address:** | Mlkraft@illinois.edu |
| **Reporter mailing address:** | 208 Roger Adams Laboratory<br>Urbana, IL 61801 |
| **Date of incident:** | 10/21/20 date confirmed |
| **Name of Principal Investigator:** | Dr. Michael J. Miller |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☒Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐YES ☒NO<br>PI has an IBC registration that included wildtype Cronobacter sakazakii, originally approved on 8/18/2017. The PI has updated his registration to include the experiment described in this report and this will be discussed at the November IBC meeting |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+ (describe specific enhancement in report)<br>☐BL3 ☐BL3+ (describe specific enhancement in report)<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III E – No Subsection |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe): |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| | ☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | **Prokaryotic Hosts:** Cronobacter sakazakii ATCC 29544 (CS29544), Escherichia coli (TOP10,DH5a)<br>**Plasmids:** pK3, pKD46, pCP20, pET11a<br>**Genes Manipiulated:** temperature-sensitive flippase (FLP) recombinase (Saccharomyces cerevisiae), flaA, flhA, fliC, fliG, motAB(C. sakazakii) |

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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)

On October 12, 2020, Division of Research Safety (DRS) received an email request for guidance on how to ship a pathogen internationally from a laboratory on campus. After further correspondence with the lab manager, she described the pathogen to be a knockout strain. DRS contacted the Principal Investigator (PI) to confirm the details of the knockout bacterial strain. On October 21, 2020, the PI confirmed that the strain was manipulated in his lab. Although the wild type pathogen was registered and approved in his IBC, it did not include the recombinant strains that included gene knockout mutants of Cronobacter sakazakii ATCC 29544. The manipulations of these materials consisted of the growth, genetic recombination, light and electron microscopic imaging, DNA and protein analysis using gel electrophoresis. The PI was asked to register the work with the IBC. The PI and the IBC have assessed the risks posed by C. sakazakii and determined that the organism may be manipulated using BL-1 precautions/practices (Section III E). However, the PI has elected to register the work using BL-2 precautions to maintain the rigor of the biosafety practices used within the laboratory. The PI completed the update on October 22, 2020.

The PI confirmed to DRS that the material is no longer being manipulated in the laboratory and is in storage only. The PI also stated that there are no plans to work with the material in the future. The PI completed NIH guidelines training on 5/28/2019 as required for working with recombinant DNA materials. The laboratory personnel that had previously constructed/manipulated the recombinant Cronobacter sakazakii is no longer affiliated with the University of Illinois.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br><br>It will be discussed at the November Meeting (Nov. 10, 2020) |
| **Please describe the root cause of this incident:** | The PI indicated that he did not thoroughly review his IBC to assure that it included all experiments. |

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 indicated that he would make sure to review and update his IBC to assure that all experiments are reviewed and approved prior to initiation. He apologized for this oversight.

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:** Wednesday, October 28, 2020 5:33 PM
**To:** NIH guidelines
**Cc:** Maddox, Carol W; Kraft, Mary L; Miller, Monica A; DRS-IBC
**Subject:** NIH Incident Report
**Attachments:** NIH Incident Report MJ Miller Oct2020.pdf

Dear OPS,
On behalf of our IBC co-chairs, please find the attached report to document an incident for failure to register an experiment falling under section III E no sub-section prior to initiation. The PI has since registered the experiment and the incident will be discussed at our next monthly IBC meeting on November 10, 2020.

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

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 11:41 AM
**To:** Driskill, Colleen; NIH guidelines
**Cc:** Greenough, Thomas; Moran, Casey; Sontheimer, Erik; Gaynor, Sharon; Klugman, Robert; Lebetkin, Kenneth; Giaya, Kris; Pustis, Daniel; NIH guidelines; Schrader, Carol; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: UMMS Notification of 103020 rsNA AAV Needlestick Incident

Dear Colleen Driskill,

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:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Tuesday, December 1, 2020 2:52 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>; Sontheimer, Erik <Erik.Sontheimer@umassmed.edu>; Gaynor, Sharon <Sharon.Gaynor@umassmemorial.org>; Klugman, Robert <Robert.Klugman@umassmemorial.org>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmed.edu>; Giaya, Kris <Krisanthi.Giaya@umassmed.edu>; Pustis, Daniel <Daniel.Pustis@umassmed.edu>; NIH guidelines <NIHguidelines@od.nih.gov>; Schrader, Carol <Carol.Schrader@umassmed.edu>
**Subject:** RE: UMMS Notification of 103020 rsNA AAV Needlestick Incident

Good Afternoon Dr. Harris,

Please see attached, the final report for the needlestick involving rsNA that took place on 10/30/20 at the University of Massachusetts Medical School. Feel free to contact me if you have any questions or concerns.

Best Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School

Obtained via FOIA by Judicial Watch Inc.

55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Tuesday, November 3, 2020 3:28 PM
**To:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Subject:** RE: UMMS Notification of 103020 rsNA AAV Needlestick Incident

Thanks Colleen, we are in receipt of this initial notification.

Kathryn

---

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Tuesday, November 3, 2020 3:26 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>; Sontheimer, Erik <Erik.Sontheimer@umassmed.edu>; Gaynor, Sharon <Sharon.Gaynor@umassmemorial.org>; Klugman, Robert <Robert.Klugman@umassmemorial.org>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmemorial.org>; Giaya, Kris <Krisanthi.Giaya@umassmed.edu>; Pustis, Daniel <Daniel.Pustis@umassmed.edu>
**Subject:** UMMS Notification of 103020 rsNA AAV Needlestick Incident

Dear Dr. Harris and Whom it May Concern at the NIH Office of Science Policy,

On Friday 10/30/20, a researcher at the University of Massachusetts Medical School, (UMMS), was injecting a mouse with Adeno-Associated Virus material in a BSL-2 vivarium procedure room, when she inadvertently stuck herself with a needle. Although all of the details of the incident have yet to be confirmed, the individual involved did wash the wound and spoke with the Employee Health Services department who are following up with her care. I will be meeting with the Principal Investigator and the researcher to review the incident, determine the root cause and to address any issues to prevent recurrences. A report will be completed and forwarded to your office.

Please feel free to contact me if you have any questions or concerns.

Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Massachusetts Medical School |
| **Date of Report:** | 11/18/20 |
| **Reporter name and position:** | Colleen Driskill, RBP, CBSP<br>Senior Biosafety Officer |
| **Telephone number:** | 508-856-5527 |
| **Email address:** | Colleen.Driskill@umassmed.edu |
| **Reporter mailing address:** | University of Massachusetts Medical School<br>Environmental Health & Safety, S9-900<br>55 Lake Ave., N.<br>Worcester, MA 01655 |
| **Date of incident:** | 10/30/20 |
| **Name of Principal Investigator:** | Dr. Erik Sontheimer |
| **Is this an NIH-funded project?** | **X** YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number: UG3 TR002668*<br>*NIH funding institute or center: NCATS P.J. Brook*<br>*NIH program officer (name, email address): P.J. Brooks, PhD (pj.brooks@nih.com)* |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>**X** Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | **X** YES ☐NO<br>If yes, date of approval:<br>Xue, W I-596 approved 06/05/19<br>(Wen Xue is a collaborator) |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4<br>**X BSL-2; ABSL-1+BBP with special precautions; Administration to animals using BSL-2 precautions/sharps safety** |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | **III-D, III-E, III-F** |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA **X** State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | **The vector involved in the incident was an AAV9 capsid expressing Cas9 from *Streptococcus pyogenes* and a single-guide RNA (sgRNA). The sgRNA targets a sequence from a reporter construct that does not exist in the human genome.** |

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.

Redacted by agreement

DESCRIPTION OF INCIDENT: (use additional space as necessary)

On Friday, 10/30/20 at approximately 10:00 am, a graduate student was working with another individual in a ABSL-1 mouse room [redacted] in the Albert Sherman Center. The student was pre-loading each needle, recapping it, and then handing it to an Animal Medicine colleague who performed tail vein injections. On the 30th of 36 injections, while recapping the needle, it went through the cap and punctured her left index finger. She rinsed the wound with 70% ethanol and then applied hand sanitizer. She contacted the Employee Health Services Triage number and left a message and contacted her Principal Investigator. A nurse returned her call at approximately 12:00 pm. She advised the researcher to watch for signs and symptoms of infection and that EHS would follow up with her.

Employee Health Services (EHS) contacted the Assistant Biosafety Officer, at approximately 3:15 pm, who sent notification describing the incident to the BSO at approximately 4:30 pm. The BSO was out of the office on 10/30 and 11/2, however on Tuesday morning (11/3), an email was sent to Dr. Sontheimer and the Graduate Student to request additional details regarding the incident and the material that was being injected into the mice at the time. An occupational injury report was sent by EHS to the IBC Chair and the BSO on 11/4/20. On 11/5/20 the BSO, Assistant BSO, the PI and the Graduate Student met. The researcher explained she had been drawing up and recapping the needles in order to give them to an employee from Animal Medicine who was conducting the injections via tail vein. The student was instructed that recapping is strongly discouraged and should only be done when absolutely necessary. In the event that this action is required, they should use a device such as the **Medi-Dose EPS NeedleSafe II** so that the researcher is not holding the cap which minimizes risk of needlesticks.

At the time of the incident the Graduate Student was wearing the following PPE: one pair of nitrile gloves, bouffant, glasses, coveralls, and one pair of shoe covers.

The Researcher's **training** included:

Environmental Health & Safety, online Laboratory Safety, including Bloodborne Pathogen Training (Annual Requirement)

- 11/13/20
- 10/11/19

IACUC training includes the following:

- Introduction to Mice-9/23/2020
- Public Health Service Policy on Humane Care and Use of Laboratory Animals-9/23/2020
- Rodent Euthanasia training-10/17/2020
- UMMS Animal Care and Use Program-9/22/2020
- Using Animals in Biomedical Research and Teaching-10/1/2020

The occupational health requirements for laboratory personnel involved in the research:

- Pre-placement physical exam on 2/21/19
- Review of recommended immunizations including tetanus and Hepatitis B. Researcher does have the right to decline
- Tuberculin skin test
- If working with animals, an initial animal allergy review

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | **X** YES ☐ NO |
| **Please describe the root cause of this incident:** | The root cause of the incident was the action of recapping the needle which went through the cap and into the researcher's finger. |

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 hazards of re-capping of needles was reviewed with the Graduate Student and the PI during the incident investigation review meeting on 11/5/20. A UMMS Biosafety FACT Sheet, entitled, Sharps Safety, that provides information on safe needle devices was distributed to Dr. Sontheimer and the researcher, on 11/9/20, which also contained information on the NeedleSafe II needle uncapper/recapper device. The NeedleSafe II for the Sontheimer lab has already been ordered. Dr. Sontheimer will discuss the incident with his entire lab and review sharps safety. Also reviewed with the graduate student was the importance of washing wounds or any exposure with soap and water for 15 minutes.

- **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:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Tuesday, December 1, 2020 2:52 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Greenough, Thomas; Moran, Casey; Sontheimer, Erik; Gaynor, Sharon; Klugman, Robert; Lebetkin, Kenneth; Giaya, Kris; Pustis, Daniel; NIH guidelines; Schrader, Carol
**Subject:** RE: UMMS Notification of 103020 rsNA AAV Needlestick Incident
**Attachments:** UMMS 103020 AAV Needlestick Final Report.docx

Good Afternoon Dr. Harris,

Please see attached, the final report for the needlestick involving rsNA that took place on 10/30/20 at the University of Massachusetts Medical School. Feel free to contact me if you have any questions or concerns.

Best Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Tuesday, November 3, 2020 3:28 PM
**To:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Subject:** RE: UMMS Notification of 103020 rsNA AAV Needlestick Incident

Thanks Colleen, we are in receipt of this initial notification.

Kathryn

---

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Tuesday, November 3, 2020 3:26 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>; Sontheimer, Erik <Erik.Sontheimer@umassmed.edu>; Gaynor, Sharon <Sharon.Gaynor@umassmemorial.org>; Klugman, Robert <Robert.Klugman@umassmemorial.org>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmemorial.org>; Giaya, Kris <Krisanthi.Giaya@umassmed.edu>; Pustis, Daniel <Daniel.Pustis@umassmed.edu>
**Subject:** UMMS Notification of 103020 rsNA AAV Needlestick Incident

Dear Dr. Harris and Whom it May Concern at the NIH Office of Science Policy,

Obtained via FOIA by Judicial Watch Inc.

On Friday 10/30/20, a researcher at the University of Massachusetts Medical School, (UMMS), was injecting a mouse with Adeno-Associated Virus material in a BSL-2 vivarium procedure room, when she inadvertently stuck herself with a needle. Although all of the details of the incident have yet to be confirmed, the individual involved did wash the wound and spoke with the Employee Health Services department who are following up with her care. I will be meeting with the Principal Investigator and the researcher to review the incident, determine the root cause and to address any issues to prevent recurrences. A report will be completed and forwarded to your office.

Please feel free to contact me if you have any questions or concerns.

Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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## Hunter, Renee (NIH/OD) [C]

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Tuesday, November 3, 2020 3:26 PM
**To:** NIH guidelines; Harris, Kathryn (NIH/OD) [C]
**Cc:** Greenough, Thomas; Moran, Casey; Sontheimer, Erik; Gaynor, Sharon; Klugman, Robert; Lebetkin, Kenneth; Giaya, Kris; Pustis, Daniel
**Subject:** UMMS Notification of 103020 rsNA AAV Needlestick Incident

Dear Dr. Harris and Whom it May Concern at the NIH Office of Science Policy,

On Friday 10/30/20, a researcher at the University of Massachusetts Medical School, (UMMS), was injecting a mouse with Adeno-Associated Virus material in a BSL-2 vivarium procedure room, when she inadvertently stuck herself with a needle. Although all of the details of the incident have yet to be confirmed, the individual involved did wash the wound and spoke with the Employee Health Services department who are following up with her care. I will be meeting with the Principal Investigator and the researcher to review the incident, determine the root cause and to address any issues to prevent recurrences. A report will be completed and forwarded to your office.

Please feel free to contact me if you have any questions or concerns.

Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, November 23, 2020 11:53 AM
**To:** Chris Doyle; NIH guidelines
**Cc:** mbusch@vitalant.com; pnorris@vitalant.com; Daniel Kavanagh; Kelly FitzGerald; David Forster; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: IBC Incident Report, Unapproved Research

Dear Dr. Christopher Doyle,

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:** Chris Doyle <cdoyle@wirb.com>
**Sent:** Friday, November 6, 2020 5:39 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** mbusch@vitalant.com; pnorris@vitalant.com; Daniel Kavanagh <dkavanagh@wirb.com>; Kelly FitzGerald <KFitzGerald@wirb.com>; David Forster <DForster@wcgclinical.com>
**Subject:** IBC Incident Report, Unapproved Research

To Whom it May Concern,

Please see the attached letter regarding IBC oversight of research at Vitalant.

Thanks,
Chris

**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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wcg IBC Services™

1019 39th Avenue SE / Suite 120
Puyallup, WA 98374
P 360.252.2500 | F 360.252.2820
www.wcgclinical.com

November 6, 2020

NIH Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

To NIH OSP:

WCG is the administrator of the sole IBC registered for Vitalant in the IBC-RMS system. The WCG-administered IBC previously reviewed and approved research at Vitalant, but has received no new submissions in recent years.

Recently WCG became aware of unapproved research apparently subject to the *NIH Guidelines* taking place a Vitalant, as per NIH-funded projects 8R01AI150449-05 (Effects of Cell-Intrinsic Immunity on Establishment and Reversal of HIV Latency), and 5R01AI119056-04 (Protective B-Cell Responses in Chikungunya Virus Infection).

Going forward, Vitalant has agreed to seek IBC approval for research requiring such approval under the *NIH Guidelines*. Vitalant affirms:

- No human gene transfer research has been conducted at Vitalant;
- There has been no loss of containment of recombinant or synthetic nucleic acid molecules at Vitalant;
- There have been no lab-acquired illnesses at Vitalant;
- Vitalant will cease research requiring IBC approval prior to initiation until such approval is obtained.

For any questions, please contact the Institutional Officials listed below.

Thank you,

Redacted by agreement

Christopher Doyle, PhD
IBC Chair
Director, WCG IBC Services

cc: Michael Busch, MD (MBusch@vitalant.org)
Philip Norris, MD (PNorris@vitalant.org)

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Chris Doyle <cdoyle@wirb.com>
**Sent:** Friday, November 6, 2020 5:39 PM
**To:** NIH guidelines
**Cc:** mbusch@vitalant.com; pnorris@vitalant.com; Daniel Kavanagh; Kelly FitzGerald; David Forster
**Subject:** IBC Incident Report, Unapproved Research
**Attachments:** OSP Incident Report, Vitalant Research, dated 11-06-2020.pdf

To Whom it May Concern,

Please see the attached letter regarding IBC oversight of research at Vitalant.

Thanks,
Chris

**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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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 11:03 AM
**To:** Kara Drolet; Sarah Byers; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: OHSU initial report of potential exposure 11/1/2020

Dear Dr. Kara Manning Drolet,

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:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Thursday, December 10, 2020 6:43 PM
**To:** Sarah Byers <byerssa@ohsu.edu>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Subject:** RE: OHSU initial report of potential exposure 11/1/2020

Dear Dr. Harris, please find the final report for this incident attached, and 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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

---

**From:** Sarah Byers
**Sent:** Friday, November 6, 2020 4:20 PM

Obtained via FOIA by Judicial Watch Inc.

**To:** 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** OHSU initial report of potential exposure 11/1/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 11/1/2020 at Oregon Health & Science University. While administering antiretroviral therapy to a non-human primate infected with recombinant SIV a staff member sustained 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.

OREGON HEALTH & SCIENCE UNIVERSITY

**Institutional Biosafety Committee**

Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
fax 503 346-6808
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

December 10, 2020

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

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 the NIH on 11/6/2020.

| | |
|---|---|
| OHSU IBC registration number | IBC-02-26 |
| OHSU project title | SIV pathogenesis and vaccine development |
| Nature of the material | Nonhuman primate infected with recombinantly derived SIV with wild type pathogenicity; NHP with no detectable viral load |
| Risk Group | III |
| Containment level | ABSL-2+; enhancement is through PPE and work practices |
| Nature of the incident | Personnel Exposure |
| PPE in use | Dedicated footwear or boot covers, scrubs, disposable gown, hair bonnet, double gloves, face shield, and fiber mask |

**Description of incident:**

A research technician was going to administer a subcutaneous injection of an antiretroviral therapy to a non-human primate that had been infected with recombinant SIV. The technician was holding a capped syringe in one hand while using their other hand to adjust the cage squeeze to position the animal for the injection. The animal pushed back and the movement caused the cap to come off the needle resulting in the technician sticking their finger with a clean needle through a dirty glove. The technician washed the site of the needle stick for 15 minutes and reported to the Infectious Disease clinic for exposure evaluation.

**Actions taken:**

The researchers noted that the latch on the cage squeeze may not have been working properly so the cage was reported to be evaluated for repairs. The supervisor also reviewed the incident with the technician and discussed how the animal should be secured for the injection before the technician picks up the syringe to administer the injection. The supervisor reviewed this incident at a weekly group meeting.

The IBC administrative group reviewed the incident and requested that the Biosafety Officer conduct follow up. The Biosafety Officer met with the technician to review the incident and to review when outer gloves should be exchanged for a new pair of clean gloves. Due to repeat cage squeeze and needle stick incidents, the Biosafety Officer also met with the unit supervisor to discuss process improvement options such as proficiency validation in the training on using a cage squeeze and evaluating other safety needle options.

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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,

Kara Drolet

Digitally signed by Kara Drolet
Date: 2020.12.10 15:41:33 -08'00'

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Thursday, December 10, 2020 6:43 PM
**To:** Sarah Byers; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: OHSU initial report of potential exposure 11/1/2020
**Attachments:** 11012020 OHSU Incident report final.pdf

Dear Dr. Harris, please find the final report for this incident attached, and 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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

---

**From:** Sarah Byers
**Sent:** Friday, November 6, 2020 4:20 PM
**To:** 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** OHSU initial report of potential exposure 11/1/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 11/1/2020 at Oregon Health & Science University. While administering antiretroviral therapy to a non-human primate infected with recombinant SIV a staff member sustained 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:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Friday, November 6, 2020 7:20 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Kara Drolet
**Subject:** OHSU initial report of potential exposure 11/1/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 11/1/2020 at Oregon Health & Science University. While administering antiretroviral therapy to a non-human primate infected with recombinant SIV a staff member sustained 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, November 20, 2020 3:28 PM
**To:** Major, Sheryl; NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: UCSD Injury 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). 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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Tuesday, November 10, 2020 1:06 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** McMahill, Angela <amcmahill@ucsd.edu>; Scott, Lance <lscott@ucsd.edu>
**Subject:** UCSD Injury 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 an animal bite from a mouse that had been administered with NALM6 tumor cells, which had been previously stably modified with pSIN-EF2-NANOG-PUR viral vector to express a luciferase gene a week earlier. This incident will be discussed with the Institutional Biosafety Committee on 11/20/2020 and the Institutional Animal Care and Use Committee on 11/18/2020.

Please let me know if you have any questions regarding this report.
Best,

Sheryl Major
Biosafety Officer (BSO)
High Containment Officer (HCO)

Obtained via FOIA by Judicial Watch Inc.

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

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | X YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, San Diego |
| **Date of Report:** | 11/10/2020 |
| **Reporter name and position:** | Sheryl Major, Biosafety Officer |
| **Telephone number:** | (858) 822-2493 |
| **Email address:** | smajor@ucsd.edu |
| **Reporter mailing address:** | 9500 Gilman Drive #0090<br>La Jolla, CA 92093 |
| **Date of incident:** | 10/14/2020 |
| **Name of Principal Investigator:** | Yingxiao (Peter) Wang |
| **Is this an NIH-funded project?** | ☐YES XNO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br><br>If yes, date of approval: 02/15/2019 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Mouse administered with NALM6 tumor cells, which had been previously stably modified with pSIN-EF2-NANOG-PUR viral vector to express a luciferase gene. |

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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 October 14, 2020, a postdoctoral researcher in a vivarium was restraining a mouse to conduct IP injection of luciferin prior to IVIS imaging of an induced tumor in the animal. The tumor was generated by injection, approximately a week previously, with NALM6 tumor cells, which had been previously stably modified with pSIN-EF2-NANOG-PUR viral vector to express a luciferase gene. When the researcher went to restrain the mouse, it twisted and bit her on the tip of the middle finger. The researcher halted work, administered first aid, including washing with soap and water for 15 minutes, and reported the incident.

The researcher was wearing a disposable gown, shoe covers, hair net, procedure mask, and one layer of nitrile gloves. Following the incident, the researcher switched to wearing two layers of nitrile gloves. Researcher is current for Bloodborne Pathogens training [07/10/2020], required laboratory safety trainings, and completed biosafety training for work with recombinant and synthetic nucleic acids on 06/23/2016. Initial training requirements for animal handling were completed in 2016, with most recent refresher training completed on 6/21/2019.

No deviations from the approved containment level or handling procedures were noted. The researcher indicated that she has been conducting animal research for only a couple of years at this point, indicating a need for additional training in restraint techniques.

The researcher initially indicated no medical treatment and during interview follow up [10/29/2020] it was determined that the bite wound had healed. The researcher did describe minor skin peeling on the finger in the day or two following the incident, but as the wound healed without complication, she expressed that it was likely due to excessively vigorous cleaning of the wound when it occurred. After further discussion, the researcher expressed interest in a tetanus shot update and was referred for medical follow up.

Additional follow up has included referral of the researcher to the Animal Care Program for retraining in restraint techniques [10/29/2020]. This incident will be reported at the next scheduled IBC meeting, November 20, 2020.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES X NO |
| **Please describe the root cause of this incident:** | It is an accident by an aggressive mouse |

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 the incident, the biosafety program and animal care program investigated the injury on 10/29/2020. The researcher switched to wearing two layers of nitrile gloves as a safety precaution. The researcher has been referred to the Animal Care Program for retraining in restraint techniques [10/29/2020]. This incident will be reported at the next scheduled IBC meeting, November 20, 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 <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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Tuesday, November 10, 2020 1:06 PM
**To:** NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance
**Subject:** UCSD Injury Report to the NIH
**Attachments:** 2020-10-14_NIH_Incident_Report_Wang_Yingxiao.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 an animal bite from a mouse that had been administered with NALM6 tumor cells, which had been previously stably modified with pSIN-EF2-NANOG-PUR viral vector to express a luciferase gene a week earlier. This incident will be discussed with the Institutional Biosafety Committee on 11/20/2020 and the Institutional Animal Care and Use Committee on 11/18/2020.

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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, November 20, 2020 3:26 PM
**To:** Dr. Ellyn D Segal PhD; NIH guidelines
**Cc:** Kathryn Ann Moler; Ruth O'hara; Mark Holodniy; Yvonne A Maldonado; Kathy McClelland; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Report from Stanford University

Dear Dr. Ellyn Segal,

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

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**From:** Dr. Ellyn D Segal PhD <esegal@stanford.edu>
**Sent:** Thursday, November 12, 2020 2:51 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Kathryn Ann Moler <kmoler@stanford.edu>; Ruth O'hara <roh@stanford.edu>; Mark Holodniy <holodniy@stanford.edu>; Yvonne A Maldonado <bonniem@stanford.edu>; Kathy McClelland <kathy.mcclelland@stanford.edu>
**Subject:** Report from Stanford University
**Importance:** High

To Whom it May Concern,

Please find the attached document reporting an event of NIH Guideline non-compliance.

If you have any questions feel free to contact me.

Sincerely,
Ellyn

Ellyn Segal, Ph.D.
Assistant Director, EH&S
Biosafety & Biosecurity Manager
Stanford University

Obtained via FOIA by Judicial Watch Inc.

Ph: 650.725.1473
esegal@stanford.edu

Obtained via FOIA by Judicial Watch Inc.

Stanford | Environmental Health & Safety

ELLYN SEGAL, PH.D.
BIOSAFETY & BIOSECURITY MANAGER

NIH Office of Biotechnology Activities
6705 Rockledge Drive
Bethesda, MD
20892-7985

Re: Report of non-compliance with Clinical Research Protocol

To Whom It May Concern: November 12, 2020

This report is to notify NIH of a Stanford lead clinical research study being in non-compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines, April 2019). Specifically, the Principle Investigator did not submit a clinical protocol involving rDNA to the Stanford University IBC (at Stanford this is the Administrative Panel on Biosafety (APB)) for review and approval prior to conducting the study. **Note that this is the same product reported to NIH on Oct. 27, 2020 but under a different Principal Investigator.**

The following is a summary of events related to this report:

On Nov. 4, 2020 the Stanford University IRB notified the Stanford Biosafety Officer of a second approved study using the same Investigational Product as that use by the previously reported study; this second study had been underway at Stanford since May 2019. The title of the study is "A Phase 3 Multi-Center, Randomized, Sham-Controlled Study to Determine the Safety and Efficacy of Renexusin Macular Telangiectasia Type 2".

The Investigator Brochure (IB, 2017) submitted to the IRB states the following regarding the Investigational Product (IP):

> ***1.3.1. T*** *The Renexus NT-501 ECT investigational product is a unique platform for the intraocular delivery of neurotrophic factors for the treatment of retinal degeneration diseases.* ***The ECT implants consist of genetically modified human retinal pigment epithelium (RPE) cells encapsulated in a section of semipermeable hollow fiber membrane (HFM).*** *The cells are loaded into the interior volume of the HFM and attach to a supportive matrix within this space and the ends are integrally sealed. The ECT implants are surgically placed in the vitreous body, yet outside of the visual axis so that visual function is not adversely affected. The implant is sutured in a manner that allows for its retrieval when desired.*

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Stanford Environmental Health & Safety

ELLYN SEGAL, PH.D.
BIOSAFETY & BIOSECURITY MANAGER

***3.2.4. Cell Lines***
*The cells encapsulated in the NT-501 investigational product constitutively express human ciliary neurotrophic factor (hCNTF) and are termed NTC-201 cells. They are derived from a human RPE continuous cell line, ARPE-19 (ATCC # CRL-2302). Neurotech established a parental master stock of ARPE-19 cells and designated them as NTC-200.* ***Transfection of NTC-200 cells with a plasmid vector produced the NTC-201 cell lines, which constitutively secrete CNTF.***

*The transfection of the NTC-200 cell line to produce the 2 NTC-201 cell lines was accomplished with the mammalian expression vector pNUT-IgSP-hCNTF. The entire vector has been sequenced and is well characterized. Secretory hCNTF expression is driven by the mouse metallothionein promoter and contains the human growth hormone polyadenylation signal. To target CNTF for secretion the genomic murine immunoglobulin signal peptide gene is fused in frame to the 5' genomic hCNTF gene, which lacks the codon for the initial methionine. As part of the constitutive secretory pathway processing, the signal sequence is cleaved from the Hcntf N-terminus, resulting in release of mature hCNTF from the cell.*

Upon inquiry by the BSO the PI provided the following information:

- Three subjects were treated between May 2019 and Nov. 2019; all three were randomized to sham treatment.
- There were no SAEs or AEs relating to the study project reported
- There were no Medwatch or CIOMS forms submitted to the FDA

The PI has been informed and has confirmed that no additional subjects will be treated under this protocol until the Stanford University Administrative Panel on Biosafety (the local IBC) reviews and approves it.

Causes and Moving Forward:

The PI was made aware of this oversight, as was the Stanford University IRB and Office of Research Compliance. At Stanford it is the policy that the PI has the responsibility for all oversight of research. The IRB assists in vetting clinical protocols for APB requirements along with the APB providing regulatory information to researchers.

In response to how this mishap occurred the PI stated that per the regulatory consultant for Neurotech (the company that makes the IP) this project was not considered gene therapy. Upon continued discussion the PI assured that they will work to be responsive to NIH Guidelines,

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BIOSAFETY & BIOSECURITY MANAGER

including early discussions in cases that may involve recombinant or synthetic DNA and gene therapy.

Sincerely,

Redacted by agreement

Ellyn Segal, Ph.D.
Assistant Director, EH&S
Manager, Biosafety & Biosecurity
Stanford University

Cc: Kathryn Moler, Ph.D., Vice Provost and Dean of Research, Stanford University
Ruth O'Hara, Ph.D., Sr. Associate Dean of Research, Stanford University School of Medicine
Kathy McClelland, Research Compliance Office Director, Stanford University
Mark Holodniy, M.D., Professor of Medicine (infectious Diseases), Stanford University
Yvonne Maldonado, Sr. Associate Dean, Professor of Pediatrics (Infectious Diseases), Epidemiology and Population Health, Stanford University

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Dr. Ellyn D Segal PhD <esegal@stanford.edu>
**Sent:** Thursday, November 12, 2020 2:51 PM
**To:** NIH guidelines
**Cc:** Kathryn Ann Moler; Ruth O'hara; Mark Holodniy; Yvonne A Maldonado; Kathy McClelland
**Subject:** Report from Stanford University
**Attachments:** NIH letter final.pdf

**Importance:** High

To Whom it May Concern,

Please find the attached document reporting an event of NIH Guideline non-compliance.

If you have any questions feel free to contact me.

Sincerely,
Ellyn

Ellyn Segal, Ph.D.
Assistant Director, EH&S
Biosafety & Biosecurity Manager
Stanford University

Ph: 650.725.1473
esegal@stanford.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, November 20, 2020 3:32 PM
**To:** Institutional Biosafety Committee; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Potential incident involving recombinant non replicating AAV - Final report

Dear Alice Lee,

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

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**From:** Institutional Biosafety Committee <ibc@uci.edu>
**Sent:** Wednesday, November 18, 2020 5:45 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Potential incident involving recombinant non replicating AAV - Final report

Dear NIH,

Please find attached a final version of the Incident Report for the potential incident involving recombinant non replicating AAV.
Please let us know if you have any questions or need additional information.

Sincerely,
Alice Lee
UCI IBC Administrator

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**From:** Institutional Biosafety Committee
**Sent:** Monday, November 16, 2020 4:14 PM
**To:** NIHGuidelines@od.nih.gov

Obtained via FOIA by Judicial Watch Inc.

**Cc:** Institutional Biosafety Committee <ibc@uci.edu>
**Subject:** RE: Potential incident involving recombinant non replicating AAV

Dear NIH,

Please find attached the completed Incident Report for the potential incident involving recombinant non replicating AAV.

Sincerely,
Alice Lee
UCI IBC Administrator

++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++

**From:** Anju Subba <asubba@uci.edu>
**Sent:** Friday, November 13, 2020 3:34 PM
**To:** NIHGuidelines@od.nih.gov
**Cc:** Institutional Biosafety Committee <ibc@uci.edu>
**Subject:** Potential incident involving recombinant non replicating AAV

Hello,

Yesterday (11/12/2020) a non-transgenic rat that had been infected with non-replicating AAV a month ago bit a lab personnel. UCI EH&S was reported of this incident today, 11/13/2020. We are investigating the incident for more information on the nature of the bite and the strain of non-replicating virus and the transgene. We will update NIH as more information becomes available.

Best regards,

**Anju Subba, MS, MS EMAP**
Biosafety Officer, RO, ICDUR
Biosafety & IBC Program, 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.

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, Irvine |
| **Date of Report:** | November 16, 2020 |
| **Reporter name and position:** | Medalyn Supnet<br>Assistant Biosafety Officer |
| **Telephone number:** | 949-824-4170 |
| **Email address:** | msupnet@uci.edu |
| **Reporter mailing address:** | 4600 Health Sciences Road<br>Irvine, CA 92697-2725 |
| **Date of incident:** | November 12, 2020 |
| **Name of Principal Investigator:** | Dr. Stephen Mahler |
| **Is this an NIH-funded project?** | X YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* BA044118<br>*NIH funding institute or center:* National Institute of Drug Abuse (NIDA)<br>*NIH program officer (name, email address):* Yu Lin (YLin1@nida.nih.gov) |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>X Other (please describe): Accidental rat (Th-Cre+) bite while rat was being placed back into its cage. |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br><br>If yes, date of approval: June 16, 2018 |
| **What was the approved biosafety level of the research?** | X BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA<br><br>Not reported to other agencies. |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Th-Cre+ rat injected (on Oct. 16, 2020) with AAV2-hSynapsin-DIO-hM3D(Gq)-mCherry (Addgene # 44361-AAV2) |

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 the morning of November 12, 2020 in an approved ABSL1 animal procedure room in a University-controlled vivarium and involved a penetrating rat bite on the wrist resulting in skin breakage. The rat was a Th-Cre+ rat that was administered an intracranial injection of AAV2-hSynapsin-DIO-hM3D(Gq)-mCherry virus particles (Addgene # 44361-AAV2) on Oct. 16, 2020.

An Assistant Specialist ("AS") was bitten on the wrist during the act of replacing the animal back in its cage. Before the incident, the rat was hand-restrained and injected (intraperitoneal) with a needle-syringe assembly containing clozapine N-oxide. Before the drug could be administered, the rat squirmed and gave a warning bite to the wrist of the AS, which prompted the AS to remove the needle and carry the animal back to its cage. During transport to the cage, the rat bit the wrist again which resulted in a penetrating wound. The AS was able to contain the rat within its cage after the bite incident. The AS believes that the rat may have been startled by a loud noise at the time of injection which resulted in the biting behavior.

A graduate student who was also present in the room when the incident occurred, checked the wound and recommended that the AS go to urgent care. Within 2 hours, the AS contacted the facility, went home, and had somebody take them to the facility where the wound was cleaned and Steri-Strips were applied. The Principal Investigator (PI) submitted the incident report to EH&S that afternoon.

The AS was wearing standard PPE for working in the indicated animal procedure room: Tyvek lab coat and a pair of disposable gloves. Other items (towels) were also available to personnel for these types of procedures to mitigate potential injuries from a rat bite, but were not used in this case. The AS was trained by the PI on animal handling and has been handling rats and carrying out intraperitoneal injections since December 2015. The AS is current in the following required institutional training courses: Laboratory Safety Fundamentals, Viral Vectors.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ☒ NO<br>The IBC will meet and review this incident on November 18, 2020. |
| **Please describe the root cause of this incident:** | Not employing the full range of available PPE/supplemental items (like towels). |

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):

Biosafety discussed the following items with the Principal Investigator on November 16, 2020.

1. The PI will remind lab personnel working in the animal areas that PPE and supplementary items (thick gloves, towels) are readily available and should be used to mitigate any potential injuries from a rat bite.
2. The PI already discussed this mitigation measure with the AS, but will also consider other PPE that may be available to help prevent similar incidents 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.

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, Irvine |
| **Date of Report:** | November 18, 2020 |
| **Reporter name and position:** | Medalyn Supnet<br>Assistant Biosafety Officer |
| **Telephone number:** | 949-824-4170 |
| **Email address:** | msupnet@uci.edu |
| **Reporter mailing address:** | 4600 Health Sciences Road<br>Irvine, CA 92697-2725 |
| **Date of incident:** | November 12, 2020 |
| **Name of Principal Investigator:** | Dr. Stephen Mahler |
| **Is this an NIH-funded project?** | X YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* BA044118<br>*NIH funding institute or center:* National Institute of Drug Abuse (NIDA)<br>*NIH program officer (name, email address):* Yu Lin (YLin1@nida.nih.gov) |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>X Other (please describe): Accidental rat (Th-Cre+) bite while rat was being placed back into its cage. |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br><br>If yes, date of approval: June 16, 2018 |
| **What was the approved biosafety level of the research?** | X BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA<br><br>Not reported to other agencies. |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Th-Cre+ rat injected (on Oct. 16, 2020) with AAV2-hSynapsin-DIO-hM3D(Gq)-mCherry (Addgene # 44361-AAV2) |

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 the morning of November 12, 2020 in an approved ABSL1 animal procedure room in a University-controlled vivarium and involved a penetrating rat bite on the wrist resulting in skin breakage. The rat was a Th-Cre+ rat that was administered an intracranial injection of AAV2-hSynapsin-DIO-hM3D(Gq)-mCherry virus particles (Addgene # 44361-AAV2) on Oct. 16, 2020.

An Assistant Specialist ("AS") was bitten on the wrist during the act of replacing the animal back in its cage. Before the incident, the rat was restrained with the left hand and injected (intraperitoneal) with a needle-syringe assembly containing clozapine N-oxide. Before the drug could be administered, the rat squirmed and gave a warning bite to the left wrist of the AS, which prompted the AS to remove the needle and carry the animal back to its cage. During transport to the cage, the rat bit the same wrist again which resulted in a penetrating wound. The AS was able to contain the rat within its cage after the bite incident. It was unclear to the AS why the rat was stressed when receiving the injection. During prior injections, the rat did not react in this manner. There was also no indication of this behavior when the rat was being weighed.

A graduate student who was also present in the room when the incident occurred, checked the wound and recommended that the AS go to urgent care. The AS washed the wound with water, wiped it down with isopropyl prep pad, and dressed it with gauze from the lab's first aid kit. Within 2 hours of the incident, the AS contacted urgent care facility, went home, and had somebody take them to the facility where the wound was cleaned and Steri-Strips were applied. The Principal Investigator (PI) submitted the incident report to EH&S that afternoon.

The AS was wearing standard PPE for working in the indicated animal procedure room: Tyvek lab coat and a pair of disposable gloves. Other items (towels) were also available to personnel for these types of procedures to mitigate potential injuries from a rat bite, for example by wrapping the towel between the lower wrist and hand to prevent a rat from biting through lab coat and nitrile gloves while the rat was being handled. However, the AS did not use one in this case because there was no prior indication (not during weighing, not from previous injections) that this rat would exhibit biting behavior. The AS was trained by the PI on animal handling and has been handling rats and carrying out intraperitoneal injections since December 2015. The AS is current in the following required institutional training courses: Laboratory Safety Fundamentals, Viral Vectors.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ☒ NO<br>The IBC will meet and review this incident on November 18, 2020. |
| **Please describe the root cause of this incident:** | Not employing available items (like towels) to protect the wrist against a rat bite during IP injections. |

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):

Biosafety discussed the following items with the Principal Investigator (PI) on November 16 and 17, 2020, and will follow up with the PI on November 25, 2020.

1. The PI will remind lab personnel working in the animal areas that PPE and supplementary items (thick gloves, towels) are readily available and should be used to mitigate any potential injuries from a rat bite.
2. The PI will add to the SOP the use of a towel to provide extra protection against a rat bite while carrying out a rat intraperitoneal (IP) injection. In lieu of a towel, wrist cuffs are recommended to be worn to protect the wrist area (this must be added to the SOP if planned to be employed).
3. The PI will add to the SOP that skin will be washed immediately with soap and water after an animal bite or any exposure to biological agents or materials.
4. The PI will explore if animal restraint devices compatible with rat IP injections are available. If yes, the PI will consider obtaining the 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 <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:** Institutional Biosafety Committee <ibc@uci.edu>
**Sent:** Wednesday, November 18, 2020 5:45 PM
**To:** NIH guidelines
**Subject:** Potential incident involving recombinant non replicating AAV - Final report
**Attachments:** Mahler_111820_Incident-Reporting-Template_42319_2.docx

Dear NIH,

Please find attached a final version of the Incident Report for the potential incident involving recombinant non replicating AAV.
Please let us know if you have any questions or need additional information.

Sincerely,
Alice Lee
UCI IBC Administrator

---

**From:** Institutional Biosafety Committee
**Sent:** Monday, November 16, 2020 4:14 PM
**To:** NIHGuidelines@od.nih.gov
**Cc:** Institutional Biosafety Committee <ibc@uci.edu>
**Subject:** RE: Potential incident involving recombinant non replicating AAV

Dear NIH,

Please find attached the completed Incident Report for the potential incident involving recombinant non replicating AAV.

Sincerely,
Alice Lee
UCI IBC Administrator

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**From:** Anju Subba <asubba@uci.edu>
**Sent:** Friday, November 13, 2020 3:34 PM
**To:** NIHGuidelines@od.nih.gov
**Cc:** Institutional Biosafety Committee <ibc@uci.edu>
**Subject:** Potential incident involving recombinant non replicating AAV

Hello,

Yesterday (11/12/2020) a non-transgenic rat that had been infected with non-replicating AAV a month ago bit a lab personnel. UCI EH&S was reported of this incident today, 11/13/2020. We are investigating the incident for more

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information on the nature of the bite and the strain of non-replicating virus and the transgene. We will update NIH as more information becomes available.

Best regards,

**Anju Subba, MS, MS EMAP**
Biosafety Officer, RO, ICDUR
Biosafety & IBC Program, Environmental Health & Safety
Office: (949) 82**4-4365**, Fax: (949) 82**4-1325**
asubba@uci.edu

University of California, Irvine
4600 Health Sciences Rd
Irvine, CA 92697-2725



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## Hunter, Renee (NIH/OD) [C]

**From:** Anju Subba <asubba@uci.edu>
**Sent:** Friday, November 13, 2020 6:34 PM
**To:** NIH guidelines
**Cc:** Institutional Biosafety Committee
**Subject:** Potential incident involving recombinant non replicating AAV

Hello,

Yesterday (11/12/2020) a non-transgenic rat that had been infected with non-replicating AAV a month ago bit a lab personnel. UCI EH&S was reported of this incident today, 11/13/2020. We are investigating the incident for more information on the nature of the bite and the strain of non-replicating virus and the transgene. We will update NIH as more information becomes available.

Best regards,

**Anju Subba, MS, MS EMAP**
Biosafety Officer, RO, ICDUR
Biosafety & IBC Program, 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:** Institutional Biosafety Committee <ibc@uci.edu>
**Sent:** Monday, November 16, 2020 7:14 PM
**To:** NIH guidelines
**Cc:** Institutional Biosafety Committee
**Subject:** RE: Potential incident involving recombinant non replicating AAV
**Attachments:** Mahler_111620_Incident-Reporting-Template_42319.docx

Dear NIH,

Please find attached the completed Incident Report for the potential incident involving recombinant non replicating AAV.

Sincerely,
Alice Lee
UCI IBC Administrator

++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++

**From:** Anju Subba <asubba@uci.edu>
**Sent:** Friday, November 13, 2020 3:34 PM
**To:** NIHGuidelines@od.nih.gov
**Cc:** Institutional Biosafety Committee <ibc@uci.edu>
**Subject:** Potential incident involving recombinant non replicating AAV

Hello,

Yesterday (11/12/2020) a non-transgenic rat that had been infected with non-replicating AAV a month ago bit a lab personnel. UCI EH&S was reported of this incident today, 11/13/2020. We are investigating the incident for more information on the nature of the bite and the strain of non-replicating virus and the transgene. We will update NIH as more information becomes available.

Best regards,

**Anju Subba, MS, MS EMAP**
Biosafety Officer, RO, ICDUR
Biosafety & IBC Program, 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:** Monday, January 4, 2021 12:04 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:** Friday, November 20, 2020 10:55 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:** Tuesday, November 17, 2020 4:51 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 Notice

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

We wanted to notify you of a low-risk potential exposure to recombinant DNA at BSL-2 involving a small splash to intact skin with replication-deficient, self-inactivating, 2nd generation lentiviral vector.

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of North Carolina at Chapel Hill |
| **Date of Report:** | 11/20/2020 |
| **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<br>1120 Estes drive<br>Campus Box 1650<br>Chapel Hill, NC 27599 |
| **Date of incident:** | 11/16/2020 |
| **Name of Principal Investigator:** | Dr. Shawn Hingtgen |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☒Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 07/08/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Recombinant replication-deficient second generation, self-inactivating (SIN) lentiviral vector expressing mCherry and Luciferase reporter genes |

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## Description of the incident:

At approximately 4:15pm on Monday, November 16, 2020 a Researcher was preparing to infect tumor cells within a biosafety cabinet (BSC) when the incident occurred. The Researcher was wearing the following personal protective equipment (PPE) for work in the BSL-2: disposable gloves, lab coat, surgical mask and prescription glasses. The Researcher was highly trained and experienced working in laboratory environments and was compliant with all required EHS trainings.

As part of the experimental procedure for infecting the tissue culture cells, the Researcher had removed an Eppendorf tube containing a diluted preparation of lentiviral vector from the freezer and placed it into an ice bucket to thaw. The viral vector was a replication-deficient, self-inactivating (SIN) 2$^{nd}$ generation lentiviral vector expressing mCherry and luciferase reporter genes. Once the tube had thawed, the Researcher wiped the tube and their gloves with ethanol, opened the tube to remove an aliquot and then tried to close the tube when done. While attempting to close the lid on the tube, the tube slipped in the Researchers hands resulting in a small amount of its contents splashing out of the tube and under the glass sash of the BSC onto the upper chest of the Researchers lab coat and exposed neck. No material splashed under the Researchers mask. The Researcher attributed the slipping of the tube to a combination of wet gloves and wet tube, both of which had just been surface decontaminated with ethanol prior to attempting to close the tube.

Following the incident, the Researcher immediately took their lab coat off and washed the skin on their neck with water and wet paper towels at the sink in the lab. The Researcher then went home and took a shower. Since the University Employee Occupational Health Center (UEOHC) was closed at this time, the Researcher reported the incident to a senior member of the lab, who then reported the incident to the Principal Investigator (PI) of the lab. The Researcher was instructed to contact the UEOHC first thing in the morning.

At approximately 8:30am the following morning (Tuesday, November 17, 2020) the Researcher contacted the UEOHC to report the incident. Given that the specific biological characteristics of the viral vector indicate that it was a replication-defective, self-inactivating vector not expressing oncogenic transgenes, and given that the incident only involved intact skin with no exposure to facial mucosa, the incident was consider an extremely low risk potential exposure.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The IBC is aware of this incident and will review it at the next IBC meeting on 12/2/2020. |
| **Please describe the root cause of this incident:** | The root cause of the incident appears to be related to the surface decon of the Researchers gloves and the sample tube with ethanol, resulting in a scenario whereby the tube became slippery and a challenge to recap. |

**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, and evaluate feasible changes to their procedures for surface decontamination of gloves and tubes (and other materials in the BSC) to reduce the risk of excess residual ethanol on gloves and other surfaces leading to a scenario where biological or biohazardous materials can slip out of the grasp of a gloved hand.

The PI will also be asked to emphasize that the recommended procedure for responding to splashes on the skin involving biological or biohazardous materials requires washing the affected area for 5 minutes with soap and water.

Lastly, the PI will be instructed to discuss with their lab the available options for reporting incidents after-hours, including the after-hours hotline and the Emergency Department for serious injuries or exposures. As part of this discussion should be an emphasis on the need to immediately report any incidents in the lab to the PI so that the PI can assist in making an appropriate risk assessment of the exposure and the need for any downstream reporting and notifications.

The expected date of completion for recommendations will be 12/4/2020.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
**Sent:** Friday, November 20, 2020 10:55 AM
**To:** NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.
**Subject:** RE: NIH Incident Report - FINAL
**Attachments:** NIH Incident Report__11202020.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:** Tuesday, November 17, 2020 4:51 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 Notice

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

We wanted to notify you of a low-risk potential exposure to recombinant DNA at BSL-2 involving a small splash to intact skin with replication-deficient, self-inactivating, 2$^{nd}$ generation lentiviral vector.

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.

Obtained via FOIA by Judicial Watch Inc.

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:** Tuesday, November 17, 2020 4:51 PM
**To:** NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.
**Subject:** NIH Incident Report - Preliminary Notice

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

We wanted to notify you of a low-risk potential exposure to recombinant DNA at BSL-2 involving a small splash to intact skin with replication-deficient, self-inactivating, 2nd generation lentiviral vector.

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

*Confidentiality Notice:*
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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, November 20, 2020 3:42 PM
**To:** O'Loughlin, Levi; NIH guidelines
**Cc:** IBC; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: WSU Incident Report

Dear Dr. J. Levi O'Loughlin,

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:** O'Loughlin, Levi <levi.oloughlin@wsu.edu>
**Sent:** Tuesday, November 17, 2020 8:53 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** IBC <or.ora.ibc@wsu.edu>
**Subject:** WSU Incident Report

Good evening,

Please see the attached incident report regarding a PI who failed to obtain IBC approval prior to working with biological agents. We have identified a number of corrective actions that have already been implemented. Nonetheless, we would appreciate your review and the opportunity to improve our program. Please let me know if you have any questions or concerns.

Thanks,
Levi

**J. Levi O'Loughlin, Ph.D.**
Associate Director | University Biosafety Officer
Research Safety Program | Office of Research Assurances
Washington State University | Neill Hall 423 | Pullman, WA 99164-3143
509.335.1585 phone | 509.335.6410 fax | levi.oloughlin@wsu.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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Washington State University |
| **Date of Report:** | 10/28/2020 |
| **Reporter name and position:** | J. Levi O'Loughlin, PhD; University Biosafety Officer |
| **Telephone number:** | 509-335-1585 |
| **Email address:** | Levi.oloughlin@wsu.edu |
| **Reporter mailing address:** | Office of Research Assurances<br>Washington State University<br>Neill Hall 423<br>Pullman, WA 99164-3143 |
| **Date of incident:** | 11/17/2020 |
| **Name of Principal Investigator:** | Travis Denton, PhD |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☒Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 11/17/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-D1, D3, and E1 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | The individual was using human cell lines (HEK293T, HeLa) and *E. coli* and recombinant vectors (pBABE, pCMV-VSV-G, psPAX2, pET-20b(+)) |

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 incident occurred in Dr. Denton's lab. His background is predominantly in Chemistry and he has since expanded research to working with biologicals. He has always used a laboratory facility that has since been certified as BSL2 and there is no knowledge of an incident or exposure. His personnel have experience working with biologicals. The incident concerns his conducting recombinant research without an approved biosafety registration. Once notified of this lapse, the PI promptly submitted the necessary paperwork to the IBC to bring his lab into compliance.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | WSU views this lack of protocol oversight as a shared responsibility between the Principal Investigator and the Institution and the remedial actions below indicate that we are adjusting our processes to prevent future incidence. |

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):

WSU held a meeting for this protocol and have approved the project. We have completed a project-specific biosafety manual as well. We have required re-training on "Responsible Conduct of Research," which covers University compliance expectations. Additional training modules include: "Introduction to Biosafety," "Recombinant DNA," University Laboratory Safety – Analyzing Biological Hazards," "Biosafety Cabinets," and "Laboratory Safety Refresher." Trainings must be completed within 30 days. The research will also be subject to initial (1 month) and quarterly monitoring for 1 year to ensure compliance by the Office or Research Assurances.

WSU has additionally revised the internal processes associated with research operations support to ensure all faculty are aware of all compliance expectations. Finally, expectations were communicated to all faculty within this department at their faculty meeting.

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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:** O'Loughlin, Levi <levi.oloughlin@wsu.edu>
**Sent:** Tuesday, November 17, 2020 8:53 PM
**To:** NIH guidelines
**Cc:** IBC
**Subject:** WSU Incident Report
**Attachments:** Incident Reporting Template - WSU Denton 11.17.2020.docx

Good evening,

Please see the attached incident report regarding a PI who failed to obtain IBC approval prior to working with biological agents. We have identified a number of corrective actions that have already been implemented. Nonetheless, we would appreciate your review and the opportunity to improve our program. Please let me know if you have any questions or concerns.

Thanks,
Levi

**J. Levi O'Loughlin, Ph.D.**
Associate Director | University Biosafety Officer
Research Safety Program | Office of Research Assurances
Washington State University | Neill Hall 423 | Pullman, WA 99164-3143
509.335.1585 phone | 509.335.6410 fax | levi.oloughlin@wsu.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 8:56 AM
**To:** Cardwell, Marissa M; NIH guidelines
**Cc:** Reid, Angela; Arlene Sharpe; LaFleur, Martin; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Initial report of incident at BL2 involving rDNA - Harvard University Nov 2020

Dear Dr. Marissa Cardwell,

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
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:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Friday, December 4, 2020 11:13 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Reid, Angela <angela_reid@harvard.edu>; Arlene Sharpe <arlene_sharpe@hms.harvard.edu>; LaFleur, Martin <Martin_LaFleur@hms.harvard.edu>
**Subject:** RE: Initial report of incident at BL2 involving rDNA - Harvard University Nov 2020

To OSP:

Attached, please find the complete report detailing an incident at Harvard University involving exposure to mouse tissue from an animal previously infected with LCMV. This report follows the initial notification to NIH/OSP made on 11/20/2020.

Please let me know if you have any questions.

Regards,
Marissa

Obtained via FOIA by Judicial Watch Inc.

**From:** Cardwell, Marissa M
**Sent:** Friday, November 20, 2020 1:48 PM
**To:** NIHGuidelines@od.nih.gov
**Cc:** Angela Reid (angela_reid@harvard.edu) <angela_reid@harvard.edu>; Sharpe, Arlene <arlene_sharpe@hms.harvard.edu>; LaFleur, Martin <Martin_LaFleur@hms.harvard.edu>
**Subject:** Initial report of incident at BL2 involving rDNA - Harvard University Nov 2020

To OSP:

I would like to make an initial report of an incident that occurred at Harvard University involving mouse tissue that was potentially contaminated with genetically modified Lymphocytic choriomeningitis virus (LCMV). During tissue harvest of mice previously infected with LCMV, a researcher sustained a puncture wound from a pair of forceps that had been used to harvest tissue. At the timepoint of harvest, LCMV is not detectable in the tissues via plaque assay, however, these mice are held at BL2-N per IBC approval. It is possible that LCMV could be present at low levels in some tissues that have not been previously assessed via plaque assay or that it is present at levels below the limit of detection. Therefore, we are making an initial report of an incident occurring at BL2.

A formal report will follow after we complete our investigation.

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

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Harvard University |
| **Date of Report:** | Initial e-mail notification: 11/20/2020<br>Formal written report: 12/4/2020 |
| **Reporter name and position:** | Marissa M. Cardwell<br>Director of Laboratory Safety & Biosafety |
| **Telephone number:** | (617) 432-0022 |
| **Email address:** | marissa_cardwell@harvard.edu |
| **Reporter mailing address:** | Harvard University / EHS<br>107 Avenue Louis Pasteur<br>Boston, MA 02115 |
| **Date of incident:** | 11/19/2020 (Biosafety office informed on 11/19/2020) |
| **Name of Principal Investigator:** | Dr. Arlene Sharpe |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* U19AI133524<br>*NIH funding institute or center:* NIAID<br>*NIH program officer (name, email address):* Joy Liu, Liu, liujoy@niaid.nih.gov |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☒Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4<br>Mice administered LCMV require BL2 containment. |
| **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<br>☐USDA ☒State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Lymphocytic choriomeningitis virus (LCMV) Armstrong strain genetically modified to express ovalbumin antigen |

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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 November 19, 2020, a research assistant was harvesting spleens from mice that had been infected with lymphocytic choriomeningitis virus (LCMV) Armstrong strain 8 days prior. When reaching for the forceps, the researcher accidentally grabbed the pointed end, which poked through her glove and skin (left thumb). The forceps had been used to harvest tissues from two mice previous to this (also infected with LCMV at the same timepoint) and were considered potentially contaminated. The researcher immediately informed her supervisor who instructed her to wash the area with soap and water for 15 minutes. She then reported this to the occupational health physician, and her supervisor submitted an email notification to the biosafety officer and a formal incident report through the online reporting system.

The occupational health physician coordinated care for the researcher with her primary care physician and set up a same-day appointment to draw baseline serology for IgM and IgG antibodies against LCMV (prevalence of LCMV antibodies in human populations range from 2% to 5%). A follow-up draw will be done in four weeks for repeat bloodwork. The researcher was informed of and told to monitor for symptoms of a flu-like illness (headaches, myalgia, etc.) and to contact the occupational health physician if any symptoms developed. The occupational health physician indicated treatment is supportive, in the case of illness. The researcher does not have any symptoms 13 days post exposure.

The LCMV strain used in the mice was modified to express ovalbumin antigen. Previous plaque assays indicated no detectable levels of LCMV in the harvested tissues at the timepoint in question (detection level is typically 100 PFU/mL). The use of the ovalbumin antigen should have also resulted in faster clearance of the virus from the animal. This suggests that risk of researcher exposure to viable LCMV is very low, however, it cannot be completely ruled out and thus this report is being made. All mice had undergone the routine screening for other infectious agents as required by the animal facility for use in the vivarium.

The incident occurred within a tissue culture room designated for BL2 work on campus. At the time of the exposure, the researcher was wearing a lab coat and gloves while working in a biological safety cabinet and following the standard operating procedures for this work. The supervisor also indicated that the researcher had demonstrated proficiency in this technique and had performed it multiple times before without incident.

Harvard Biosafety was made aware of the incident on November 19, 2020. The biosafety officer immediately reached out to glean more information on the nature of the exposure. Further discussion with the supervising faculty revealed that the injury was a potential exposure to recombinant virus that potentially could still be present in the animals. Review of the IBC protocol indicated that the use of LCMV was approved, but not the use of a strain expressing ovalbumin antigen. The supervisor was surprised to hear this and had been under the understanding that the protocol allows for LCMV Armstrong strains (including Clone 13 and they thought Armstrong-OVA). Realizing this unintentional misinterpretation, the supervisor and Sharpe lab halted to use of this agent and have submitted an IBC and IACUC amendment to

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allow for proper use of this Armstrong variant strain. The IACUC amendment has been approved and the COMS amendment is awaiting approval. The use of the genetically modified strain, which would have produced a more rapid immunological response in the mouse, and the timepoint of the injury following agent administration also suggest lower risk of exposure.

**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 Sharpe laboratory regularly works with a large number of animals and performs a large number of procedures. Given this, the relative incidence of errors is quite low. Regardless, the lab is committed to improving any training or engineering protocols to decrease the likelihood of these incidents.

The laboratory reviewed their IBC protocol and confirmed the language was not inclusive of the LCMV strain modified for expression of the ovalbumin antigen. They communicated that they would immediately cease use of this strain and begin working on an amendment to their IBC protocol to include this LCMV variant before use again. The IACUC amendments has been approved and the IBC amendment is submitted and awaiting approval.

Additionally, the lab has purchased blunt-tipped forceps and scissors to reduce risk of further sharps injuries and will implement those as soon as they are received. Decontamination of the forceps was considered between animals, but the supervisor indicated that this might actually increase the risk of injury, as it would require contact with the sharp end of the instruments to remove remaining organic matter that could not be removed simply through a rinse. Trace remnants of the chemical on the tools would also potentially have negative effects on the research aims. Storage of the forceps with the contaminated end contained (e.g. pointing down in a falcon tube) was also considered, but it was determined that the holder would add to clutter of the already crowded work surface, presenting potentially more risk than a benefit. The laboratory also plans to reemphasize safe sharps practices and careful handling of infected animals.

The researcher completed initial training for biological safety on May 13, 2020. Safe sharps practices and injury prevention are emphasized in this training. Other completed and relevant laboratory safety trainings for this individual are outlined below in Table A.

*Table A. Trainings completed by the injured researcher.*

| Course Title | Completion |
|---|---|
| General Laboratory Safety | 13-MAY-2020 |
| Laboratory Biosafety | 13-MAY-2020 |

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br><br>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 was determined to be the root cause of this injury. Additionally, sharp forceps were used instead of blunt forceps at the time of injury. The sharp forceps do offer superior dissection ability but in the case of BL2 work are no longer worth the risk. |

- **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:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Friday, December 4, 2020 11:13 AM
**To:** NIH guidelines
**Cc:** Reid, Angela; Arlene Sharpe; LaFleur, Martin
**Subject:** RE: Initial report of incident at BL2 involving rDNA - Harvard University Nov 2020
**Attachments:** 2020_1119_NIH_incident_report_Sharpe.pdf

To OSP:

Attached, please find the complete report detailing an incident at Harvard University involving exposure to mouse tissue from an animal previously infected with LCMV. This report follows the initial notification to NIH/OSP made on 11/20/2020.

Please let me know if you have any questions.

Regards,
Marissa

---

**From:** Cardwell, Marissa M
**Sent:** Friday, November 20, 2020 1:48 PM
**To:** NIHGuidelines@od.nih.gov
**Cc:** Angela Reid (angela_reid@harvard.edu) <angela_reid@harvard.edu>; Sharpe, Arlene <arlene_sharpe@hms.harvard.edu>; LaFleur, Martin <Martin_LaFleur@hms.harvard.edu>
**Subject:** Initial report of incident at BL2 involving rDNA - Harvard University Nov 2020

To OSP:

I would like to make an initial report of an incident that occurred at Harvard University involving mouse tissue that was potentially contaminated with genetically modified Lymphocytic choriomeningitis virus (LCMV). During tissue harvest of mice previously infected with LCMV, a researcher sustained a puncture wound from a pair of forceps that had been used to harvest tissue. At the timepoint of harvest, LCMV is not detectable in the tissues via plaque assay, however, these mice are held at BL2-N per IBC approval. It is possible that LCMV could be present at low levels in some tissues that have not been previously assessed via plaque assay or that it is present at levels below the limit of detection. Therefore, we are making an initial report of an incident occurring at BL2.

A formal report will follow after we complete our investigation.

Please let me know if you have any questions.

Regards,
Marissa

---

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**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.

## Hunter, Renee (NIH/OD) [C]

**From:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Friday, November 20, 2020 1:48 PM
**To:** NIH guidelines
**Cc:** Reid, Angela; Arlene Sharpe; LaFleur, Martin
**Subject:** Initial report of incident at BL2 involving rDNA - Harvard University Nov 2020

To OSP:

I would like to make an initial report of an incident that occurred at Harvard University involving mouse tissue that was potentially contaminated with genetically modified Lymphocytic choriomeningitis virus (LCMV). During tissue harvest of mice previously infected with LCMV, a researcher sustained a puncture wound from a pair of forceps that had been used to harvest tissue. At the timepoint of harvest, LCMV is not detectable in the tissues via plaque assay, however, these mice are held at BL2-N per IBC approval. It is possible that LCMV could be present at low levels in some tissues that have not been previously assessed via plaque assay or that it is present at levels below the limit of detection. Therefore, we are making an initial report of an incident occurring at BL2.

A formal report will follow after we complete our investigation.

Please let me know if you have any questions.

Regards,
Marissa

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**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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, January 5, 2021 10:47 AM
**To:** Caitlyn Ann Hauke; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report

Dear Dr. Caitlyn Hauke,

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:** Caitlyn Ann Hauke <Caitlyn.Ann.Hauke@dartmouth.edu>
**Sent:** Tuesday, November 24, 2020 3:06 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident Report

Good afternoon,

I am forwarding you a copy of the incident reporting template for a mouse bite incident that occurred today involving a graduate student at Dartmouth College. The mouse was a transgenic strain (CD111c-DTR), but was otherwise free of any external rDNA or pathogens at the time of the incident. The bite was minor and the student was treated by Occupational Medicine and released back to the lab shortly after. Further information is described in the report. The student will be provided with retraining and additional oversight.

Please let me know if you would like additional information.

Thank you,
Caitlyn

**Caitlyn A. Hauke, Ph.D.**
Biological Safety Officer
Dartmouth College Environmental Health & Safety
37 Dewey Field Rd, HB 6216/RM 129
Hanover, NH 03755

Obtained via FOIA by Judicial Watch Inc.

Phone: 603-646-2182
caitlyn.ann.hauke@dartmouth.edu
https://www.dartmouth.edu/~ehs/

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*?** | X YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Dartmouth College |
| **Date of Report:** | 11/24/20 |
| **Reporter name and position:** | Caitlyn Hauke, Biosafety Officer |
| **Telephone number:** | 518-588-5461 |
| **Email address:** | Caitlyn.a.hauke@dartmouth.edu |
| **Reporter mailing address:** | 37 Dewey Field Rd.<br>Suite 6216<br>Hanover, NH 03755 |
| **Date of incident:** | 11/24/20 |
| **Name of Principal Investigator:** | Yina Huang |
| **Is this an NIH-funded project?** | ☐YES X NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ X YES ☐NO<br><br>If yes, date of approval: June 5, 2019 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Transgenic mouse strain CD111c-DTR. *These mice are on the C57BL/6 background. They harbor a transgene that expresses DTR on myeloid cells expressing the CD11c receptor. https://www.jax.org/strain/004509* |

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 graduate student was working alone during business hours, handling a non-infected wildtype CD111c-DTR mouse in the specific pathogen free vivarium for an IP injection of CD4-depleting antibodies (had not been injected yet). The mice were also not infected with any pathogens and had not been injected with diphtheria toxin. As the student was preparing to inject the mouse, it turned and bit their left thumb, breaking the skin through their glove. The student removed their glove, washed their hand, and immediately reported to their PI and then Occupational Medicine. OccMed treated the student for the minor scrape to the thumb and the student returned to work. No further recommendations were provided.

Additional PPE (beyond nitrile gloves) worn during the incident included a disposable gown, bouffant cap, shoe covers, and face mask. The student has received animal handling (2019), laboratory safety (2019), and BSL2 training (2020). They were listed on the approved IACUC protocol to perform this work and had been cleared by OccMed to work with mice. No deviations from SOP or IBC approved research were made.

The incident occurred due to improper scruffing of the mouse. To address this, the student will be re-trained on scruffing technique and will be monitored until they are more comfortable handling mice and can demonstrate consistently appropriate scruffing technique.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES X NO<br>The incident was reported to the IBC chair (11/24/20) and will be shared with the committee at their meeting next week (12/2/20). |
| **Please describe the root cause of this incident:** | Poor mouse scruffing 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):

The student will be re-trained on proper mouse scruffing technique by their supervisor prior to continuation with their mouse work and will be monitored until they demonstrate consistently appropriate handling and are comfortable doing so.

- **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:** Caitlyn Ann Hauke <Caitlyn.Ann.Hauke@dartmouth.edu>
**Sent:** Tuesday, November 24, 2020 3:06 PM
**To:** NIH guidelines
**Subject:** Incident Report
**Attachments:** NIH Incident Report-Dartmouth-11-24-20.docx

Good afternoon,

I am forwarding you a copy of the incident reporting template for a mouse bite incident that occurred today involving a graduate student at Dartmouth College. The mouse was a transgenic strain (CD111c-DTR), but was otherwise free of any external rDNA or pathogens at the time of the incident. The bite was minor and the student was treated by Occupational Medicine and released back to the lab shortly after. Further information is described in the report. The student will be provided with retraining and additional oversight.

Please let me know if you would like additional information.

Thank you,
Caitlyn

**Caitlyn A. Hauke, Ph.D.**
Biological Safety Officer
Dartmouth College Environmental Health & Safety
37 Dewey Field Rd, HB 6216/RM 129
Hanover, NH 03755

Phone: 603-646-2182
caitlyn.ann.hauke@dartmouth.edu
https://www.dartmouth.edu/~ehs/

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 10:51 AM
**To:** Indiana University IBC; NIH guidelines
**Cc:** Logrip, Marian L; Biosafety Program at IUPUI; Baumann, John R; Vidal, Ruben; Dong, X Charlie; Swank, Eric D.; Jones, Stephanie; Lookatch, Kristin Angela; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: 30 Day Report - IU IBC
**Signed By:** michelle.mckinney@nih.gov

Dear Holly Moore,

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:** Indiana University IBC <ibc@iu.edu>
**Sent:** Friday, December 4, 2020 10:51 AM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Logrip, Marian L <mlogrip@iupui.edu>; Biosafety Program at IUPUI <ehsbio@iupui.edu>; Baumann, John R <baumannj@iu.edu>; Vidal, Ruben <rvidal@iupui.edu>; Dong, X Charlie <xcdong@iupui.edu>; Swank, Eric D. <edswank@iu.edu>; Jones, Stephanie <strrober@iu.edu>; Lookatch, Kristin Angela <klookatc@iu.edu>
**Subject:** RE: 30 Day Report - IU IBC

Good morning Dr. Harris,

The IBC considers work with AAV in animals, that does not involve oncogenes or toxins, to be appropriately contained at ABL-1. However, due to facility policy where these animals are located, the AAV infected rats are housed at ABL-2 for the first 72 hours when the possibility of AAV shedding exists, and for the first cage change, because only ABL-2 cages have their bedding autoclaved. As far as AAV infected rodents are concerned, the IBC sees this as ABL-1. The majority of other AAV infected rodents are housed in facilities that autoclave ABL-1 bedding as well as ABL-2, and those animals are housed at ABL-1 immediately following AAV injection.

Please let me know if you have any additional questions or if we can provide further information on the incident.

Many thanks and have a wonderful weekend!

Obtained via FOIA by Judicial Watch Inc.

*Holly*




**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
Indiana University
**Phone:** 812.855.0656
**Email:** holmoore@iu.edu
**Web:** https://research.iu.edu/compliance/

*****Please note that the IBC Office email address has changed. Moving forward, please use IBC@iu.edu to contact our office.**

**Click here see upcoming IBC meeting dates and deadlines.**

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, December 3, 2020 4:39 PM
**To:** Indiana University IBC <ibc@iu.edu>
**Cc:** Logrip, Marian L <mlogrip@iupui.edu>; Biosafety Program at IUPUI <ehsbio@iupui.edu>; Baumann, John R <baumannj@iu.edu>; Vidal, Ruben <rvidal@iupui.edu>; Dong, X Charlie <xcdong@iupui.edu>; Swank, Eric D. <edswank@iu.edu>; Jones, Stephanie <strrober@iu.edu>; Lookatch, Kristin Angela <klookatc@iu.edu>
**Subject:** [External] RE: 30 Day Report - IU IBC

Dear Holly:

Thank you for your email. Can you confirm the biosafety level this incident occurred at? (BL1?).

Regards,

Dr. Kathryn Harris

---

**From:** Indiana University IBC <ibc@iu.edu>
**Sent:** Thursday, December 3, 2020 1:46 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Logrip, Marian L <mlogrip@iupui.edu>; Biosafety Program at IUPUI <ehsbio@iupui.edu>; Baumann, John R <baumannj@iu.edu>; Vidal, Ruben <rvidal@iupui.edu>; Dong, X Charlie <xcdong@iupui.edu>; Swank, Eric D. <edswank@iu.edu>; Jones, Stephanie <strrober@iu.edu>; Lookatch, Kristin Angela <klookatc@iu.edu>
**Subject:** 30 Day Report - IU IBC

Dear NIH OSP:

Please find below the details of an incident involving recombinant DNA from the Indiana University Purdue University Indianapolis (IUPUI) Institutional Biosafety Committee.

**Date of Incident:** November 02, 2020

**Name of PI:** Marian Logrip

Obtained via FOIA by Judicial Watch Inc.

**Nature of Incident:** Spill

**Description:** Dr. Logrip had just completed changing a rat cage of a rat in the 72 hour post-injection with AAV. As she was transporting the dirty cage to the autoclave, the water bottle slipped out of the bag and broke on the floor. The bottle was approximately half full of water. No one was splashed or injured as a result of the broken bottle.

**Nature of recombinant or synthetic material involved:** The bottle was from the cage of a rat who had been infused intracranially with AAVrg-Cre and AAV-DIO-hM3dq (both replication deficient) more than 72 hours before the incident. These agents are not known to be oncogenic or toxic. No concentrated virus was present in the room at the time of the event.

**Cause:** The incident was an accident.

**Actions Taken:** Immediately after the bottle broke, the Logrip lab removed all rats to another room to complete rehousing and prevent exposure of rats to the strong bleach smell. Dr. Logrip added concentrated bleach to the spill zone and waited >15 minutes for the bleach to fully decontaminate all materials. The materials were then cleaned up with paper towels and the decontaminated broken glass was disposed of in a glass waste container. The lab members were wearing the appropriate PPE for work related to the incident (lab coat, gloves, mask, and safety goggles or face shield). After the materials were properly decontaminated and disposed of, Dr. Logrip contacted the Biosafety Office to report the incident. The Biosafety Manager asked the PI to cover spills with paper towels before applying concentrated disinfectant.

At the November 19, 2020 IBC meeting, the Committee discussed the incident and the actions taken. The Committee was satisfied with the PI's response to the incident and the actions taken.

If you have any questions regarding the incident, please feel welcome to contact the IU IBC Office at IBC@iu.edu.

Regards,

*Holly*




**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
Indiana University
**Phone:** 812.855.0656
**Email:** holmoore@iu.edu
**Web:** https://research.iu.edu/compliance/

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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Indiana University IBC <ibc@iu.edu>
**Sent:** Thursday, December 3, 2020 1:46 PM
**To:** NIH guidelines
**Cc:** Logrip, Marian L; Biosafety Program at IUPUI; Baumann, John R; Vidal, Ruben; Dong, X Charlie; Swank, Eric D.; Jones, Stephanie; Lookatch, Kristin Angela
**Subject:** 30 Day Report - IU IBC
**Signed By:** ibc@iu.edu

Dear NIH OSP:

Please find below the details of an incident involving recombinant DNA from the Indiana University Purdue University Indianapolis (IUPUI) Institutional Biosafety Committee.

**Date of Incident:** November 02, 2020

**Name of PI:** Marian Logrip

**Nature of Incident:** Spill

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If you have any questions regarding the incident, please feel welcome to contact the IU IBC Office at IBC@iu.edu.

Regards,

*Holly*

Obtained via FOIA by Judicial Watch Inc.




**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
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**Phone:** 812.855.0656
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## Hunter, Renee (NIH/OD) [C]

**From:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Thursday, December 3, 2020 4:39 PM
**To:** 'Indiana University IBC'
**Cc:** Logrip, Marian L; Biosafety Program at IUPUI; Baumann, John R; Vidal, Ruben; Dong, X Charlie; Swank, Eric D.; Jones, Stephanie; Lookatch, Kristin Angela
**Subject:** RE: 30 Day Report - IU IBC
**Signed By:** harriskath@mail.nih.gov

Dear Holly:

Thank you for your email. Can you confirm the biosafety level this incident occurred at? (BL1?).

Regards,

Dr. Kathryn Harris

---

**From:** Indiana University IBC <ibc@iu.edu>
**Sent:** Thursday, December 3, 2020 1:46 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Logrip, Marian L <mlogrip@iupui.edu>; Biosafety Program at IUPUI <ehsbio@iupui.edu>; Baumann, John R <baumannj@iu.edu>; Vidal, Ruben <rvidal@iupui.edu>; Dong, X Charlie <xcdong@iupui.edu>; Swank, Eric D. <edswank@iu.edu>; Jones, Stephanie <strrober@iu.edu>; Lookatch, Kristin Angela <klookatc@iu.edu>
**Subject:** 30 Day Report - IU IBC

Dear NIH OSP:

Please find below the details of an incident involving recombinant DNA from the Indiana University Purdue University Indianapolis (IUPUI) Institutional Biosafety Committee.

**Date of Incident:** November 02, 2020

**Name of PI:** Marian Logrip

**Nature of Incident:** Spill

**Description:** Dr. Logrip had just completed changing a rat cage of a rat in the 72 hour post-injection with AAV. As she was transporting the dirty cage to the autoclave, the water bottle slipped out of the bag and broke on the floor. The bottle was approximately half full of water. No one was splashed or injured as a result of the broken bottle.

**Nature of recombinant or synthetic material involved:** The bottle was from the cage of a rat who had been infused intracranially with AAVrg-Cre and AAV-DIO-hM3dq (both replication deficient) more than 72 hours before the incident. These agents are not known to be oncogenic or toxic. No concentrated virus was present in the room at the time of the event.

**Cause:** The incident was an accident.

Obtained via FOIA by Judicial Watch Inc.

**Actions Taken:** Immediately after the bottle broke, the Logrip lab removed all rats to another room to complete rehousing and prevent exposure of rats to the strong bleach smell. Dr. Logrip added concentrated bleach to the spill zone and waited >15 minutes for the bleach to fully decontaminate all materials. The materials were then cleaned up with paper towels and the decontaminated broken glass was disposed of in a glass waste container. The lab members were wearing the appropriate PPE for work related to the incident (lab coat, gloves, mask, and safety goggles or face shield). After the materials were properly decontaminated and disposed of, Dr. Logrip contacted the Biosafety Office to report the incident. The Biosafety Manager asked the PI to cover spills with paper towels before applying concentrated disinfectant.

At the November 19, 2020 IBC meeting, the Committee discussed the incident and the actions taken. The Committee was satisfied with the PI's response to the incident and the actions taken.

If you have any questions regarding the incident, please feel welcome to contact the IU IBC Office at IBC@iu.edu.

Regards,

*Holly*




**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
Indiana University
**Phone:** 812.855.0656
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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 8:38 AM
**To:** O'Shea, Brian J (US); NIH guidelines
**Cc:** Elsass, Karen E (US); Spurbeck, Rachel R (US); ^BCO Institutional Biosafety Committee; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Battelle NIH Notification of rDNA Exposure

Dear Dr. Brian O'Shea,

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:** O'Shea, Brian J (US) <oshea@battelle.org>
**Sent:** Wednesday, December 23, 2020 10:16 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Elsass, Karen E (US) <ELSASSK@battelle.org>; Spurbeck, Rachel R (US) <spurbeck@battelle.org>; ^BCO Institutional Biosafety Committee <IBC@battelle.org>
**Subject:** Battelle NIH Notification of rDNA Exposure

NIH-OSP,

Please find the incident report attached describing the exposure of a Battelle pathology staff member to recombinant vaccinia virus on 12/01/2020.

If you have any questions or concerns, please feel free to contact me at any time.

Sincerely,

**Brian J. O'Shea PhD, CBSP, SM(NRCM)**
*Chair – Institutional Biosafety Committee*
*Biological Safety Program Manager*
Safety Health and Emergency Response
Office: 614.424.4831 | Mobile: Redacted by agreement
oshea@battelle.org

Obtained via FOIA by Judicial Watch Inc.

**Battelle**
1425 Plain-City Georgesville Road
West Jefferson, Ohio 43162
http://www.battelle.org

*This message 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/or otherwise 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, any disclosure, dissemination, distribution, copying or other use of this communication or its substance is prohibited. If you have received this communication in error, please return to the sender and delete from your computer system.*

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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Battelle |
| **Date of Report:** | 12/23/2020 |
| **Reporter name and position:** | Brian O'Shea, PhD; IBC Chair |
| **Telephone number:** | 614-424-4831 |
| **Email address:** | oshea@battelle.org |
| **Reporter mailing address:** | 1425 Plain-City Georgesville Road<br>West Jefferson, Ohio 43162 |
| **Date of incident:** | 12/01/2020 |
| **Name of Principal Investigator:** | Karen Elsass |
| **Is this an NIH-funded project?** | ☐YES X NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO If yes, date of approval:<br>4/6/2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-D-1<br>Section III-D-4 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC<br>☐ USDA<br>☐ FDA<br>☐ EPA<br>☐ OSHA<br>X Funding agency/sponsor<br>☐ State or local Public Health<br>☐ Law enforcement<br>☐ Other (please describe): |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Oncolytic (cancer-fighting) Vaccinia virus (Copenhagen strain) being developed by the client. The virus is attenuated (replication restricted), which has been modified to target cancer cells and kill them.<br>Virus contains the following recombinant aspects:<br>• synthetic human (interleukin 2 with 4 mutations)<br>  ○ IL2 is an immunostimulatory cytokine<br>• synthetic - firefly (luciferase) and jellyfish (green fluorescent protein)<br>• Synthetic Herpes Simplex Virus-1 (thymidine kinase gene with a single point mutation) |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| | ○ HSV TK confers sensitivity of virus infected cells to guanosine e.g. ganciclovir |

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 approximately 1545 hrs on 12/1/2020, a pathology technician was working within a Class II type B2 biological safety cabinet within the BSL-2 pathology suite Redacted by agreement conducting a necropsy on an NHP recently administered recombinant test article (vaccinia virus referenced above) from study T06030. The technician was using a "church key" chisel type tool to pry open the femur of the NHP when the tool slipped from her right hand and impacted the medial portion of her left thumb. The church key is not a sharp object, but it did cause a break in both pairs of nitrile gloves on her left hand and broke the skin causing her to bleed. The technician followed emergency response procedures and immediately notified others within the suite, removed the outer gloves from her hands and began scrubbing the wound with a provided chlorohexidine scrub at the nearby hand washing sink. The technician recruited help from colleagues to scrub and flush the wound for 15 minutes. Other colleagues during this time were containing and decontaminating the blood that had spilled onto the floor on her way to the sink area. All spill cleanup procedures followed our internal bloodborne pathogen standards as well as spill cleanup procedures. Once the wound was scrubbed for 15 minutes, the technician (and an escort) proceeded to go to the adjacent building and consult with onsite medical staff. Calls were made to medical staff to inform them of the situation, as well to the biological safety officer (IBC Chair) while the technician was in route to medical staff. Once the technician arrived at onsite medical, she was evaluated for her injuries and treated accordingly. The technician discussed the incident with the biological safety officer and all pertinent staff were notified (IBC committee, PI, management, etc.)

At the time of the incident, the technician was wearing the following PPE while working inside of the BSCII:

- Facility dedicated scrubs
- Facility dedicated shoes
- Safety glasses with side shields
- Double nitrile gloves
- Reverse closing gown
- Tyvek sleeves

The technician has been previously vaccinated for vaccinia virus within the past 10 years.

The technician was treated for her injuries and antivirals were prescribed for the potential exposure to Macacine Herpes B virus, which will also be efficacious in the treatment of exposure to this recombinant vaccina virus strain due to the incorporation of herpes simplex type 1 thymidine kinase in the virus. Medical surveillance for B virus exposure is conducted at initial injury, 1 week, 1 month and 3 months. The technician will also be evaluated at 2 days and 1 week post exposure to evaluate for potential development of vaccinia at the site of the injury. The technician is doing well after the injury and tolerating the antiviral medications.

The technician was fully trained in the procedures required to perform her job at the time of the incident. The training summary for the technician involved is listed below.

Obtained via FOIA by Judicial Watch Inc.

**Training Summary for Injured Technician as of, 28 April 2020**

| Category | Date(s) |
|---|---|
| **GLP/Regulatory Training** | |
| GLP Orientation | 4/04 |
| GLP Documentation | 12/13, 12/11, 7/09, 1/07, 1/06, 12/04 |
| GLP Documentation Training/Exercise | 11/09 |
| **Computer/Data Acquisition Systems** | |
| Provantis Data Collection System – Necropsy Technician Initial Training | 03/20 |
| Pilgrim SmartSolve Quality Management System Orientation Training | 02/20 |
| **Health & Safety** | |
| PAPR Training | 3/20 |
| Animal Safety on Inhalation Studies | 10/06 |
| Animal Welfare | 2/20,4/10 |
| Bloodborne Pathogens | 6/13, 6/12, 7/06, 6/05, 10/04, 5/04 |
| Environment, Safety, Health, and Quality Orientation | 4/04 |
| Euthanasia | 2/20, 4/10, 3/09,4/08 |
| Formaldehyde/Formalin Training (Annual) | 2/20, 12/11, 6/09, 3/07, 2/06, 8/04, 3/04 |
| Health and Safety Emergency Awareness | 2/20 |
| Hazard Communication | 9/13, 4/04 |
| Hazardous Waste Management Training | 5/05 |
| Hearing Conservation Program Training | 10/06 |
| Herpes B Prevention | 2/20, 4/10, 3/09, 4/08, 1/07, 2/06, 12/04, 3/04 |
| Lab Animal Allergens | 2/20, 4/10, 3/09, 4/08, 1/07, 2/06, 12/04, 3/04 |
| Lab Waste Handling | 4/04 |
| Personal Protective Equipment | 4/04 |
| Radiation Safety Training | 7/05 |
| Radiation Worker Training and Refresher | 9/07,7/06, 7/05 |
| Radiation Safety Refresher (Unsealed Sources) | 7/08 |
| Respiratory Protection Training and Refresher | 6/05, 4/04 |

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**Training Summary for Injured Technician as of, 28 April 2020**

| Category | Date(s) |
|---|---|
| **Laboratory Training** | |
| Detection of Sperm in a Vaginal Lavage Sample | 3/05, 6/04 |
| Decapitation of Mouse Pups for Termination and Blood Collection | 12/05 |
| 8-Flavoring Agents | 4/07 |
| Embedding | 7/06 |
| Hand-Written Organ Weights | 4/04 |
| Molecular Tissue Collection (Oncogene) | 8/04 |
| Necropsy-Rodents and Rabbits (Rats, Mice, Rabbits, Guinea Pigs, Cotton Rats, Hamsters, Squirrels, Gerbils, Chinchilla) | 3/20, 3/04 |
| Necropsy-Carnivores and Non-Human Primates (Monkeys-Any Species, Apes-Including Chimpanzees, Dogs, Cats, Ferrets) | 2/05 |
| Necropsy-Ruminants and Swine | 12/06 |
| Necropsy-Ferret | 7/07 |
| Necropsy-Rabbit | 9/05 |
| Necropsy-Canine | 7/04 |
| Necropsy-Mice | 5/04 |
| Necropsy-Rat | 4/04 |
| Restraint-Sling/Mask-Canine; Restraint-Manual-Canine Identification-Tattoo-Canine; Sexing-Canine | 10/06 |
| Staining | 8/05 |
| Tissue Trim | |
| • Rodents | 3/20 |
| • Rats | 4/04 |
| • Mice | 8/04 |
| • Non-Human Primate | 1/06 |
| • Swine | 1/07 |
| • Dogs | 11/05 |
| • Rabbits | 10/05 |
| **Instrumentation Training** | |
| Caliper Measuring | 2/07 |
| Use of Micro Centrifuge in Clinical Pathology | 11/07 |

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TRAINING SUMMARY FOR Injured Technician as of, 28 April 2020

| Category | Date(s) |
|---|---|
| **Courses/Seminars** | |
| Creating a Safety Culture | 7/06 |
| Safety in the Histology Laboratory | 05/05 |
| Analyte Specific Reagents | 05/05 |
| Importance & Utility of Immunohistochemistry in Surgical Neuropathology | 05/05 |
| Communicating Across Generations | 1/07 |
| Tissue Identification for the Histologist | 2/07 |
| IHC Cross Reactivity and Detection Systems for Animal Tissue | 3/07 |
| Introduction to PCR: Assays with Application to Solid Tumor Analysis | 4/07 |
| Hazard Communication | 3/20 |
| Standards of Ethics and Conduct | 3/20 |
| Cyber Security Awareness | 3/20 |
| Total Time- Reporting Annual Review | 3/20 |
| Total Time-Correction of Time Reported | 3/20 |
| Total Time-Induction to Total Time Reported | 3/20 |
| Total Time- Time Reporting | 3/20 |
| Total Time - What is time worked | 3/20 |
| Lab Safety | 3/20 |
| Workplace Harassment | |

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO |
| **Please describe the root cause of this incident:** | Church key slipped from hand and struck non-dominant hand causing a break in the skin. |

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 day after the incident occurred (12/2/2020), pathology staff incorporated the use of a cut resistant glove on their non-dominant hand during all necropsies in BSL-2 labs. This is a practice that was put into place for all BSL-3 necropsies previously as well.

- **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:** O'Shea, Brian J (US) <oshea@battelle.org>
**Sent:** Wednesday, December 23, 2020 10:16 AM
**To:** NIH guidelines
**Cc:** Elsass, Karen E (US); Spurbeck, Rachel R (US); ^BCO Institutional Biosafety Committee
**Subject:** Battelle NIH Notification of rDNA Exposure
**Attachments:** Battelle NIH Notification 12-23-2020.pdf

NIH-OSP,

Please find the incident report attached describing the exposure of a Battelle pathology staff member to recombinant vaccinia virus on 12/01/2020.

If you have any questions or concerns, please feel free to contact me at any time.

Sincerely,

**Brian J. O'Shea PhD, CBSP, SM(NRCM)**
*Chair – Institutional Biosafety Committee*
*Biological Safety Program Manager*
Safety Health and Emergency Response
Office: 614.424.4831 | Mobile: Redacted by agreement
oshea@battelle.org

**Battelle**
1425 Plain-City Georgesville Road
West Jefferson, Ohio 43162
http://www.battelle.org

*This message 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/or otherwise 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, any disclosure, dissemination, distribution, copying or other use of this communication or its substance is prohibited. If you have received this communication in error, please return to the sender and delete from your computer system.*

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## Hunter, Renee (NIH/OD) [C]

**From:** O'Shea, Brian J (US) <oshea@battelle.org>
**Sent:** Thursday, December 3, 2020 9:41 AM
**To:** NIH guidelines
**Cc:** Spurbeck, Rachel R (US); ^BCO Institutional Biosafety Committee
**Subject:** Battelle rVACV Exposure

NIH/OSP,

I wanted to make you aware of an incident that occurred late Tuesday afternoon in one of our ABSL-2 research labs at Battelle. This email serves as the initial notification and the NIH Incident Report template is currently being completed for submission soon.

During a necropsy of an NHP, a pathology staff member received an injury which broke both layers of nitrile gloves she was wearing as well as breaking the skin. The NHP was previously dosed with a recombinant vaccinia virus (Copenhagen strain) test article which carries genes responsible for human IL-2 and IL-4 expression as well as the thymine kinase gene from Herpes simplex virus type 1 (HSV-1).

All emergency exposure procedures were immediately and correctly followed as well as immediate consultation with onsite medical providers. Currently the staff member is doing well and will continue to be monitored for days/weeks to come.

Our investigation is ongoing and findings will be included in the NIH Incident Report.

Please feel free to reach out to me with any questions, and the incident report will be filed in the coming days.

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

**Battelle**
1425 Plain-City Georgesville Road
West Jefferson, Ohio 43162
http://www.battelle.org

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 8:58 AM
**To:** Cardwell, Marissa M; NIH guidelines
**Cc:** Reid, Angela; Arlene Sharpe; LaFleur, Martin; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Report of incident at BL1 involving rDNA - Harvard University Oct 2020

Dear Dr. Marissa Cardwell,

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:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Friday, December 4, 2020 11:23 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Reid, Angela <angela_reid@harvard.edu>; Arlene Sharpe <arlene_sharpe@hms.harvard.edu>; LaFleur, Martin <Martin_LaFleur@hms.harvard.edu>
**Subject:** Report of incident at BL1 involving rDNA - Harvard University Oct 2020

To OSP:

Attached, please find a report detailing an incident at Harvard University involving exposure to transduced mouse cells. These cells were approved for handling at BL1 per the Harvard IBC.

Please let me know if you have any questions.

Regards,
Marissa

---

**Marissa M. Cardwell, PhD, RBP**
Director of Laboratory Safety & Biosafety
Harvard University

Obtained via FOIA by Judicial Watch Inc.

Environmental Health & Safety
107 Avenue Louis Pasteur
Boston, MA 02115
Office: (617) 432-0022
Cell: Redacted by agreement
ehs.harvard.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*?** | ☒YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Harvard University |
| **Date of Report:** | 12/4/2020 |
| **Reporter name and position:** | Marissa M. Cardwell<br>Director of Laboratory Safety & Biosafety |
| **Telephone number:** | (617) 432-0022 |
| **Email address:** | marissa_cardwell@harvard.edu |
| **Reporter mailing address:** | Harvard University / EHS<br>107 Avenue Louis Pasteur<br>Boston, MA 02115 |
| **Date of incident:** | 10/28/2020 (Biosafety office informed on 10/28/2020) |
| **Name of Principal Investigator:** | Dr. Arlene Sharpe |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4<br>BL1-N containment was approved for administration of the materials involved in the exposure to mice. |
| **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<br>☐USDA ☒State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Exposure via needlestick to naive murine T cells derived from Lin-Sca1+Kit- cells (LSK) that were previously transduced with lentiviral vector pXPR053 from Addgene. This vector has a gRNA cloning site. The lab had cloned in a gRNA to the murine Stat3 gene. |

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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 October 28, 2020, a research assistant stuck himself with a needle attached to a syringe loaded with murine T cells derived from Lin-Sca1+Kit- cells (LSK) that had been previously genetically modified with a 3rd generation lentiviral vector to knockout the murine Stat3 TF gene using a gRNA complementary to murine Stat3. The needle had also been used in other wildtype mice to administer the same cells. Though the animals were all housed in the BL2-N facility, no agents requiring BL2-N containment had been used in the mice at the time of the exposure. All mice had undergone the routine screening required by the animal facility for use in the barrier.

The researcher was preparing to perform an intravenous injection into the tail vein of a wildtype mouse when he missed the mouse tail and stuck his left index finger with the needle. He noted that the glove ripped and there was blood at the site. He immediately removed his PPE and left the animal facility to wash the injury site. He washed his finger with soap and water for a few minutes and then followed with alcohol-based hand gel prior to calling to report the event to his supervisor and to the occupational health provider. The occupational health provider instructed the researcher to monitor the site over the next several days for signs of infection and to seek medical attention if any occurred. No prophylactic medication was indicated, and no further illness has been reported. The supervisor sent an email notification to the laboratory's biosafety officer and filed an official injury report through the online reporting system.

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 was using a tail restrainer to perform the injection, as was indicated as routine by his supervisor. The supervisor also indicated that the researcher had demonstrated proficiency in this technique and had performed it multiple times before without incident. Difficulty in hand-eye coordination in this incident was attributed to the exposure.

Harvard Biosafety was made aware of the incident on October 28, 2020. The biosafety officer immediately reached out to glean more information on the source of the cells and nature of the exposure. Further discussion with the supervising faculty revealed that the injury was an exposure to recombinant material.

Risk associated with exposure to these cells takes into account their source (murine) and genetic modifications. The 3rd generation lentiviral vectors used to transduce the cells have been tested by the lab to assess replication incompetence. The IBC has approved the downgrade of the transduced cell lines to BL1 following replication incompetence testing. Administration of the washed and stably genetically modified cells to mice, following the testing for replication incompetence, is approved under BL1-N. At the time of injection, no packaged viral vector should have been present, and the researcher would only have been exposed to the stably transduced murine cells. The mice were housed at BL2-N for this procedure because the

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following day they were to be infected with LCMV Clone 13 (agent requiring BL2 containment). At the time of the incident the mice had not been exposed to any infectious agents.

**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 Sharpe laboratory regularly works with a large number of animals and performs a large number of procedures. Given this, the relative incidence of errors is quite low. Regardless, the lab is committed to improving any training or engineering protocols to decrease the likelihood of these incidents.

The supervisor stated that the use of cut-resistant gloves in the BL2-N animal facility had been considered by the lab in addition to the use of the restraining device for IV injections. However, the lab found that dexterity was significantly impacted by the cut-resistant gloves. Additionally, the cut-resistant gloves are shown to protect against cuts or abrasions but are not considered effective against puncture wounds (e.g. bites, needlesticks). Thus, it is unlikely that the addition of these gloves would have prevented this injury.

The laboratory has already reflected greatly on engineering controls, work practices, and PPE to reduce potential for injury in the animal facility. Continued use of these controls, as well as hands-on retraining of the laboratory staff in animal handling, including injection technique is already being implemented.

The researcher completed training for biological safety on January 27, 2020. Safe sharps practices and injury prevention are emphasized in this course. Other completed and relevant laboratory safety trainings for this individual are outlined below in Table A. The researcher was trained in this technique (intravenous injection) and proper use of needles by a lab supervisor. After this incident, the researcher was retrained in this technique to help prevent future issues though this incident was really the result of poor execution of the technique as opposed to poor knowledge of the technique.

*Table A. Trainings completed by the injured researcher.*

| **Course Title** | **Completion** |
|---|---|
| General Laboratory Safety | 27-JAN-2020 |
| Laboratory Biosafety | 27-JAN-2020 |

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br><br>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 was determined to be the root cause of this injury. The mouse in this situation did not precipitate this incident by squirming or moving. The mouse was in a restrainer in which the mouse is contained and only the tail is accessible. The researcher missed the tail and hit his finger. |

- **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:** Cardwell, Marissa M <marissa_cardwell@harvard.edu>
**Sent:** Friday, December 4, 2020 11:23 AM
**To:** NIH guidelines
**Cc:** Reid, Angela; Arlene Sharpe; LaFleur, Martin
**Subject:** Report of incident at BL1 involving rDNA - Harvard University Oct 2020
**Attachments:** 2020_1028_NIH_Incident_Report_Sharpe.pdf

To OSP:

Attached, please find a report detailing an incident at Harvard University involving exposure to transduced mouse cells. These cells were approved for handling at BL1 per the Harvard IBC.

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

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 11:20 AM
**To:** Brian Eggert; NIH guidelines
**Cc:** Ron Hart; Aimee Beaulieu; Jose Roman; Mark McLane; Alejandro Alex Ruiz; Biosafety; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: NIH report of non-compliance

Dear Brian Eggert,

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:** Brian Eggert <brian.eggert@rutgers.edu>
**Sent:** Monday, December 7, 2020 1:54 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Ron Hart <rhart@rutgers.edu>; Aimee Beaulieu <ab1550@njms.rutgers.edu>; Jose Roman <jr1504@research.rutgers.edu>; Mark McLane <mark.mclane@rutgers.edu>; Alejandro Alex Ruiz <ruiz@rutgers.edu>; Biosafety <biosafety@ipo.rutgers.edu>
**Subject:** NIH report of non-compliance

Good afternoon,

Please find attached to this email a report for work performed without an approved IBC protocol. Please let me know if additional information is required.

Sincerely,

-Brian

**Brian Eggert, MPH, RBP**
*Biosafety Officer*
Institutional Planning and Operations

Obtained via FOIA by Judicial Watch Inc.

Rutgers Environmental Health and Safety
brian.eggert@rutgers.edu | 848.445.3053 | 973.573.6734

SUPPORTING TODAY,
ENVISIONING TOMORROW.

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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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Rutgers, The State University of New Jersey |
| **Date of Report:** | December 7, 2020 |
| **Reporter name and position:** | Brian Eggert, MPH, RBP<br>Biosafety Officer |
| **Telephone number:** | 848-445-2550 |
| **Email address:** | brian.eggert@rutgers.edu |
| **Reporter mailing address:** | Rutgers Environmental Health & Safety<br>74 Street 1603<br>Piscataway, NJ 08854 |
| **Date of incident:** | November 12, 2020 |
| **Name of Principal Investigator:** | Steven Libutti, M.D., PhD |
| **Is this an NIH-funded project?** | ☐YES ☒NO |

| | |
|---|---|
| **What was the nature of the** | ☐Failure to follow approved containment conditions |

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| | |
|---|---|
| **incident?** | ☒Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 11/18/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA<br><br>No other reports will be made. |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Feline Immunodeficiency Virus (FIV)-based lentiviral vector expressing Cre-recombinase, specifically, FIV-CMV-Cre VSVG, obtained from the University of Iowa Viral Vector Core. |

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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.**

On November 12, 2020, in accordance with the IACUC hazard assessment and request by the vivarium supervisor, Rutgers Environmental, Health and Safety (REHS) was updating hazard signage on a vivarium animal room and noted that the lentiviral vector (FIV-CMV-Cre VSVG) administered by the Principal Investigator's (PI) laboratory personnel was not listed on his approved IBC protocol. The BSO checked the PI's associated IACUC protocol and noted that a Lenti-Cre vector was listed but had been missed by the Biosafety group during a congruency review in April 2020. Based on the finding, REHS notified the Principal Investigator (PI), the IBC co-chairs, the Director of Veterinary Services and the Office of Research and Economic Development of the non-compliance issue and the PI was instructed to immediately stop administering the vector until registering it with the IBC and obtaining approval. The PI indicated that he was unaware that under the NIH Guidelines he is required to register each vector construct when he already had IBC approval to use a lentivirus vector.

The vector was neither modified, nor propagated in the laboratory and was administered via intratracheal intubation by a Laboratory Manager who completed laboratory safety/biosafety training on 3/5/2020. The Laboratory Manager followed biosafety level 2 precautions contained in their existing approved lentiviral protocol and utilized proper engineering controls (i.e., worked within a certified biological safety cabinet) and personal protective equipment (i.e., eye protection, disposable gloves, lab coat/gown) for this work. Vivarium personnel used appropriate personnel protective equipment (i.e., N95s, eye protection, disposable gloves, lab coat/gown) and engineering controls (i.e., cage and bedding changes performed in a biosafety cabinet).

In addition to completing laboratory safety/biosafety training in 2020, the PI's laboratory personnel were provided with Viral Vector training which was completed between 11/13/20 and 11/18/20.

There were no injuries or illness associated with the incident, need for additional medical surveillance or equipment failures. All protocols are reviewed and assessed by medical personnel for exposures, prophylactic, and allergy concerns.

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Although there was a failure to register the vector with the IBC and a failure in the congruency review process, the non-compliance was identified due to additional checks and balances including good communication between the PI's staff and vivarium staff regarding hazardous agent usage, the posting of agent signs on vivarium doors, and REHS checking for IBC approval of agents and constructs before creating vivarium hazard signage.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | The PI was approved for another lentiviral vector and did not realize that each different lentiviral construct is required to be registered with the IBC. Additionally, the PI had received approval from the IACUC to use the new construct, and the new construct was not identified as needing to be registered with the IBC during the safety review of his IACUC protocol. |

**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):**

On 11/13/20, the PI submitted an amendment to add the vector to his protocol, and it was reviewed and approved by the IBC on 11/18/20. The Senior Biosafety Officer reminded the PI of the requirements of the NIH guidelines and will work with the Biosafety group to avoid omissions during future congruency reviews comparing IACUC protocols and IBC protocols. The PI has discussed the NIH Guidelines requirements with his laboratory staff, and they will register future vector constructs with the IBC for prior to beginning work. REHS sent a reminder to all persons in our biosafety system regarding the requirement for IBC protocol approval prior to conducting certain experiments, including when adding additional viral vectors. Also, safety training modules are currently being updated to re-emphasize the need to register each vector construct with the IBC regardless of the source and to contact the Biosafety group for guidance, as needed.

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:** Brian Eggert <brian.eggert@rutgers.edu>
**Sent:** Monday, December 7, 2020 1:54 PM
**To:** NIH guidelines
**Cc:** Ron Hart; Aimee Beaulieu; Jose Roman; Mark McLane; Alejandro Alex Ruiz; Biosafety
**Subject:** NIH report of non-compliance
**Attachments:** NIH incident report Libutti 2020.pdf

Good afternoon,

Please find attached to this email a report for work performed without an approved IBC protocol. Please let me know if additional information is required.

Sincerely,

-Brian

**Brian Eggert, MPH, RBP**
*Biosafety Officer*
Institutional Planning and Operations
Rutgers Environmental Health and Safety
brian.eggert@rutgers.edu | 848.445.3053 | 973.573.6734

SUPPORTING TODAY,
ENVISIONING TOMORROW.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 8:44 AM
**To:** Debra A. Dwyer; NIH guidelines
**Cc:** Joshua E. Turse; Christine A. Bellezza; Mark Hurwitz; Colin Ross Parrish; Esther R. Angert; David G. Russell; Michael I. Betteken; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Final report of potential exposure at Cornell University 12/8/2020

Dear Debra Dwyer,

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:** Debra A. Dwyer <dad3@cornell.edu>
**Sent:** Wednesday, December 23, 2020 10:56 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Joshua E. Turse <joshturse@cornell.edu>; Debra A. Dwyer <dad3@cornell.edu>; Christine A. Bellezza <cab37@cornell.edu>; Mark Hurwitz <mfh37@cornell.edu>; Colin Ross Parrish <crp3@cornell.edu>; Esther R. Angert <era23@cornell.edu>; David G. Russell <dgr8@cornell.edu>; Michael I. Betteken <mib46@cornell.edu>
**Subject:** Final report of potential exposure at Cornell University 12/8/2020

To whom it may concern:

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 reported on 12/8/2020 found below.

Best,
Deb

---

**From:** Michael I. Betteken
**Sent:** Tuesday, December 8, 2020 4:15 PM
**To:** NIHGuidelines@od.nih.gov
**Cc:** Joshua E. Turse <joshturse@cornell.edu>; Debra A. Dwyer <dad3@cornell.edu>; Christine A. Bellezza <cab37@cornell.edu>; Mark Hurwitz <mfh37@cornell.edu>; Colin Ross Parrish <crp3@cornell.edu>; Esther R. Angert

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<era23@cornell.edu>; David G. Russell <dgr8@cornell.edu>
**Subject:** Initial notification of potential exposure at Cornell University 12/8/2020

To whom it may concern:

The Cornell IBC just received notification of a potential exposure event with this email serving as our initial notification to NIH.

Yesterday afternoon, personnel were splashed with culture when a 96-well optical bottom plate leaked. The plate contained human macrophages infected with Mycobacterium tuberculosis strain Erdman, which was modified with a plasmid containing mCherry. All PPE remained intact. A person was splashed and another was in the room at the time of the potential exposure. Incident follow-up is ongoing. Both personnel have been seen by medical providers.

We are currently conducting our investigation and will provide a full report to the NIH as soon as it is available. Please let me 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

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Cornell University |
| **Date of Report:** | 12/08/2020 |
| **Reporter name and position:** | Michael Betteken, IBC Administrator |
| **Telephone number:** | 607-255-0741 |
| **Email address:** | Cu_ibc@cornell.edu |
| **Reporter mailing address:** | Cornell University<br>East Hill Office Building<br>395 Pine Tree Road<br>Suite 320-H |
| **Date of incident:** | December 7, 2020 |
| **Name of Principal Investigator:** | David Russell |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* 1R01AI155319-01<br>*NIH funding institute or center:* NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES<br>*NIH program officer (name, email address):*<br>Daniel J. Frank, Daniel.frank@nih.gov |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 11/11/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☐BL2 ☐BL2+<br>☒BL3 ☐BL3+<br>☐BL4 |
| **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 agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Mycobacterium tuberculosis* strain Erdman transformed with a plasmid expressing mCherry. |

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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

DESCRIPTION OF INCIDENT: (use additional space as necessary)

At approximately 1 pm on December 7, 2020, a postdoctoral researcher and graduate student

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were working in laboratory within the multi-room BSL-3 research suite. Both personnel were working with human macrophages infected with *Mycobacterium tuberculosis*, Erdman expressing mCherry. Work is performed in a 96-well optical bottom plates (15 ml. total volume) with black polystyrene upper structure. Typical of these plates, lids are loose-fitting. This arrangement allows researchers to image infected macrophages. While examining a plate outside primary containment, a lid came loose and a small amount of the culture medium containing Mycobacterium tuberculosis was spilled onto the postdoctoral researcher while the graduate student was approximately 2 feet away. The postdoctoral researcher placed the plate and lid onto an adjacent research bench.

The graduate student observed spilled medium on the postdoctoral researcher's shoes, wrap-around gown, gloves, and scrub pants. A similar visual exam of the graduate student by the postdoctoral researcher did not reveal any visible droplets on their person. There was some visible liquid on the adjacent bench, sink, and floor around the postdoctoral researcher which was avoided during the following process. Immediately following this visual assessment:

- The graduate student retrieved an autoclave bag for waste collection from a nearby cabinet, while the postdoctoral researcher remained in place.
- The graduate student held the waste bag for postdoctoral researcher to doff outer gloves.
- The graduate student supplied the postdoctoral researcher with a new set of outer gloves.
- The postdoctoral researcher removed their contaminated Tyvek wrap-around lab coat and placed it in the waste bag.
- The postdoctoral researcher doffed outer and inner gloves and placed them in the waste bag.
- The postdoctoral researcher donned new gloves.
- The postdoctoral researcher doffed scrubs, hairnet, socks, foam clogs, exiting the laboratory wearing underclothes, a half-face elastomeric respirator, and gloves.
- Gloves were removed before exiting the containment boundary of the suite and entering the research suite's anteroom/changing area.
- The postdoctoral researcher immediately proceeded to the shower while wearing their respirator. The postdoctoral researcher showered with soap and water, washing their hair for 10-15 minutes. While showering the respirator was washed, then removed so the postdoctoral researcher could wash their face.
- The shower was taken while wearing undergarments. The undergarments were removed after soaping, during the shower. Undergarments were collected for processing.

While the postdoctoral researcher was doffing and proceeding to the shower, the graduate student placed a call to the College of Veterinary Medicine Biosafety Engineer to notify them of the incident. The Biosafety Engineer notified the University Biosafety Officer via phone. The Biosafety Engineer and Biosafety Specialist from the College of Veterinary Medicine (spill team) responded to the Research and Diagnostic Annex BSL-3, arriving at approximately 1:15 pm.

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After completing the phone call the graduate student similarly doffed their PPE to exit the laboratory:

- The graduate student removed their outer gloves and placed in the biohazard bag.
- The graduate student doffed their Tyvek wrap-around lab coat, and hairnet and placed them in the waste bag.
- The graduate student removed safety glasses, scrubs, socks, foam clogs, exiting the laboratory wearing underclothes, N95 respirator, and 'inner' gloves.
- Gloves and N95 respirator were removed and disposed of before exiting the containment boundary of the suite and entering the research suite's anteroom/changing area.
- After the postdoctoral researcher completed showering, the graduate student showered for 10-15 minutes with soap and water. The shower was taken while wearing undergarments. The undergarments were removed after soaping, during the shower. Undergarments were collected for processing.

RESPONSE

Immediately after the spill, and after research personnel had completed showering, the spill team interviewed the research personnel to determine the location of the spill, the nature of the spilled material, and the associated circumstances. At approximately 1:45 pm the spill team started spill response moving from the anteroom area, through the entry to the containment zone, a common corridor, and laboratory using a pump sprayer and CiDecon phenolic disinfectant to treat the floor along the entire path:

Arriving at the lab, the spill team surveyed the lab and saw the pile of PPE (2 gowns, 2 pairs of scrub tops and pants, socks, and shoes along with safety glasses) on the floor of the room, next to a partially-filled red bag a few feet inside the door in the location they reported the spill had occurred. Three 96-well plates were on the adjacent research bench.

While entering, the floor and pile of PPE was liberally sprayed with CiDecon. The vertical casework, benchtop, nearby freezer, incubator, laboratory stool, and remaining plates were sprayed during this process.

- A large inverted autoclavable biohazard bag was used to collect the PPE and bag on the floor which held the doffed gloves, hairnets, and Tyvek. That bag was double-bagged, moved to a corridor by the spill team. The floor where the PPE pile had been was sprayed with CiDecon.
- Inverted "Ziploc" bags were used to collect the three plates; after closing the bags the plates were placed in a new autoclavable biohazard bag with paper towels and other waste generated during the cleanup.
- At this point, the total amount of contact time for the floor and surfaces sprayed was over 20 minutes. Clean water and a mop were used to remove the CiDecon from floor surfaces while paper towels were used to wipe down casework, the incubator, and the

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freezer. These surfaces and the phone were sprayed with PreEmpt, an accelerated hydrogen peroxide disinfectant. The second round of CiDecon was sprayed on the lab, common corridor, and anteroom flooring.
- This second application of CiDecon was allowed 10 minutes of residence time and mopped with clean water.
- All waste was collected in autoclavable biohazard bags and autoclaved using standard facility procedures.
- The spill team doffed their PPE, placing it in autoclavable bags for later disposal. Respirators worn by the spill team were sprayed with PreEmpt.
- The spill team collected the researcher's undergarments for laundry with the facility scrubs.

TRAINING

Cornell's training for BSL-3 researchers includes bloodborne pathogen training, laboratory safety training, classroom BSL-3 training, in-facility BSL-3 training, and mentor-apprentice training.

- The postdoctoral researcher completed their training during the summer of 2019
- The graduate student completed their training during the summer of 2017.
- Both personnel completed the recent annual refresher BSL-3 class in November 2020.

PPE

Personal protective equipment and clothing for researchers in the Research and Diagnostic Annex include: facility-provided scrubs, socks, foam clogs, hairnet, wrap-around impervious (Tyvek) gown, double gloves and respiratory protection. Due to some PPE shortages caused by the COVID-19 pandemic respiratory protection for some users is an elastomeric respirator with appropriate cartridges while others are using disposable N95 respirators.

OCCUPATIONAL HEALTH REQUIREMENTS and MEDICAL

All researchers in Cornell's tuberculosis research program receive regular tuberculosis testing by either PPD or blood tests. Due to the potential risk of exposure to the postdoctoral researcher and graduate student both were able to contact medical providers the day of the incident and blood tests (QuantiFERON) were administered the following day (December 8). This test was administered as a 'baseline' test since it had been several months since the last test for either researcher. Both researchers will self-monitor for symptoms of TB and be retested in several weeks, per advice from a medical professional. There is currently no additional reported illness. The university biosafety office will continue to follow up with the researchers.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br><br>The IBC Chairs were informed of the incident by the BSO |

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| | |
|---|---|
| | on December 8, 2020. The IBC met on December 8, 2020 and was informed. The incident investigation was ongoing at the time of that meeting. The IBC will be updated on January 12, 2021, with the full report. |
| **Please describe the root cause of this incident:** | The root cause of this incident is a loose-fitting cover which opened inadvertently allowing contents to be spilled. |

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 Principal Investigator has reviewed the procedure with the researchers, emphasizing that plates are not to be observed in the manner the plates were and containment of plates is to be maintained.

The Principal Investigator, researchers, spill team, and Biosafety Officer have reviewed the incident and incident response. During the response to the spill, researchers decided to disrobe within the lab, rather than exit the lab and disrobe at the door to the lab, before exiting the facility. Though this doesn't create a new hazard, it does prolong the time researchers spend in a laboratory with a spill.

- **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:** Debra A. Dwyer <dad3@cornell.edu>
**Sent:** Wednesday, December 23, 2020 10:56 AM
**To:** NIH guidelines
**Cc:** Joshua E. Turse; Debra A. Dwyer; Christine A. Bellezza; Mark Hurwitz; Colin Ross Parrish; Esther R. Angert; David G. Russell; Michael I. Betteken
**Subject:** Final report of potential exposure at Cornell University 12/8/2020
**Attachments:** Incident-Reporting-NIH-12.7.2020.docx

To whom it may concern:

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 reported on 12/8/2020 found below.

Best,
Deb

---

**From:** Michael I. Betteken
**Sent:** Tuesday, December 8, 2020 4:15 PM
**To:** NIHGuidelines@od.nih.gov
**Cc:** Joshua E. Turse <joshturse@cornell.edu>; Debra A. Dwyer <dad3@cornell.edu>; Christine A. Bellezza <cab37@cornell.edu>; Mark Hurwitz <mfh37@cornell.edu>; Colin Ross Parrish <crp3@cornell.edu>; Esther R. Angert <era23@cornell.edu>; David G. Russell <dgr8@cornell.edu>
**Subject:** Initial notification of potential exposure at Cornell University 12/8/2020

To whom it may concern:

The Cornell IBC just received notification of a potential exposure event with this email serving as our initial notification to NIH.

Yesterday afternoon, personnel were splashed with culture when a 96-well optical bottom plate leaked. The plate contained human macrophages infected with Mycobacterium tuberculosis strain Erdman, which was modified with a plasmid containing mCherry. All PPE remained intact. A person was splashed and another was in the room at the time of the potential exposure. Incident follow-up is ongoing. Both personnel have been seen by medical providers.

We are currently conducting our investigation and will provide a full report to the NIH as soon as it is available. Please let me 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

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**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

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## Hunter, Renee (NIH/OD) [C]

**From:** Michael I. Betteken <mib46@cornell.edu>
**Sent:** Tuesday, December 8, 2020 4:15 PM
**To:** NIH guidelines
**Cc:** Joshua E. Turse; Debra A. Dwyer; Christine A. Bellezza; Mark Hurwitz; Colin Ross Parrish; Esther R. Angert; David G. Russell
**Subject:** Initial notification of potential exposure at Cornell University 12/8/2020

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Thanks,
Michael

Michael I. Betteken, PhD
IBC - Administrator
Institutional Biosafety Committee
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CornellResearch

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, January 5, 2021 10:44 AM
**To:** Karen McCulloch; NIH guidelines
**Cc:** Chris Doyle (cdoyle@wirb.com); Sarah Roberge; Amanda L. Fletcher; Amanda M. Jolly; Ari VanderWalde; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: IBC Incident Report - The West Clinic

Dear Karen McCulloch,

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:** Karen McCulloch <KMcCulloch@wcgclinical.com>
**Sent:** Tuesday, December 8, 2020 11:51 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Chris Doyle (cdoyle@wirb.com) <cdoyle@wirb.com>; Sarah Roberge <sroberge@wirb.com>; Amanda L. Fletcher <afletcher@WESTCLINIC.com>; Amanda M. Jolly <ajolly@WESTCLINIC.com>; Ari VanderWalde <avanderwalde@westclinic.com>
**Subject:** IBC Incident Report - The West Clinic

To Whom it May Concern,
Please see the attached incident report related to a personnel exposure. Please feel free to reach out with any questions or if I can provide additional details.
Best,
Karen

**Karen A. McCulloch | IBC Chair**
**WCG IBC Services**
1019 39th Avenue SE
Suite 120
Puyallup, WA 98374
o/ +1 651.429.1058
m/ Redacted by agreement
**kmcculloch@wcgclinical.com | www.wcgirb.com**

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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | The West Clinic<br>7945 Wolf River Blvd.<br>Germantown, TN 38138 |
| **Date of Report:** | 12-08-2020 |
| **Reporter name and position:** | Karen McCulloch, BS<br>IBC Co-Chair The West Clinic |
| **Telephone number:** | 651-429-1058 |
| **Email address:** | kmcculloch@wcgclinical.com |
| **Reporter mailing address:** | 1019 39th Ave SE, Suite 120<br>Puyallup, WA 98374 |
| **Date of incident:** | 11-23-2020 |
| **Name of Principal Investigator:** | Ari VanderWalde, MD, MPH, FACP |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval:<br>Initial: 01-04-2019<br>Continuing: 01-07-2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Attenuated, conditionally replicating oncolytic virus based on HSV-1 encoding the human GM-CSF transgene and the GALV-GP-R- transgene. |

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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: A study staff member was in the process of injecting the study agent into the right calf of a subject when 0.5 mL of the study agent squirted out of the syringe and landed onto the arm of the study staff member performing the injection and the arm of an assistant. These two staff members were wearing gloves, lab coats and a mask with an integrated eyeshield and the exposure occurred between the glove and the lab coat. Both staff members followed the IBC-approved Biosafety SOP and scrubbed the exposed area with soap and water for 15 minutes. Of note, the Biosafety SOP states that a gown should be worn during administration of the study agent.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO |
| **Please describe the root cause of this incident:** | Staff members wore lab coats rather than disposable gowns. |

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):

According to the Institution, "staff members have been reeducated on the importance of wearing the gown and that no skin is exposed." In addition, staff members have recently been reeducated on the Biosafety SOP.

- **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:** Karen McCulloch <KMcCulloch@wcgclinical.com>
**Sent:** Tuesday, December 8, 2020 11:51 AM
**To:** NIH guidelines
**Cc:** Chris Doyle (cdoyle@wirb.com); Sarah Roberge; Amanda L. Fletcher; Amanda M. Jolly; Ari VanderWalde
**Subject:** IBC Incident Report - The West Clinic
**Attachments:** OSP Incident Report, Dr. VanderWalde, dated 12-08-2020.pdf

To Whom it May Concern,
Please see the attached incident report related to a personnel exposure. Please feel free to reach out with any questions or if I can provide additional details.
Best,
Karen

**Karen A. McCulloch | IBC Chair**
**WCG IBC Services**
1019 39th Avenue SE
Suite 120
Puyallup, WA 98374
o/ +1 651.429.1058
m/ Redacted by agreement
**kmcculloch@wcgclinical.com | www.wcgirb.com**

The Trusted Partner in Ethical Review

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, February 17, 2021 12:53 PM
**To:** Kara Drolet; NIH guidelines
**Cc:** Sarah Byers; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: OHSU Initial report of potential exposure 12/11/2020

Dear Dr. Kara Manning Drolet,

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:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Tuesday, January 26, 2021 2:12 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Sarah Byers <byerssa@ohsu.edu>
**Subject:** RE: OHSU Initial report of potential exposure 12/11/2020

Hello Dr. Harris,
Please find attached a follow up report for this incident and let us know if there are any questions.
Thank you,
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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

**From:** Sarah Byers
**Sent:** Tuesday, December 15, 2020 5:03 PM
**To:** 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** OHSU Initial report of potential exposure 12/11/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 12/11/2020 at Oregon Health & Science University. A researcher was splashed in the eye while cleaning forceps used to process tissue from a non-human primate that was experimentally infected with a recombinant strain of 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

Obtained via FOIA by Judicial Watch Inc.

OREGON HEALTH & SCIENCE UNIVERSITY

**Institutional Biosafety Committee**

Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
fax 503 346-6808
ibc@ohsu.edu

**Kara M. Drolet, Ph.D.**
*Associate Vice President Research Integrity*
tel 503 494-6727
manninck@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

January 26, 2021

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

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 12/15/2020.

| | |
|---|---|
| OHSU IBC registration number | IBC-201700057 |
| OHSU project title | Inflammation induced pathology and viral reservoir persistence |
| Date of incident | 12/11/2020 |
| Nature of the material | Tissue from non-human primate infected with recombinantly derived SIV with wild type pathogenicity |
| Risk Group | III |
| Containment level | BSL-2+, enhancement is through PPE and work practices |
| Nature of the incident | Personnel Exposure |
| PPE in use | Lab coat, gloves |

**Description of incident:**

A researcher was splashed in the eye while washing surgical tools that had been used to dissect tissue from a non-human primate infected with a recombinant SIV. The surgical tools had been briefly wiped down with 70% ethanol prior to being transported from the surgical suite to the laboratory for cleaning and sterilization.

The research immediately rinsed their eyes in the eye wash and the incident was evaluated by Occupational Health.

**Actions taken:**

The root cause of the incident was lack of clarity regarding tasks that should be conducted with eye protection. The lab members were reminded via email by the lab manager to wear lab-provided eye protection for tasks involving potentially infectious material. Researchers have also posted additional signage in the work area reminding researchers to wear eye protection.

The biosafety officer has met with the laboratory to address questions regarding tasks that should involve eye protection. The biosafety officer has also reviewed options to disinfect the tools earlier in the cleaning and sterilization process to reduce the potential for exposure to infectious material.

The IBC has determined that this incident has now been resolved with the submission of this report to OSP. If the individual develops symptoms related to this exposure the OHSU IBC will notify NIH-OSP.

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Sincerely,

Kara Drolet

Digitally signed by Kara Drolet
Date: 2021.01.26 11:10:18 -08'00'

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Tuesday, January 26, 2021 2:12 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Sarah Byers
**Subject:** RE: OHSU Initial report of potential exposure 12/11/2020
**Attachments:** 12112020 OHSU eye splash final report.pdf

Hello Dr. Harris,
Please find attached a follow up report for this incident and let us know if there are any questions.
Thank you,
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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

---

**From:** Sarah Byers
**Sent:** Tuesday, December 15, 2020 5:03 PM
**To:** 'Harris, Kathryn (NIH/OD) [C]' <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** OHSU Initial report of potential exposure 12/11/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 12/11/2020 at Oregon Health & Science University. A researcher was splashed in the eye while cleaning forceps used to process tissue from a non-human primate that was experimentally infected with a recombinant strain of 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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## Hunter, Renee (NIH/OD) [C]

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Tuesday, December 15, 2020 8:03 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Kara Drolet
**Subject:** OHSU Initial report of potential exposure 12/11/2020

Dear Dr. Harris,

This email serves as the initial notification of a potential exposure that occurred on 12/11/2020 at Oregon Health & Science University. A researcher was splashed in the eye while cleaning forceps used to process tissue from a non-human primate that was experimentally infected with a recombinant strain of 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

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, January 5, 2021 4:13 PM
**To:** Major, Sheryl; NIH guidelines
**Cc:** Gutkind, Silvio; Scott, Lance; McMahill, Angela; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Report of Mouse Bite

Dear Sheryl Major,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). No further information is required at this time. However, we note that the incident occurred on November 3, 2020, and was not reported to NIH OSP until December 17, 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.

We also note that the researcher did not seek medical evaluation immediately. We recommend reminding staff that 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
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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Thursday, December 17, 2020 4:19 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Gutkind, Silvio <sgutkind@UCSD.EDU>; Scott, Lance <lscott@ucsd.edu>; McMahill, Angela <amcmahill@ucsd.edu>
**Subject:** Report of Mouse Bite

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 an animal bite from a mouse that had been administered with B2905 murine melanoma cells genetically modified with a lentiviral vector to express GFP-Luciferase gene,

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two weeks earlier. This incident was discussed with the Institutional Biosafety Committee on 11/20/2020 and the Institutional Animal Care and Use Committee on 11/18/2020.

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*?** | X YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, San Diego |
| **Date of Report:** | 12/17/2020 |
| **Reporter name and position:** | Sheryl Major, Biosafety Officer |
| **Telephone number:** | (858) 822-2493 |
| **Email address:** | smajor@ucsd.edu |
| **Reporter mailing address:** | 9500 Gilman Drive #0090, La Jolla, CA 92093 |
| **Date of incident:** | 11/05/2020 |
| **Name of Principal Investigator:** | Silvio Gutkind |
| **Is this an NIH-funded project?** | X YES NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | YES X NO<br><br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-3 Experiments involving the use of infectious or defective Risk Group 2 viruses Expression using viral vectors in vitro, tissue culture<br><br>III-D-4-a Transfected cells being transplanted into animals. |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | The lab is working with HIV-1 viral vector pLVX-HET-1 construct in human and murine cell cultures. The gene of interest inserted into the lentiviral vector expresses signaling pathway genes, GFP-Luciferase. |

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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 Nov 03, 2020, a postdoctoral researcher in a vivarium was restraining a mouse to start an experiment when the mouse turned his head and bit the post-doc's hand. He noticed that his glove was torn at the site of the bite and there was blood coming from his left index finger knuckle. Two weeks prior to the incident, the mouse was treated with B2905 murine melanoma cells genetically modified with a lentiviral vector to express GFP-Luciferase gene. The researcher halted work, administered first aid, including washing with soap and water for 15 minutes, and reported the incident. The researcher was wearing a disposable gown, shoe covers, hair net, procedure mask, and one layer of nitrile gloves. Following the incident, the researcher switched to wearing two layers of nitrile gloves to provide increased dermal protection.

Researcher is current for Bloodborne Pathogens training, required laboratory safety trainings, and completed biosafety training for work with recombinant and synthetic nucleic acids.

Initial training requirements for animal research orientation was completed in 6/1/2017. Training on Anesthesia & Surgery in Small Animals on 2/5/2020 and Breeding Colony Basics on 3/14/2020.

The researcher indicated that he has been conducting animal research for only 2 months and this is his first time in handling mice, indicating a need for additional training in restraint techniques.

The researcher indicated no medical treatment and during interview follow up [11/5/2020] it was determined that the bite wound had healed. The researcher was referred to Occupational Health Medical team for medical follow up.

Additional follow up has included referral of the researcher to the Animal Care Program for retraining in restraint techniques [11/5/2020].

This incident was reported at IBC meeting on November 20, 2020.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | XYES NO |
| **Please describe the root cause of this incident:** | This incident was discovered due to a mouse bite incident that was found by the vivarium safety officer that the mouse that bit the researcher was treated with B2905 cells. |

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 the incident, the biosafety program and animal care program (ACP) investigated the injury on 11/5/2020. The biosafety team recommended the following:

1. The PI and Lab manager was instructed to submit a BUA amendment to add work for B2905 cell line and link it to your IACUC protocol.
2. Researcher must switch to a double layer of nitrile gloves to provide increased dermal protection.
3. ACP will provide animal handling refresher training.

This incident was reported at IBC meeting on November 20, 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.**

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## Hunter, Renee (NIH/OD) [C]

**From:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Thursday, December 17, 2020 4:19 PM
**To:** NIH guidelines
**Cc:** Gutkind, Silvio; Scott, Lance; McMahill, Angela
**Subject:** Report of Mouse Bite
**Attachments:** 2020-11_NIH_Incident_Report_Gutkind.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 an animal bite from a mouse that had been administered with B2905 murine melanoma cells genetically modified with a lentiviral vector to express GFP-Luciferase gene, two weeks earlier. This incident was discussed with the Institutional Biosafety Committee on 11/20/2020 and the Institutional Animal Care and Use Committee on 11/18/2020.

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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, February 1, 2021 1:03 PM
**To:** Rausch, Tamara (Tammy); NIH guidelines
**Cc:** Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Corsmo, Jeremy; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: CCHMC VPF Incident

Dear Tamara Rausch,

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:** Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
**Sent:** Thursday, January 14, 2021 5:06 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Waggoner, Stephen <Stephen.Waggoner@cchmc.org>; Gulick, James <James.Gulick@cchmc.org>; Dowdy, Tabitha <Tabitha.Dowdy@cchmc.org>; Corsmo, Jeremy <Jeremy.Corsmo@cchmc.org>
**Subject:** CCHMC VPF Incident

Good afternoon,

Attached is the final report of the spill incident that was reported to you by e-mail on 12/18/2020.

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



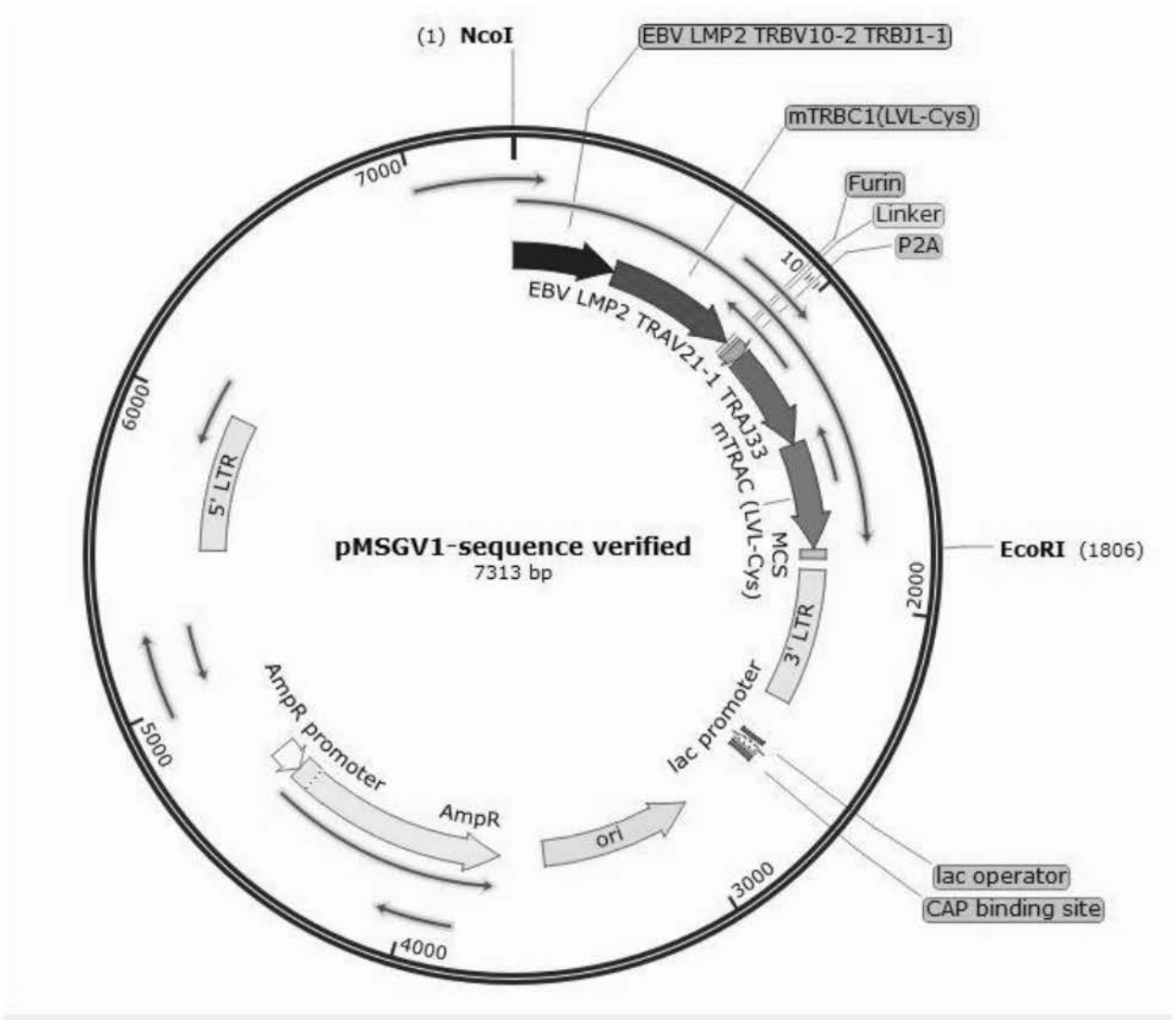
Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ✓YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Cincinnati Children's |
| **Date of Report:** | January 14, 2021 |
| **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<br>MLC 70<br>Cincinnati, OH 45229 |
| **Date of incident:** | December 17, 2021 |
| **Name of Principal Investigator:** | Carolyn Lutzko, PhD |
| **Is this an NIH-funded project?** | ☐YES ✓NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>✓ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ✓ YES ☐ NO<br>If yes, date of approval:<br>10/20/2020<br>IBC2020-00677 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>✓ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-2<br>III-D-3<br>III-D-6<br>III-E |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ✓ Other (please describe):<br>☐ 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 Gamma Retroviral vector supernatant with an RD114 envelope. The map is included in the report. |

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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 an approved BSL 2 ISO 7 cleanroom, Redacted by agreement in the Vector Production Facility (VPF) on 12/17/2020.

- Who was involved in the incident/violation, including others present at the incident location? The following were present during the incident: VPF Supervisor, two GxP Technicians (GxP Technician #1, GxP Technician #2) and a GxP 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:

- 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 Supervisor | 3/2/2015 | 12/3/2018 | 11/8/2018 | 10/22/2018 |
| GxP Technician #1 | 1/4/2020 | 1/13/2020 | 2/6/2020 | 1/16/2020 |
| GxP Technician #2 | 6/8/2020 | 7/16/2020 | 10/8/2020 | 7/13/2020 |
| GxP Specialist | 4/22/2016 | 6/22/2016 | 6/22/2016 | 4/22/2016 |

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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.

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

On December 17, 2020 in suite Redacted by agreement in the VPF, staff were working in an ISO 7 cleanroom. The VPF staff was in the process of completing the last harvest of a gamma retroviral product (EBV-LMP2). 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.

A 10 L bioprocess bag containing the product was connected to an empty 2 L bioprocess bag inside the biosafety cabinet via QuickConnect fittings. The connected bags were removed from the biosafety cabinet in order to weigh the 2 L bag during the transfer of vector supernatant from the 10 L bag. After the transfer, the 2 L bag was removed from the scale. The technician holding the 2 L bag dropped it and the two bags disconnected. Approximately 100 mL of vector supernatant spilled onto the floor from the 2 L bag.

Redacted by agreement

Staff immediately cleaned the spill with 70% isopropyl alcohol. The 2 L bag was removed from the cleanroom, treated with bleach solution and discarded. At the end of the processing day, Redacted by agreement and its exit airlock, biosafety cabinet, floors, doors, furniture, work surfaces, horizontal surfaces and accessible equipment exteriors were cleaned and disinfected per the VPF Cleanroom Cleaning SOP. All waste was disposed according to the VPF Biohazard Waste SOP.

The VPF staff notified the institutional safety hotline, 803-SAFE, to report the incident. The VPF Director, Biosafety Officer and QA Officer were also notified.

There were no personnel exposures.

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| | |
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| **Has the IBC reviewed this incident?** | ✓YES ☐NO<br><br>The incident was discussed and reviewed at the January 12, 2021 IBC meeting. |
| **Please describe the root cause of this incident:** | The root cause of the incident was personnel error. The technician dropped the bioprocess bags, causing them to disconnect from one another. |

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 VPF has already implemented a routine practice of placing any bioprocess bags which must rest on the floor inside large plastic bins to contain any potential leaks or spills and protect the cleanliness of the product. This process was being followed at the time of the event. However, the 2 L bag was being physically moved from the scale and was not in the bin at the time of the incident. The staff will review transport and handling of bags.

- **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, January 14, 2021 5:06 PM
**To:** NIH guidelines
**Cc:** Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Corsmo, Jeremy
**Subject:** CCHMC VPF Incident
**Attachments:** CCHMC VPF Gamma Retroviral Vector NIH Incident Report 12172020.pdf

Good afternoon,

Attached is the final report of the spill incident that was reported to you by e-mail on 12/18/2020.

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, December 18, 2020 8:25 AM
**To:** NIH guidelines
**Cc:** Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Corsmo, Jeremy
**Subject:** Spill Incident at CCHMC

Good morning,

This e-mail is to inform you of a spill incident that occurred at the Cincinnati Children's Viral Vector Production Facility on the night of December 17, 2020. The tubing from a labtainer became disconnected and approximately 50 – 100 mL of a gamma retro viral vector spilled onto the floor. I am in the process of investigating the incident. Upon completion of the investigation, a formal report will be submitted.

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



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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, January 5, 2021 10:55 AM
**To:** Joseph, Elaine; NIH guidelines
**Cc:** Calzonetti, Frank; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Subject to the NIH Guidelines

Dear Dr. Elaine Joseph,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). No further information is required at this time.

However, we note that the incident occurred on November 24, 2020, and was not reported to NIH OSP until December 21, 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Joseph, Elaine <Elaine.Joseph@UToledo.Edu>
**Sent:** Monday, December 21, 2020 9:57 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Calzonetti, Frank <frank.calzonetti@utoledo.edu>
**Subject:** Incident Subject to the 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.
Project Administrator, IACUC/IBC/IRE
Research and Sponsored Programs
R1 Building/Suite 1020E, Mail Stop 218
University of Toledo

Obtained via FOIA by Judicial Watch Inc.

2801 W. Bancroft St.
Toledo, Ohio 43606-3390
Office: 419-383-4251

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

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## 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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Toledo |
| **Date of Report:** | December 21, 2020 |
| **Reporter name and position:** | Frank Calzonetti, Ph.D.<br>Vice President of Research |
| **Telephone number:** | 419-530-4749 |
| **Email address:** | frank.calzonetti@utoledo.edu |
| **Reporter mailing address:** | University of Toledo<br>2801 Bancroft St, MS 218<br>Toledo, OH 43606 |
| **Date of incident:** | November 24, 2020 |
| **Name of Principal Investigator:** | Saori Furuta, Ph.D. |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: February 1, 2016 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Experiment III-D-1-a |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Lentivirus |

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

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

On November 24, 2020, a graduate student was harvesting virus-containing media from virus-producing cells in a Biosafety 2 level facility. She accidentally attached a needle to the syringe and stuck herself in the left hand with lentivirus. This is not normal procedure, as a needle is not needed for this procedure. The student reported to the emergency room and her supervisory faculty member (the principal investigator of the protocol). The incident was subsequently reported to Occupational Health and Safety, Environmental Health and Radiation Safety and the Institutional Biosafety Committee (IBC).

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | The student was not following correct procedure for collecting virus. In addition, a safety needle was not used. |

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 student has been retrained in the procedure and a supervisor has been observing her whenever she is collecting virus. An email has been sent to all IBC principal investigators reminding them of the importance of using safety needles for all procedures that require needles in the laboratory. This email also reminded all IBC principal investigators of the requirement to self-report all exposures or injuries occurring during an IBC experiment through the appropriate channels (i.e., Occupational Health, Environmental Health and Radiation Safety, and the IBC).

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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:** Joseph, Elaine <Elaine.Joseph@UToledo.Edu>
**Sent:** Monday, December 21, 2020 9:57 AM
**To:** NIH guidelines
**Cc:** Calzonetti, Frank
**Subject:** Incident Subject to the NIH Guidelines
**Attachments:** Incident Reporting November 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.
Project Administrator, IACUC/IBC/IRE
Research and Sponsored Programs
R1 Building/Suite 1020E, Mail Stop 218

University of Toledo
2801 W. Bancroft St.
Toledo, Ohio 43606-3390
Office: 419-383-4251

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 11:53 AM
**To:** Fischer, Matthew; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: UMB incident report 12/4/2020

Dear Dr. Matthew Fischer,

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:** Fischer, Matthew <matthew.fischer@umaryland.edu>
**Sent:** Tuesday, December 22, 2020 9:15 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** UMB incident report 12/4/2020

Good morning. Please find an incident report attached to this email.

Please let me know if there are any questions.

Thanks,
Matt

*Matthew A. Fischer, PhD, RBP, CBSP*
*Biosafety Officer and Assistant Director of Environmental Health and Safety*
*University of Maryland, Baltimore*
*matthew.fischer@umaryland.edu*
*(410) 706-7845*

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☑YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Maryland Baltimore |
| **Date of Report:** | December 22, 2020 |
| **Reporter name and position:** | Matthew Fischer, Biosafety Officer |
| **Telephone number:** | 410-706-7845 |
| **Email address:** | matthew.fischer@umaryland.edu |
| **Reporter mailing address:** | 714 W. Lombard Street<br>Baltimore, MD 21201 |
| **Date of incident:** | December 4, 2020 |
| **Name of Principal Investigator:** | Isabel Jackson |
| **Is this an NIH-funded project?** | ☐YES ☑NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☑ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☑ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☑ YES ☐ NO<br>If yes, date of approval: February 11, 2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☑ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Lentivirus pLVTH-sip53 (expresses shRNA to downregulate p53) |

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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 December 4th in a BL2 laboratory, a research specialist and research assistant were centrifuging tubes that contained a lentivirus solution. They typically use sealed (gasketed) swing buckets that are removed from the rotor and brought to a biosafety cabinet to open. However, they had purchased a new type of tube and these did not fit into the sealed buckets, so they proceeded with unsealed buckets.

When they went to unload the tubes, they discovered that a tube had failed (leaked) and approximately 2 milliliters of solution was in the bottom of a centrifuge bucket. As the centrifuge was outside of a biosafety cabinet, this is considered a spill outside of primary containment. PPE worn by the individuals throughout the incident included laboratory coats, goggles, double gloves, and surgical masks that covered their noses and mouths. The individuals did not have any direct contact with the lentivirus solution.

The individuals immediately closed the centrifuge and vacated the lab for 30 minutes to let any potential aerosols settle. Upon return, the individuals carefully transferred the rotor and buckets to a biosafety cabinet and decontaminated them using a 1:10 dilution of household bleach followed by isopropyl alcohol. The researchers decided there was a low risk of exposure, so while the incident was reported to the program manager (their direct supervisor), it was not appropriately reported to the Office of Environmental Health and Safety. It was decided that use of the new tubes would be immediately discontinued and use of the sealed centrifuge buckets would be reinstated.

On December 21st, the program manager completed a periodic review questionnaire for the IBC protocol and indicated that there had been a spill outside of containment. The UMB occupational health physician was contacted and she determined that post exposure prophylaxis was not appropriate.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ☑ NO<br>The incident will be reviewed at the next convened meeting on January 8, 2021. |
| **Please describe the root cause of this incident:** | Failure of tube within a centrifuge, not utilizing a sealed rotor or buckets that are only opened in a biosafety cabinet. |

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):

There are two main areas for improvement from this incident.

First, Risk Group 2 or higher materials should be centrifuged in sealed rotors or buckets that are transferred to a biosafety cabinet to open. This provides containment in the event that there was a spill or leak during centrifugation as was the case here. While this was normally the case, the practice was discontinued to try out a new type of tube. The new tubes will not be used again and sealed centrifuge buckets will be used moving forward.

Second, any accidents involving biological materials should be promptly reported so that an occupational health physician (and not the researchers themselves) can evaluate the probability of an exposure and initiate care if needed. For lentivirus specifically, our occupational health physician stressed that time is of the essence for post exposure prophylaxis. A biosafety specialist has provided training to the researchers on prompt reporting.

- **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:** Fischer, Matthew <matthew.fischer@umaryland.edu>
**Sent:** Tuesday, December 22, 2020 9:15 AM
**To:** NIH guidelines
**Subject:** UMB incident report 12/4/2020
**Attachments:** Jackson spill 120420.pdf

Good morning. Please find an incident report attached to this email.

Please let me know if there are any questions.

Thanks,
Matt

*Matthew A. Fischer, PhD, RBP, CBSP*
*Biosafety Officer and Assistant Director of Environmental Health and Safety*
*University of Maryland, Baltimore*
*matthew.fischer@umaryland.edu*
*(410) 706-7845*

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 8:51 AM
**To:** Myers, Cynthia; NIH guidelines
**Cc:** Cukierman, Edna; Rudolph, Daniel P; Dillard, Christen; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Reportable incident 12-22-20

Dear Cynthia Myers,

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

-----Original Message-----
From: Myers, Cynthia <Cynthia.Myers@fccc.edu>
Sent: Wednesday, December 30, 2020 5:10 PM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: Cukierman, Edna <Edna.Cukierman@fccc.edu>; Rudolph, Daniel P <Daniel.Rudolph@fccc.edu>; Dillard, Christen <Christen.Dillard@fccc.edu>
Subject: Reportable incident 12-22-20

Dear NIH.

Enclosed is our incident report for the exposure that occurred at Fox Chase Cancer Center on December 22, 2020.

Please let us know if you need any additional information about the incident.

Regards,

Cindy

Obtained via FOIA by Judicial Watch Inc.

Cynthia B. Myers
Senior Scientific Associate
Manager of the Laboratory Safety Program Acting Biosafety Officer, IBC Organic Synthesis Facility Fox Chase Cancer Center
215-728-2543
R458

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This electronic message is intended to be for the use of the named recipient, and may contain information that is confidential or privileged. This communication may contain protected health information (PHI) that is legally protected from inappropriate disclosure by the Privacy Standards of the Health Insurance Portability and Accountability Act (HIPAA) and relevant Pennsylvania Laws. You can direct questions concerning PHI or HIPAA to the Corporate Compliance and Privacy Officer at (215) 707-5605. If you are not the intended recipient, please note that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this message in error, you should notify the sender immediately by telephone or by return e-mail and delete and destroy all copies of this message.

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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Fox Chase Cancer Center (FCCC) |
| **Date of Report:** | December 30, 2020 |
| **Reporter name and position:** | Cynthia B. Myers, Senior Scientific Associate, Manager of Laboratory Safety Program, acting Biosafety Officer, IBC |
| **Telephone number:** | 215-728-2543 |
| **Email address:** | cynthia.myers@fccc.edu |
| **Reporter mailing address:** | Fox Chase Cancer Center, 333 Cottman Avenue, Phildelphia, PA 19111 |
| **Date of incident:** | December 22, 2020 |
| **Name of Principal Investigator:** | Dr. Lori Rink |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☒ Personnel exposure<br>☒ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒ YES ☐ NO<br>If yes, date of approval: 10/8/2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☒ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-3 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 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Lentivirus, produced in HEK293T. Packaging vectors – pMD2-G and pCMV-dR8.91. The lentivirus contained only sgRNA to CD55 (without Cas9). |

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 took place in a tissue culture room located in the West building on December 22, 2020 at 1:30 pm. A female graduate student was working alone in the tissue culture room wearing a lab coat, gloves and goggles. She was harvesting cell culture medium from HEK293T cells, producing lentivirus, in a LABCONCO Purifier Class II tissue culture biosafety cabinet. The lentivirus had only sgRNA to CD55 without Cas9. While working in the BSC, her googles fogged up due to wearing a surgical mask for Covid-19 protection (FCCC policy). She raised the googles off of her eyes to allow the googles to clear. She knew that her eyes were protected by the BSC sash. She forgot to lower the googles back down on top of her eyes prior to this next step. After harvesting the cells, she removed the tubes from the BSC and placed them into a centrifuge. One of the tubes with cell culture medium was not closed properly, it dropped out from the student's hand and splashed a couple of drops into her eye, and approximately 2-3 milliliters onto the laboratory bench. Immediately, the student went to the eyewash station and flushed out the eye for several minutes. Next, she cleaned up the spill on the bench using freshly made 10% bleach and paper towels. These were discarded into a red biohazard bag. She notify her PI, who contacted the Safety Officer for advice on how to proceed. As directed, the student called the Occupational Health Office, and they directed her to proceed to the office, where she was seen by the Occupational Health doctor. Based on the particulars of this worker's very low risk exposure, Occupational Health doctor placed the graduate student on seven days of post-exposure prophylaxis with both an integrase inhibitor and nucleoside reverse transcriptase inhibitors. The student completed this treatment on December 29th and Occupational Health doctors recommend no further treatment or surveillance was needed.

The work described above was not funded by NIH and was reviewed and approved by the FCCC IBC on October 8, 2020. The PI had an appropriate BSL-2+ SOP in place to cover the work. The SOP was being followed at the time of the incident. The only deviations were not wearing the goggles over the eyes to provide protection and not tightly closing all containers before removing them from the BSC. The graduate student had been provided hands-on lentivirus training by the post-doc who works in the laboratory on February 24, 2020 prior to starting the project. The graduate student was up to date on their Laboratory Safety (9/22/2020) and Bloodborne Pathogen (9/22/2020) trainings.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒ YES ☐ NO |
| **Please describe the root cause of this incident:** | This incident was caused by two human errors occuring at the same time. The researcher forgot to replace the goggles over the eyes after defogging them. In addition, the researcher did not cap the tube properly before moving the samples from BSC to centrifuge. If either one of these two errors had be eliminated this exposre would not have occurred. |

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 will re-train/remind all laboratory staff using the BSL-2+ SOP by January 5, 2021. In addition, PI will review with laboratory staff the importance of wearing eye protection and tightly closing tubes when handling Lentivirus samples. Also, the PI will review the different types of eye protection that are available in the FCCC stockroom.

All researchers at FCCC will be reminded/re-trained on the importance of wearing eye protection when working in the laboratory with hazardous materials. Reminder/re-training will include the following information: in the event that eye protection is frequently fogging up due to surgical masks being worn (Center policy) that the researcher should do the following: 1) be sure to replace the eye protection immediately after defogging them; 2) use an anti-fogging agent on the eye protection; 3) use a different type of eye protection that will not fog up as frequently (face shield). This reminder/re-training will be included in the annual mandatory on-line laboratory safety training beginning January 1, 2021. In addition, an e-mail containing this information will be distributed to all research staff in January 2021. Both reminder and safety training module will reinforce the need to wear eye protection when using hazardous biological and chemical materials and present the different types of eye protection that are availble in the FCCC stockroom. The reminder/re-training information will also include the importance of checking that all tubes are properly closed when removing them from the BSC. It should be noted that standard safety glasses were distributed to all employees in December 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.**

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Myers, Cynthia <Cynthia.Myers@fccc.edu>
**Sent:** Wednesday, December 30, 2020 5:10 PM
**To:** NIH guidelines
**Cc:** Cukierman, Edna; Rudolph, Daniel P; Dillard, Christen
**Subject:** Reportable incident 12-22-20
**Attachments:** NIH Incident-Report_12_30_2020_Final.docx

Dear NIH.

Enclosed is our incident report for the exposure that occurred at Fox Chase Cancer Center on December 22, 2020.

Please let us know if you need any additional information about the incident.

Regards,

Cindy

Cynthia B. Myers
Senior Scientific Associate
Manager of the Laboratory Safety Program Acting Biosafety Officer, IBC Organic Synthesis Facility Fox Chase Cancer Center
215-728-2543
R458

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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Myers, Cynthia <Cynthia.Myers@fccc.edu>
**Sent:** Tuesday, December 22, 2020 4:17 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Rudolph, Daniel P; Cukierman, Edna; Dillard, Christen
**Subject:** Over exposure?

Hi Kathryn,

I am e-mailing you about a possible overt exposure that occurred this afternoon at Fox Chase Cancer Center to obtain your opinion on whether this is a NIH reportable incident or not.

The person performing the research, who was exposed, was wearing eye protection that fogged up (due to surgical mask). They placed their eye protection on top of their head while they were harvesting the lentivirus from HEK293T cells in the BSC. Forgot to lower their eye protection and when taking the tube/tubes out accidentally splashed a few drops of the cell culture media into their eye. Here is their description of the event: Today I harvested lentivirus from HEK293T and accidentally splashed a couple of drops of cell culture medium (potentially with lentivirus) into my eye. The lentivirus has only sgRNA to CD55 (without Cas9), so it can't do any genetic changes. Moreover, I think that the titer of virus is really low (because most of the cells producing it were dead yesterday already).

The person flushed out their eye with eyewash and contacted the PI. The PI contacted me to get help with the next steps. We sent the person to Occupational Health immediately to be evaluated. More information will be received after the medical evaluation.

Please advise if you think that this is considered an overt exposure and we are required to fill out the incident report.

Regards,

Cindy

Cynthia B. Myers
Senior Scientific Associate
Laboratory Safety/IBC
Organic Synthesis Facility
Fox Chase Cancer Center
215-728-2543
R458

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This electronic message is intended to be for the use of the named recipient, and may contain information that is confidential or privileged. This communication may contain protected health information (PHI) that is legally protected from inappropriate disclosure by the Privacy Standards of the Health Insurance Portability and Accountability Act (HIPAA) and relevant Pennsylvania Laws. You can direct questions concerning PHI or HIPAA to the Corporate Compliance and Privacy Officer at (215) 707-5605. If you are not the intended recipient, please note that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this message in error, you should notify the sender immediately by telephone or by return e-mail and delete and destroy all copies of this message.

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, January 4, 2021 10:58 AM
**To:** Smith, David (RED+F-Facility Mgt-EHS); NIH guidelines
**Cc:** # biosafety; Figueroa, Marta; Paul, Jeremy; Jelinek, Warren; Mays, Natalie; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident exposure-Chikungunya virus

Dear Dr. David Smith,

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

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**From:** Smith, David (RED+F-Facility Mgt-EHS) <David.Smith3@nyulangone.org>
**Sent:** Saturday, December 26, 2020 7:10 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** # biosafety <biosafety@nyulangone.org>; Figueroa, Marta <Marta.Figueroa@nyulangone.org>; Paul, Jeremy <Jeremy.Paul@nyulangone.org>; Jelinek, Warren <Warren.Jelinek@nyulangone.org>; Mays, Natalie <Natalie.Mays@nyulangone.org>
**Subject:** Incident exposure-Chikungunya virus

Hello,

Please see the attached report.

Thank you,

Obtained via FOIA by Judicial Watch Inc.

David E. Smith, Ph.D., ASP

Institutional Biosafety Officer

NYU Langone Health

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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*?** | XYES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | NYU Langone Health |
| **Date of Report:** | December 26, 2020 |
| **Reporter name and position:** | David E. Smith, PhD<br>Institutional Biosafety officer |
| **Telephone number:** | 212-263-5159 |
| **Email address:** | David.Smith3@nyulangone.org |
| **Reporter mailing address:** | NYU Langone Health<br>Environmental Health and Safety<br>Real Estate Development and Facilities<br>Greenberg Hall<br>545 1st Avenue<br>New York, NY 10016 |
| **Date of incident:** | December 21, 2020 |
| **Name of Principal Investigator:** | Dr. Kenneth Stapleford |
| **Is this an NIH-funded project?** | ☐YES X**NO**<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X **Personnel exposure**<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | **XYES** ☐NO<br>If yes, date of approval: 5/28/2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>**X BL3** ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | La Reunion strain of Chikungunya (CHIKV) made from cDNA clone |

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)
Incident occurred Monday December 21 2020. Graduate student accidently stuck himself with forceps while harvesting wings and legs from CHIKV infected mosquitoes. Graduate student was following standard procedure removing legs and wings and placing in tube. The forceps were not in direct contact with the virus. The sharp incident occurred when the forceps were on the bench between mosquitos, and disrupted when material on bench was moved.
Incident occurred in the ABSL3 facility with procedure rooms for arboviruses:
Standard PPE worn: PAPR, TYVEC suit, double gloves, with procedure performed on bench.
Medical Surveillance and follow-up with Occupational Health Services (OHS) is occurring.
Training: Graduate student received 4 hours of training on this procedure from the PI, and he was working with a colleague who also received 4 hours of supervised training.
Note: PI, EH&S and OHS were not informed until December 24, 2020. I, David Smith, the institutional biosafety officer, told researcher to contact OHS and provide more information to me concerning exposure, more information did not arrive until today December 26, 2020.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | XYES ☐NO |
| **Please describe the root cause of this incident:** | Procedure using sharps (forceps) to remove legs and wings of infected mosquitos. Forceps placed on bench, not secured and resulted in finger-stick when material on bench was moved. |

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 immediately followed-up with PI and researcher to further investigate the procedure, training and alternatives to sharps being used. PI agreed to look into using blunt forceps and/or puncture proof gloves. Also if sharp is still required it will be secured by placing in 50 ml conical tube containing 70% isopropanol when not being used. Further training needs to be given to researchers concerning the need to immediately contact OHS and EH&S biosafety group, when exposure incident occurs. We routinely provide such exposure reporting information to all BSL2, BSL3 labs. It is written in their Standard Operating Procedures.

This template for reporting is acceptable.

- **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**

Obtained via FOIA by Judicial Watch Inc.

**you must report whether the use of this template is acceptable.**

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | NYU Langone Health |
| **Date of Report:** | December 26, 2020 |
| **Reporter name and position:** | David E. Smith, PhD<br>Institutional Biosafety officer |
| **Telephone number:** | 212-263-5159 |
| **Email address:** | David.Smith3@nyulangone.org |
| **Reporter mailing address:** | NYU Langone Health<br>Environmental Health and Safety<br>Real Estate Development and Facilities<br>Greenberg Hall<br>545 1st Avenue<br>New York, NY 10016 |
| **Date of incident:** | December 21, 2020 |
| **Name of Principal Investigator:** | Dr. Kenneth Stapleford |
| **Is this an NIH-funded project?** | ☐YES X**NO**<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X **Personnel exposure**<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | **XYES** ☐NO<br>If yes, date of approval: 5/28/2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>**X BL3** ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-D-3-b for the production of the Chikungunya virus made from cDNA in tissue culture cells |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | La Reunion strain of Chikungunya (CHIKV) made from cDNA clone |

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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)
Incident occurred Monday December 21 2020. Graduate student accidently stuck himself with forceps while harvesting wings and legs from CHIKV infected mosquitoes. Graduate student was following standard procedure removing legs and wings and placing in tube. The forceps were not in direct contact with the virus. The sharp incident occurred when the forceps were on the deck and moved some materials.
Incident occurred in the ABSL3 facility with procedure rooms for arboviruses:
Standard PPE worn: PAPR, TYVEC suit, double gloves, with procedure performed on bench.
Medical Surveillance and follow-up with Occupational Health Services (OHS) is occurring.
Training: Graduate student received 4 hours of training on this procedure from the PI, and he was working with a colleague who also received 4 hours of supervised training.
Note: PI, EH&S and Occupational Health services were not informed until December 24, 2020. I, David Smith, the institutional biosafety officer, told researcher to contact OHS and provide more information to me concerning exposure, more information did not arrive until today December 26, 2020.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | XYES ☐NO |
| **Please describe the root cause of this incident:** | Procedure using sharps(forceps) to remove legs and wings of infected mosquitos |

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 immediately followed-up with PI and researcher to further investigate the procedure, training and alternatives to sharps being used. PI agreed to look into using blunt forceps and/or puncture proof gloves. Also if sharp is still required it will be secured by placing in 50 ml conical tube containing 70% isopropanol when not being used. Further training needs to be given to researchers concerning the need to immediately contact OHS and EH&S when exposure incident occurs. We routinely provide such exposure reporting information to all BSL2, BSL3 labs. It is written in their Standard Operating Procedures.

This template for reporting is acceptable.

- **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**

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**you must report whether the use of this template is acceptable.**

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## Hunter, Renee (NIH/OD) [C]

**From:** Jelinek, Warren <Warren.Jelinek@nyulangone.org>
**Sent:** Sunday, December 27, 2020 12:33 AM
**To:** Smith, David (RED+F-Facility Mgt-EHS)
**Cc:** NIH guidelines; # biosafety; Figueroa, Marta; Paul, Jeremy; Mays, Natalie
**Subject:** Re: Incident exposure-Chikungunya virus
**Attachments:** Incident-Report Stapleford Lab 12_26_20.docx

David,

Sorry for the delay; I was away from my computer until now.

I added the applicable Section of the NIH Guidelines for the production of the virus, although the actual experiment was the use of the virus that was produced.

Warren Jelinek
Department of Biochemistry and Molecular Pharmacology
NYU School of Medicine
550 First Avenue
New York, NY 10016
warren.jelinek@nyulangone.org

> On Dec 26, 2020, at 7:09 PM, Smith, David (RED+F-Facility Mgt-EHS) <David.Smith3@nyulangone.org> wrote:
>
> Hello,
>
> Please see the attached report.
>
> Thank you,
>
> David E. Smith, Ph.D., ASP
> Institutional Biosafety Officer
> NYU Langone Health
>
> <Incident-Report Stapleford Lab 12_26_20.docx>

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the presence of viruses. The organization accepts no liability for any damage caused by any virus transmitted by this email.
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## Hunter, Renee (NIH/OD) [C]

**From:** Smith, David (RED+F-Facility Mgt-EHS) <David.Smith3@nyulangone.org>
**Sent:** Saturday, December 26, 2020 7:10 PM
**To:** NIH guidelines
**Cc:** # biosafety; Figueroa, Marta; Paul, Jeremy; Jelinek, Warren; Mays, Natalie
**Subject:** Incident exposure-Chikungunya virus
**Attachments:** Incident-Report Stapleford Lab 12_26_20.docx

Hello,

Please see the attached report.

Thank you,

David E. Smith, Ph.D., ASP
Institutional Biosafety Officer
NYU Langone Health

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## Hunter, Renee (NIH/OD) [C]

**From:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Monday, February 1, 2021 11:15 AM
**To:** Driskill, Colleen
**Cc:** Greenough, Thomas; Moran, Casey; Giaya, Kris; Pietila, Mike; Pustis, Daniel; Lebetkin, Kenneth; Fazio, Frank
**Subject:** RE: Question regarding reporting requirement

Dear Colleen:

Thank you for this update.

Regards,

Kathryn

---

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Sunday, January 31, 2021 11:48 AM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>; Giaya, Kris <Krisanthi.Giaya@umassmed.edu>; Pietila, Mike <Mike.Pietila@umassmed.edu>; Pustis, Daniel <Daniel.Pustis@umassmed.edu>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmemorial.org>; Fazio, Frank <Frank.Fazio@umassmed.edu>
**Subject:** RE: Question regarding reporting requirement

Hello Dr. Harris,

As per our discussion on Friday afternoon, it has been determined that the incident which occurred on 12/30/20 (described below) is not reportable due to the fact that the operation was not covered under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules. The entity at which this incident occurred, UMMS MassBiologics, had received vaccine product under a contract from an outside customer. The entity did not use the product for research at the site. The product was used in a filling line operation and the incident occurred after a vial filling. After filling by MBL, the vials containing vaccine product were to be returned to the customer.

Thanks,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Thursday, January 7, 2021 10:48 AM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] (HarrisKath@mail.nih.gov) <HarrisKath@mail.nih.gov>
**Cc:** Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>; Fazio, Frank <Frank.Fazio@umassmed.edu>; Schrader, Carol <Carol.Schrader@umassmed.edu>; Giaya, Kris <Krisanthi.Giaya@umassmed.edu>; Pustis, Daniel <Daniel.Pustis@umassmed.edu>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmed.edu>; Pietila, Mike <Mike.Pietila@umassmed.edu>
**Subject:** UMMS Notification of 123020 Release

Dear Dr. Harris and Whom it May Concern at the NIH Office of Science Policy,

On Friday 12/30/20, there was a minor, potentially biohazardous release at the MassBiologics, Fall River location of Massachusetts Medical School, (UMMS). Two workers were preparing to conduct a filter integrity test, after processing a drug substance through the filter. The vaccine product contained an HSV-2 mutated strain. It is attenuated by a specific mutation to a gene that codes for infected Cell Protein 0 (ICPO). Upon starting the Water For Injection (WFI) flush using a peristaltic pump, the tubing connecting the pump to the filter disconnected at the filter inlet. The pump was immediately shut off and the operators report approximately 10 ml of material sprayed on the work surface and floor. Some drops did contact one of the operators on his arm which he immediately washed.

This incident continues to be investigated. A complete report will be finalized and submitted to your office prior to or by 01/30/21.

Please feel free to contact me if you have any questions or concerns.

Best Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
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## Hunter, Renee (NIH/OD) [C]

**From:** Giaya, Kris <Krisanthi.Giaya@umassmed.edu>
**Sent:** Friday, January 29, 2021 11:48 AM
**To:** NIH guidelines; Harris, Kathryn (NIH/OD) [C]
**Cc:** Driskill, Colleen; Greenough, Thomas; Cooper, Sheldon; Moran, Casey
**Subject:** Question regarding reporting requirement

Hi Dr Harris,

After further investigating the incident covered in the notification below ( UMMS Notification of 123020 Release) we think that the incident it is not subject to the NIH Reporting Guidelines.

The following is our understanding:

*To construct the HSV2 ICPO deletion mutants, recombinant DNA techniques were used, and so the actual construction of the viral mutants would have been regulated by the NIH Guidelines*
*However, the UMMS PI acquired these mutants (i.e., did not construct them, or even further genetically manipulate them), so the use of the acquired existing mutant viruses by a UMMS entity (e.g., filling vials) would not be regulated by the NIH Guidelines, which is why we don't think that an exposure to the unregulated virus product would need to be reported to NIH.*

Please let me know if a final Incident Report is still required.

Thank you,

**Kris Giaya, MS**
Assistant Biosafety Officer, ARO
Environmental Health & Safety
University of Massachusetts Medical School
55 Lake Ave North
Worcester, MA 01655
Office: (508) 856-3298
Pager: Redacted by agreement

---

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Thursday, January 7, 2021 10:48 AM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] (HarrisKath@mail.nih.gov) <HarrisKath@mail.nih.gov>
**Cc:** Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>; Fazio, Frank <Frank.Fazio@umassmed.edu>; Schrader, Carol <Carol.Schrader@umassmed.edu>; Giaya, Kris <Krisanthi.Giaya@umassmed.edu>; Pustis, Daniel <Daniel.Pustis@umassmed.edu>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmed.edu>; Pietila, Mike <Mike.Pietila@umassmed.edu>
**Subject:** UMMS Notification of 123020 Release

Dear Dr. Harris and Whom it May Concern at the NIH Office of Science Policy,

Obtained via FOIA by Judicial Watch Inc.

On Friday 12/30/20, there was a minor, potentially biohazardous release at the MassBiologics, Fall River location of Massachusetts Medical School, (UMMS). Two workers were preparing to conduct a filter integrity test, after processing a drug substance through the filter. The vaccine product contained an HSV-2 mutated strain. It is attenuated by a specific mutation to a gene that codes for infected Cell Protein 0 (ICPO). Upon starting the Water For Injection (WFI) flush using a peristaltic pump, the tubing connecting the pump to the filter disconnected at the filter inlet. The pump was immediately shut off and the operators report approximately 10 ml of material sprayed on the work surface and floor. Some drops did contact one of the operators on his arm which he immediately washed.

This incident continues to be investigated. A complete report will be finalized and submitted to your office prior to or by 01/30/21.

Please feel free to contact me if you have any questions or concerns.

Best Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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## Hunter, Renee (NIH/OD) [C]

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Sunday, January 31, 2021 11:48 AM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Greenough, Thomas; Moran, Casey; Giaya, Kris; Pietila, Mike; Pustis, Daniel; Lebetkin, Kenneth; Fazio, Frank
**Subject:** RE: Question regarding reporting requirement

Hello Dr. Harris,

As per our discussion on Friday afternoon, it has been determined that the incident which occurred on 12/30/20 (described below) is not reportable due to the fact that the operation was not covered under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules. The entity at which this incident occurred, UMMS MassBiologics, had received vaccine product under a contract from an outside customer. The entity did not use the product for research at the site. The product was used in a filling line operation and the incident occurred after a vial filling. After filling by MBL, the vials containing vaccine product were to be returned to the customer.

Thanks,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
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**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Thursday, January 7, 2021 10:48 AM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] (HarrisKath@mail.nih.gov) <HarrisKath@mail.nih.gov>
**Cc:** Greenough, Thomas <Thomas.Greenough@umassmed.edu>; Moran, Casey <Casey.Moran@umassmed.edu>; Fazio, Frank <Frank.Fazio@umassmed.edu>; Schrader, Carol <Carol.Schrader@umassmed.edu>; Giaya, Kris <Krisanthi.Giaya@umassmed.edu>; Pustis, Daniel <Daniel.Pustis@umassmed.edu>; Lebetkin, Kenneth <Kenneth.Lebetkin@umassmed.edu>; Pietila, Mike <Mike.Pietila@umassmed.edu>
**Subject:** UMMS Notification of 123020 Release

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was immediately shut off and the operators report approximately 10 ml of material sprayed on the work surface and floor. Some drops did contact one of the operators on his arm which he immediately washed.

This incident continues to be investigated. A complete report will be finalized and submitted to your office prior to or by 01/30/21.

Please feel free to contact me if you have any questions or concerns.

Best Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
Office: (508) 856-5527 Cell: Redacted by agreement

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## Hunter, Renee (NIH/OD) [C]

**From:** Driskill, Colleen <Colleen.Driskill@umassmed.edu>
**Sent:** Thursday, January 7, 2021 10:48 AM
**To:** NIH guidelines; Harris, Kathryn (NIH/OD) [C]
**Cc:** Greenough, Thomas; Moran, Casey; Fazio, Frank; Schrader, Carol; Giaya, Kris; Pustis, Daniel; Lebetkin, Kenneth; Pietila, Mike
**Subject:** UMMS Notification of 123020 Release

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Please feel free to contact me if you have any questions or concerns.

Best Regards,

**Colleen Driskill, RBP, SM(NRCM), CBSP**
Senior Biosafety Officer, RO
Environmental Health & Safety Department
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655
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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, February 1, 2021 12:22 PM
**To:** Wallace,Ronald; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Section III-B-1 review request and Incident Report from UCONN Health

Dear Dr. Ron Wallace,

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:** Wallace,Ronald <rwallace@uchc.edu>
**Sent:** Friday, January 8, 2021 3:31 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Wallace,Ronald <rwallace@uchc.edu>
**Subject:** Section III-B-1 review request and Incident Report from UCONN Health

Dear Dr. Harris,

In this email please find a two-fold submission to NIH-OSP. The first is for NIH-OSP authorization for a Principal Investigator to use a plasmid containing a modified tetanus toxin light-chain sequence (attachment 1) believed to fall under Section III-B-1 of the NIH Guidelines. The PI has chosen experiment #89 in the Appendix F Toxin List (attachment 2) as the most like their experiment. The UCONN Health IBC supports BSL-1 for amplification of the plasmid in E. coli K-12 and microinjection into *C. elegans* because of the controls over expression of the sequence inherent in the plasmid. These are discussed in Appendix2 of the registration (attachment 3) .

Second, it will be noticed that this is an as-is reauthorization of this registration taking place nearly a year after it should have in 2019. The attached (#4) incident report covers this oversight by the IBC Coordinator that

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began shortly after the meeting this registration was first brought to the IBC in December 2017. When follow-up actions for the registration after the meeting review were missed, timely review of the toxin by NIH-OSP was also missed. In addition, the PI violated the NIH Guidelines by performing some of the experiments covered by the submitted, but unapproved registration. The PI has stated that the plasmid containing the toxin sequence has not been used since it was received (see email below).

Lastly, I wish to apologize that this submission is not within 30 days of the discovery of these issues. Redacted by agreement

Redacted by agreement

Sincerely,

Ron G. Wallace, PhD, CIH, RBP

Biological Safety Officer/ IBC Coordinator

Office of the Vice President for Research

UCONN Health

Environmental Health and Safety Office

263 Farmington Ave., MC1514

Farmington, CT 06032-1514

Ph: 860 679 3781 Fax: 860 679 3826

https://ovpr.uchc.edu

**From:** Wang,Zhao-Wen <zwwang@uchc.edu>
**Sent:** Friday, December 18, 2020 2:32 PM
**To:** Wallace,Ronald <rwallace@uchc.edu>
**Cc:** Wang,Kepeng <kewang@uchc.edu>; Wang,Zhao-Wen <zwwang@uchc.edu>
**Subject:** RE: IBC17-019 reauthorization

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Dear Ron,

Many thanks for your careful work. Here are my answers to your comments:

1. You have acquired the plasmid with the toxin, but you have not used or amplified it yet.

   Correct.

2. When you amplify the toxin, it will be in an E. coli K12 strain, like DH5alpha, TOP 10 or other derivative K12 strain.

   Correct.

3. Do you agree with my adaptation in Appendix 2 of the information you submitted in answer to my questions.

   I made some minor changes to it (see the Word file with tracked changes). These changes had been incorporated into the signed PDF.

4. Do you agree this (Appendix 3) is the most likely sequence for the toxin in the pWD199 plasmid you acquired.

   Yes.

5. See the updated list of toxin experiments

   #89 still appears to be the best match.

Please let me know if you have further questions. Happy holidays!

Zhao-Wen

**Zhao-Wen Wang, Ph.D.**
Professor
Department of Neuroscience
University of Connecticut Medical School
263 Farmington Avenue
Farmington, CT 06030-3401, USA
Phone: 860-679-7659
Fax: 860-679-8766
Email: zwwang@uchc.edu
Website: https://health.uconn.edu/worm-lab/

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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Wallace,Ronald <rwallace@uchc.edu>
**Sent:** Friday, January 8, 2021 3:31 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Wallace,Ronald
**Subject:** Section III-B-1 review request and Incident Report from UCONN Health
**Attachments:** UCONN Health Incident 202011.docx

Dear Dr. Harris,

In this email please find a two-fold submission to NIH-OSP. The first is for NIH-OSP authorization for a Principal Investigator to use a plasmid containing a modified tetanus toxin light-chain sequence (attachment 1) believed to fall under Section III-B-1 of the NIH Guidelines. The PI has chosen experiment #89 in the Appendix F Toxin List (attachment 2) as the most like their experiment. The UCONN Health IBC supports BSL-1 for amplification of the plasmid in E. coli K-12 and microinjection into *C. elegans* because of the controls over expression of the sequence inherent in the plasmid. These are discussed in Appendix2 of the registration (attachment 3) .

Second, it will be noticed that this is an as-is reauthorization of this registration taking place nearly a year after it should have in 2019. The attached (#4) incident report covers this oversight by the IBC Coordinator that began shortly after the meeting this registration was first brought to the IBC in December 2017. When follow-up actions for the registration after the meeting review were missed, timely review of the toxin by NIH-OSP was also missed. In addition, the PI violated the NIH Guidelines by performing some of the experiments covered by the submitted, but unapproved registration. The PI has stated that the plasmid containing the toxin sequence has not been used since it was received (see email below).

Lastly, I wish to apologize that this submission is not within 30 days of the discovery of these issues. Redacted by agreement

Redacted by agreement

Sincerely,

Ron G. Wallace, PhD, CIH, RBP

Biological Safety Officer/ IBC Coordinator

Obtained via FOIA by Judicial Watch Inc.

Office of the Vice President for Research

UCONN Health

Environmental Health and Safety Office

263 Farmington Ave., MC1514

Farmington, CT 06032-1514

Ph: 860 679 3781 Fax: 860 679 3826

https://ovpr.uchc.edu

---

**From:** Wang,Zhao-Wen <zwwang@uchc.edu>
**Sent:** Friday, December 18, 2020 2:32 PM
**To:** Wallace,Ronald <rwallace@uchc.edu>
**Cc:** Wang,Kepeng <kewang@uchc.edu>; Wang,Zhao-Wen <zwwang@uchc.edu>
**Subject:** RE: IBC17-019 reauthorization

Dear Ron,

Many thanks for your careful work. Here are my answers to your comments:

1. You have acquired the plasmid with the toxin, but you have not used or amplified it yet.

   Correct.

2. When you amplify the toxin, it will be in an E. coli K12 strain, like DH5alpha, TOP 10 or other derivative K12 strain.

   Correct.

3. Do you agree with my adaptation in Appendix 2 of the information you submitted in answer to my questions.

   I made some minor changes to it (see the Word file with tracked changes). These changes had been incorporated into the signed PDF.

4. Do you agree this (Appendix 3) is the most likely sequence for the toxin in the pWD199 plasmid you acquired.

   Yes.

5. See the updated list of toxin experiments

Obtained via FOIA by Judicial Watch Inc.

#89 still appears to be the best match.

Please let me know if you have further questions. Happy holidays!

Zhao-Wen

**Zhao-Wen Wang, Ph.D.**
Professor
Department of Neuroscience
University of Connecticut Medical School
263 Farmington Avenue
Farmington, CT 06030-3401, USA
Phone: 860-679-7659
Fax: 860-679-8766
Email: zwwang@uchc.edu
Website: https://health.uconn.edu/worm-lab/

https:ovpr.uchc.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*?** | ☒ YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | UCONN Health<br>(formerly University of Connecticut Health Center) |
| **Date of Report:** | January 7, 2020 |
| **Reporter name and position:** | Ron G. Wallace, PhD, CIH, RBP<br>Biological Safety Officer and IBC Coordinator |
| **Telephone number:** | (860) 679-3781 |
| **Email address:** | rwallace@uchc.edu |
| **Reporter mailing address:** | Ron G. Wallace, PhD, CIH, RBP<br>UCONN Health<br>Environmental Health and Safety<br>263 Farmington Ave. MC1514<br>Farmington, CT 06032-1514 |
| **Date of incident:** | December 12, 2017 through November 12, 2020 |
| **Name of Principal Investigator:** | Drs. Zhao-Wen Wang (1,2 below, contact for this registration) and Bojun Chen (3 below) |
| **Is this an NIH-funded project?** | ☒ YES ☐NO<br><br>If yes, please provide the following information (if known)<br>*NIH grant of contract number*: (1)5R01 MH085927; (2)R01 NS109388; (3) R01 GM113004<br>*NIH funding institute or center:* (1) NIMH; (2) NINDS; (3) NIGMS<br>*NIH program officer (name, email address):*<br>(1) Dr. Douglas S. Kim, douglas.kim@nih.gov ;<br>(2) Dr. Miriam Leenders, leenderm@ninds.nih.gov;<br>(3) Dr. Zhongzhen Nie, zhongzhen.nie@nih.gov |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☒ Failure to obtain IBC approval Failure of PI to wait for approval after submission of an IBC registration.<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☒ Other (please describe): Failure of the IBC Coordinator to complete processing (approval and reporting of a cloned toxin experiment to OSP) of a registration after review by the IBC. Cloned toxin experiment has not yet occurred. |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ☒ NO<br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☒ BL1 Proposed Level<br>☐ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-F-8; III-D-4; III-B-1 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe): Not applicable<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Plasmids, recombinant *E. coli* K12 and recombinant *C. elegans*. One plasmid containing tetanus toxin light-chain was proposed, but not used by the PI. This plasmid is now included for review under Section III-B-1 in the email to which this report is attached. |

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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)

Two violations of the NIH Guidelines have been discovered. The IBC Coordinator failed to notify the PI about and subsequently lost track of a submitted and reviewed registration (violation 1). The PI performed experiments covered by the registration without approval (violation 2). The registration covers introduction of recombinant nucleic acids into *C. elegans*. One proposed experiment involves a plasmid containing the sequence for a modified tetanus toxin light-chain. The PI states this experiment has not been performed to date, though other worm lines have been made.

During the December 2017 IBC meeting review there were unresolved questions about the plasmid containing the toxin sequence, which prevented immediate approval of the registration at the meeting. Without the toxin, the registration would have been approved.

Although the PI acquired the plasmid containing the tetanus toxin light-chain (see accompanying request for OSP toxin review under Section III-B-1) and reported it in the registration in 2017, they state it still has not been used (see email string that is part of the email attaching this report).

During the November 2020 IBC meeting review it was brought out that the nature of the toxin sequence to be used in the experiment was not clear and this as well as OSP toxin review under Section III-B-1 was requested by the IBC prior to approval.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒ YES ☐NO |
| **Please describe the root cause of this incident:** | Around 2017 at UCONN Health, the duties of a Biosafety Officer and IBC Coordinator were becoming too much for one person to perform well. In addition, no procedures to double check completeness of work thought to be completed were being performed at that 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 taken, please include a timeline for their implementation (use additional space as necessary):

The IBC will issue a letter to the PI informing them of their violation and the need for follow-up by the IBC before registered experiments are commenced. The IBC will see that the PI completes the upcoming round of IBC/DURC/Biosafety training for UCH PIs.

Systematic review of the IBC program output: A periodic review of the fates of registration numbers issued during the previous year will be instituted to determine if the outcomes for each number issued were appropriate. A retroactive review of registration numbers back to 2016 has taken place so far.

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A holistic electronic biological materials tracking program (BioRaft) has been purchased by the University of Connecticut which will be shared with UCONN Health. The IBC program will gradually move from Word documents distributed by email and tracked on a Filemaker database to the BioRaft system that we hope will keep the IBC better apprised of what is occurring in the laboratories in real(er) time. BioRaft will be implemented for training, materials monitoring and inspections at this point.

At the end of 2019, a search was concluded to hire an FTE in compliance whose duties are split between the IACUC and the IBC. They began the first work day of 2020 and have spent time mainly on BioRaft implementation, COVID-19 related respirator fit-tests (saving the BSO/IBC Coordinator from this duty), IBC administration and some IACUC administration.

- **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:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, February 17, 2021 12:11 PM
**To:** Kirchhoff, Louis; NIH guidelines
**Cc:** Mortensen, Nyree E; Sinn, Haley W; 'Adam'; Jones, Bradley; Haim, Hillel; 'Len'; Martino-Cardona, Maria C; Sheets, Jim T; Stapleton, Jack; Xiang, Jinhua; Huang, Chou-Long; Abel, Dale; Piper, Robert C; Lassner, Jennifer L; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: <<210106 Report of incident involving AAV-GFP>>

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:** Friday, January 29, 2021 6:13 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Mortensen, Nyree E <nyree-mortensen@uiowa.edu>; 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>; Kirchhoff, Louis <louis-kirchhoff@uiowa.edu>; Huang, Chou-Long <chou-long-huang@uiowa.edu>; Abel, Dale <dale-abel@uiowa.edu>; Piper, Robert C <robert-piper@uiowa.edu>; Lassner, Jennifer L <jennifer-lassner@uiowa.edu>
**Subject:** <<210106 Report of incident involving AAV-GFP>>

Please see the attached report of an incident involving AAV-GFP 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

Obtained via FOIA by Judicial Watch Inc.

University of Iowa
Iowa City, Iowa
☎ Office: 319-356-7227
☎ 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

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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*?** | xYES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Iowa |
| **Date of Report:** | |
| **Reporter name and position:** | Louis V. Kirchhoff, MD, MPH<br>Chair, Institutional Biosafety Committee |
| **Telephone number:** | 319-356-7227 |
| **Email address:** | louis-kirchhoff@uiowa.edu |
| **Reporter mailing address:** | UIHC SW54 GH<br>Department of Internal Medicine<br>200 Hawkins Dr<br>Iowa City, IA 52242 |
| **Date of incident:** | January 06, 2021 |
| **Name of Principal Investigator:** | Chou-Long Huang, MD, PhD |
| **Is this an NIH-funded project?** | ☐YES x NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br><br>If yes, date of approval: 05/03/2018 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-E-3 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Razor blade that had been used to section tissues from a mouse that was infected with replication-defective AAV expressing GFP |

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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 6, 2021, a researcher was using a cryostat to section frozen tissues from a mouse that had been infected with a replication-defective AAV vector expressing a GFP reporter. The cryostat became jammed and while attempting to clear the jam, the researcher's right middle finger came into contact with the blade and was cut.

The researcher was wearing gloves and a lab coat at the time of the incident.

Following the incident, the researcher cleaned the wound with soap and water and proceeded to the emergency room for medical treatment. The researcher received stiches for the wound, which healed without incident.

Prior to the incident, the researcher had been trained on the proper operation of the cryostat by the Central Microscopy Research Facility staff, as is standard for all personnel using the facility. The researcher had been trained to either remove the blade or cover the blade with the guard prior to cleaning but forgot to do so prior to attempting to clear the jam that had occurred.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | xYES ☐NO |
| **Please describe the root cause of this incident:** | Failure to follow proper safety protocols, which resulted in the researcher's finger being cut by a contaminated cryostat blade. |

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 the incident, the researcher's supervisor talked to him and reminded him of the safety protocol that dictates that the blade should be removed or covered with the guard before cleaning. The supervisor also discussed this requirement with other members of the lab.

The Biosafety Officer will also reach out to Central Microscopy Research Facility staff to ensure they are emphasizing sharps safety when providing training on the cryostat machines.

- **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:** Friday, January 29, 2021 6:13 PM
**To:** NIH guidelines
**Cc:** Mortensen, Nyree E; Sinn, Haley W; 'Adam'; Jones, Bradley; Haim, Hillel; 'Len'; Martino-Cardona, Maria C; Sheets, Jim T; Stapleton, Jack; Xiang, Jinhua; Kirchhoff, Louis; Huang, Chou-Long; Abel, Dale; Piper, Robert C; Lassner, Jennifer L
**Subject:** <<210106 Report of incident involving AAV-GFP>>
**Attachments:** 210106 Report of incident involving AAV-GFP.docx

Please see the attached report of an incident involving AAV-GFP 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

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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, January 8, 2021 11:07 AM
**To:** NIH guidelines
**Subject:** Potential exposure to recombinant DNA

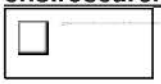
This is an immediate notification to report a potential exposure to recombinant AAV.

A researcher was potentially exposed to the recombinant virus from a contaminated cryostat razor blade . The researcher was using a cryostat to section tissues from a mouse that had been infected with AAV-GFP. When cleaning the bottom of the cryostat that was jammed with shavings, the researcher's right middle finger came into contact with blade and was cut.

We 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,

**Nyree Mortensen, PhD, RBP**
Biological Safety Officer/Select Agent RO, Environmental Health and Safety
122 Grand Avenue Court, Iowa City, Iowa 52242
Office: 319-353-5679
**ehs.research.uiowa.edu**



Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Monday, February 1, 2021 12:27 PM
**To:** Kathryn Obrien; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report for University of Southern California

Dear Dr. Kate O'Brien,

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:** Kathryn Obrien <kathryno@usc.edu>
**Sent:** Thursday, January 14, 2021 6:42 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident Report for University of Southern California

Hello,

Please, find attached an incident report involving a researcher that was bitten by a transgenic rat.

Please, let me know if you need anything else.

Thank you,
Kate

**Kate O'Brien, PhD, RBP (ABSA)**| Biosafety Officer & High Containment Officer
Environmental Health & Safety
kathryno@usc.edu
Desk: 323-442-2204
Cell: Redacted by agreement

USC University of Southern California

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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Southern California<br>Los Angeles, CA |
| **Date of Report:** | 1/14/2021 |
| **Reporter name and position:** | Kathryn O'Brien, PhD<br>Biosafety Officer and High Containment Officer |
| **Telephone number:** | Office: 323-442-2204<br>Cell: 617-640-0035 |
| **Email address:** | kathryno@usc.edu |
| **Reporter mailing address:** | 2001 South Soto Street, SBA #329<br>Los Angeles, CA |
| **Date of incident:** | December 27, 2020 |
| **Name of Principal Investigator:** | Alex Wong, MD |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☒ Personnel exposure – **Bitten by transgenic rat**<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ ☒ YES ☐ NO<br>If yes, date of approval: **7/18/2019** |
| **What was the approved biosafety level of the research?** | ☒ BL1<br>☐ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | **NIH Guidelines Section III:**<br>**Section III E-3**<br>**Section III F-8, Appendix C-VII, Appendix C-VIII** |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | **Transgenic Rat – Expressing Prox1-GFP (Prospero homeobox protein 1 fusion to Green Fluorescent Protein)**<br><br>**Modification considered endogenous and restricted to animals own lymphatic tissue.** |

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)

**The Post Doc began working in the lab summer/fall 2020. The Post Doc took animal training from the USC Department of Animal Resources for working with rats including online and hands-on modules in the summer and fall of 2020.**

**The incident took place on 12/27/2020. The Post Doc arrived to the lab at approximately 9:30am. The incident took place in laboratory space in CSA 222 at approximately 1:00pm. The rat in question was going to be euthanized due to the fact that it had an eye deformity that meant it could not be used for experiments or breeding. The Post Doc was being observed by a lab-mate. The Post Doc removed the animal from its cage and the animal turned and bit him on his left thumb. The bite went through his gloves and broke skin. Some bleeding did occur. The Post Doc washed the injured thumb for approximately 5 to 10 minutes and then scrubbed the area with chlorohexidine. The Post Doc was wearing a lab coat and gloves. The Post Doc was working on an open bench.**

**The Post Doc contacted the Department of Public Safety (DPS) as per university policy to report the injury. An officer from DPS was dispatched to the lab location to interview the Post Doc. The Post Doc also contacted the lab manager who told him to seek medical attention. DPS in the meantime contacted the on call EH&S person. This person conversed with the Post Doc via cell phone and mentioned he should seek medical attention, but the Post Doc was reluctant to do so.**

**The on-call EH&S person contact the Biosafety Officer to discuss the situation. The EH&S on-call person then spoke with the Post Doc once again and suggested that he should call the on-call student health nurse line at least to discuss the incident with a health care professional. The Post Doc did phone the on-call nurse.**

**Department Of Animal Resources Trainings Completed:**

- **8th Edition Guide for the Care and Use of Laboratory Animals: online module 6/9/2020**
- **Introduction to Animal Care Laws: online module 6/9/2020**
- **A2- Aseptic Techniques for Rodent Survival Surgery: online module 6/9/2020**
- **Common Compliance Issues: online module 6/9/2020**
- **B2- Rat: online module 6/9/2020**
- **Level 1-Basic Animal Care and Use Training: Hands-on 10/19/2020**

**Environmental Health and Safety Trainings Completed:**

- **General Lab Safety: online zoom training 5/12/2020**
- **Principles of Biosafety: online zoom training 5/15/2020**
- **Bloodborne Pathogens: online zoom training 7/10/2020**

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | Post Doc's inexperience working with rats |

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):

Post Doc is to remain under the supervision of more experienced personnel until he is adequately skilled at handling rats.

- **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:** Kathryn Obrien <kathryno@usc.edu>
**Sent:** Thursday, January 14, 2021 6:42 PM
**To:** NIH guidelines
**Subject:** Incident Report for University of Southern California
**Attachments:** Incident-Reporting USC_Kathryn OBrien reporter 14jan21.pdf

Hello,

Please, find attached an incident report involving a researcher that was bitten by a transgenic rat.

Please, let me know if you need anything else.

Thank you,
Kate

**Kate O'Brien, PhD, RBP (ABSA)**| Biosafety Officer & High Containment Officer
Environmental Health & Safety
kathryno@usc.edu
Desk: 323-442-2204
Cell: Redacted by agreement

USC University of Southern California

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, February 17, 2021 12:18 PM
**To:** Craigen, Amanda Doris; NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.; Coulson, Garry Brian; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: NIH Incident Report- Final

Dear Amanda Craigen,

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 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

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**From:** Craigen, Amanda Doris <craigena@email.unc.edu>
**Sent:** Thursday, January 28, 2021 9:24 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
**Subject:** NIH Incident Report- Final

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting incidents subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed two completed incident reports involving potential exposure to 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.

**Amanda Craigen**
Associate Biosafety Officer
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5726

Obtained via FOIA by Judicial Watch Inc.

Email: craigena@email.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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of North Carolina at Chapel Hill |
| **Date of Report:** | 1/27/2021 |
| **Reporter name and position:** | Amanda Craigen, Associate Biosafety Officer |
| **Telephone number:** | 919.962.5726 |
| **Email address:** | craigena@email.unc.edu |
| **Reporter mailing address:** | Environment, Health and Safety<br>1120 Estes drive<br>Campus Box 1650<br>Chapel Hill, NC 27599 |
| **Date of incident:** | 01/23/2021 |
| **Name of Principal Investigator:** | Dr. Scott Magness |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:* R01DK115806<br>*NIH funding institute or center:* NIDDK<br>*NIH program officer (name, email address):* Patricia Greenwel (patricia.greenwel@nih.gov) |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐YES ☒NO<br><br>The PI believed that the cell lines were exempt from the *NIH Guidelines* and, therefore, exempt from registration with the IBC. Following the incident, it was made clear to the PI that experiments that may be exempt from the NIH Guidelines are still required to be registered with the IBC at UNC and that use of potential exempt cell lines (under Section III-F) in animals would no longer be exempt (Section III-D). The PI has already submitted required protocols to the IBC for review and approval. |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation,** | Human intestinal epithelial cells with deletion of *sox9* gene engineered to conditionally express *sox9* using PiggyBac transposon. |

Obtained via FOIA by Judicial Watch Inc.

## Description of the incident:

At approximately 11:15am on Saturday, January 23, 2021 the Researcher was completing an experiment in a biological safety cabinet (BSC) in the BSL-2 lab when the incident occurred. At the time of the incident, the Researcher was only wearing disposable gloves and a surgical mask for personal protective equipment (PPE), and not the prescribed PPE for the space, which required the use of a lab coat, safety glasses, a face mask and nitrile gloves. The Researcher has significant experience working in laboratory environments, with approximately two-years direct experience on this specific procedure. The Researcher is compliant with all applicable EHS trainings.

The Researcher was using a syringe to disassociate cellular monolayers of primary human intestinal epithelial cells containing a deletion of the *sox9* gene (achieve using CRISPR/Cas9) and engineered to conditionally overexpress the *sox9* gene by transformation with a PiggyBac transposon. After dissociating the monolayers, the Researcher temporarily placed the used syringe down on the BSC surface to start working on a subsequent monolayer culture. The Researcher accidentally bumped the used syringe with a pipet resulting in in the syringe flipping up and sticking the back side of the right hand at the 5$^{th}$ metacarpal.

Immediately after the incident, the Researcher removed their gloves and washed their hands with soap and water before finishing the experiment.

After completing their experiments, the Researcher then called the University Employee Occupational Health Clinic (UEOHC) to report the incident.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The IBC is aware of this incident and will review it at the next IBC meeting on 2/3/2021. |
| **Please describe the root cause of this incident:** | The root cause of the incident appears to be related to poor sharps safety and improper disposal of used syringes. |

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, and discuss the importance of appropriate sharps handling and safety. The PI must review "Preventing Cuts and Punctures" (https://ehs.unc.edu/files/2015/09/cuts_punctures.pdf) with their lab, which stresses that uncapped needles should never be stored on bench tops and should always be disposed of in appropriate sharps containers.

The PI will also be instructed to discuss with their lab the requirement for all personnel to always wear the prescribed PPE while in the lab. The PI must review the "Laboratory Personal Protective Equipment (PPE) PDF (https://ehs.unc.edu/wp-content/uploads/sites/229/2020/11/ppe-fact-sheet.pdf) with their lab which describes the minimum PPE requirements for working in a biological lab.

Additionally, the PI will also be instructed to discuss with their lab the requirement for immediately reporting all incidents and accidents in the laboratory to the University Employee Occupational Health Clinic (UEOHC). Personnel should not delay reporting to the UEOHC in order to complete their experiments.

Lastly, the PI will be asked to review 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 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..

The expected date of completion for recommendations will be 2/5/2021.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Craigen, Amanda Doris <craigena@email.unc.edu>
**Sent:** Thursday, January 28, 2021 9:24 AM
**To:** NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.; Coulson, Garry Brian
**Subject:** NIH Incident Report- Final
**Attachments:** NIH Incident Report_01272021.pdf; NIH Incident Report_01282021.pdf

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting incidents subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed two completed incident reports involving potential exposure to 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.

**Amanda Craigen**
Associate Biosafety Officer
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5726
Email: craigena@email.unc.edu

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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, January 25, 2021 4:10 PM
**To:** NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.
**Subject:** NIH Incident Report - Preliminary Notice

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

We wanted to notify you of a potential exposure to recombinant DNA at BSL-2 involving a needlestick with primary human intestinal cells engineered by PiggyBac to overexpress the Sox9 gene.

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:** Institutional Biosafety Committee <ibc@uci.edu>
**Sent:** Wednesday, March 3, 2021 11:56 AM
**To:** Harris, Kathryn (NIH/OD) [C]; Institutional Biosafety Committee
**Cc:** Anju Subba
**Subject:** RE: Currently Investigating Possible Reportable Incident at UC Irvine

Dear Dr. Harris,

Apologies for not confirming earlier. It was determined that the incident was NOT NIH reportable as the mouse involved was neither transgenic nor any experiments had been done on the C57BL/6 mouse. The male mouse was used to harvest sperm.

Best regards,

**Anju Subba, MS, MS EMAP**
Campus Biosafety Officer, Responsible Official, Institutional Contact for DURC
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




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**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Wednesday, March 3, 2021 7:12 AM
**To:** Institutional Biosafety Committee <ibc@uci.edu>
**Subject:** RE: Currently Investigating Possible Reportable Incident at UC Irvine

Dear Alice:

I am just following up on this incident notification in the event I missed something coming in? Has there been a determination regarding whether the incident was reportable under the *NIH Guidelines*?

Regards,

Dr. Kathryn Harris

---

**From:** Institutional Biosafety Committee <ibc@uci.edu>
**Sent:** Thursday, January 28, 2021 7:54 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Anju Subba <asubba@uci.edu>
**Subject:** Currently Investigating Possible Reportable Incident at UC Irvine

Obtained via FOIA by Judicial Watch Inc.

Dear NIH OSP,

There may have been a potential transgenic mouse bite. We are investigating the incident and will file a report if it falls under NIH guidelines.

Thank you,
Alice Lee

**Alice Lee**
Institutional Biosafety Committee (IBC) Administrator
Environmental Health & Safety and Risk Services
Office: (949) 82**4-8024**, Fax: (949) 824-1325
alicecl@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:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Wednesday, March 3, 2021 10:12 AM
**To:** Institutional Biosafety Committee
**Subject:** RE: Currently Investigating Possible Reportable Incident at UC Irvine

Dear Alice:

I am just following up on this incident notification in the event I missed something coming in? Has there been a determination regarding whether the incident was reportable under the *NIH Guidelines*?

Regards,

Dr. Kathryn Harris

---

**From:** Institutional Biosafety Committee <ibc@uci.edu>
**Sent:** Thursday, January 28, 2021 7:54 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Anju Subba <asubba@uci.edu>
**Subject:** Currently Investigating Possible Reportable Incident at UC Irvine

Dear NIH OSP,

There may have been a potential transgenic mouse bite. We are investigating the incident and will file a report if it falls under NIH guidelines.

Thank you,
Alice Lee

**Alice Lee**
Institutional Biosafety Committee (IBC) Administrator
Environmental Health & Safety and Risk Services
Office: (949) 824-8024, Fax: (949) 824-1325
alicecl@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:** Institutional Biosafety Committee <ibc@uci.edu>
**Sent:** Thursday, January 28, 2021 7:54 PM
**To:** NIH guidelines
**Cc:** Anju Subba
**Subject:** Currently Investigating Possible Reportable Incident at UC Irvine

Dear NIH OSP,

There may have been a potential transgenic mouse bite. We are investigating the incident and will file a report if it falls under NIH guidelines.

Thank you,
Alice Lee

**Alice Lee**
Institutional Biosafety Committee (IBC) Administrator
Environmental Health & Safety and Risk Services
Office: (949) 824-8024, Fax: (949) 824-1325
alicecl@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:** Wednesday, February 17, 2021 12:18 PM
**To:** Craigen, Amanda Doris; NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.; Coulson, Garry Brian; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: NIH Incident Report- Final

Dear Amanda Craigen,

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 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Craigen, Amanda Doris <craigena@email.unc.edu>
**Sent:** Thursday, January 28, 2021 9:24 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
**Subject:** NIH Incident Report- Final

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting incidents subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed two completed incident reports involving potential exposure to 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.

**Amanda Craigen**
Associate Biosafety Officer
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5726

Obtained via FOIA by Judicial Watch Inc.

Email: craigena@email.unc.edu

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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:** Thursday, January 28, 2021 9:59 AM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Craigen, Amanda Doris
**Subject:** RE: NIH Incident Report- Final

HI Kathryn,

Correct - the incident report dated 01282021 is the follow-up to the initial preliminary report on 1/25.

As you know, we take reporting of incidents here at UNC to the NIH OSP very seriously and always submit preliminary initial reports immediately. The second report (dated 1/12) did not have an initial report since our initial internal investigation of the incident suggested the cells involved were unmodified mouse cells, and not recombinantly-modified cells. Therefore, we did not immediately submit a preliminary report as we always do. Only as we were wrapping up the final details of our internal incident report did the involvement of recombinant DNA become known, leading to the unfortunate delay in reporting.

(Please note Redacted by agreement Amanda, our current ABSO, will temporarily be taking over the NIH reporting responsibilities until the vacant BSO position is filled).

Kind regards,
Garry

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, January 28, 2021 9:41 AM
**To:** Craigen, Amanda Doris <craigena@email.unc.edu>
**Cc:** Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
**Subject:** RE: NIH Incident Report- Final

Hi Amanda:

I just wanted to verify, I believe one of these is the follow up to an incident initially reported on 1/25 (see attached email). The other one (which occurred on 1/12) I have no record of an initial report. Please let me know if you did previously notify us in the event I missed an email.

Regards,

Dr. Kathryn Harris

---

**From:** Craigen, Amanda Doris <craigena@email.unc.edu>
**Sent:** Thursday, January 28, 2021 9:24 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Brennan, Catherine <crbrennan@ehs.unc.edu>; Cyr, Douglas M. <douglas_cyr@med.unc.edu>; Coulson, Garry Brian <garry.coulson@ehs.unc.edu>
**Subject:** NIH Incident Report- Final

Dear NIH Office of Science Policy (OSP),

Obtained via FOIA by Judicial Watch Inc.

In fulfillment of our requirement for reporting incidents subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed two completed incident reports involving potential exposure to 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.

**Amanda Craigen**
Associate Biosafety Officer
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5726
Email: craigena@email.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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of North Carolina at Chapel Hill |
| **Date of Report:** | 1/26/2021 |
| **Reporter name and position:** | Amanda Craigen, Associate Biosafety Officer |
| **Telephone number:** | 919.962.5726 |
| **Email address:** | craigena@email.unc.edu |
| **Reporter mailing address:** | Environment, Health and Safety<br>1120 Estes drive<br>Campus Box 1650<br>Chapel Hill, NC 27599 |
| **Date of incident:** | 01/12/2021 |
| **Name of Principal Investigator:** | Dr. Matthew Flick |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:* R01CA211098<br>*NIH funding institute or center:* NCI<br>*NIH program officer (name, email address):* Grace Ault (ga5k@nih.gov) |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☒NO<br><br>Date(s) of IBC approval: 4/24/2019 and 5/2/2019. |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Murine pancreatic tumor cells engineered to express Cas9 and puromycin through plasmid transfection. |

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## Description of the incident:

At approximately 2:00pm on Tuesday, January 12, 2021 a Researcher was performing orthotopic surgery on a mouse within a biosafety cabinet (BSC) when the incident occurred. The Researcher was wearing the following personal protective equipment (PPE): disposable gloves, lab coat, surgical mask and gown. The Researcher was highly trained and experienced performing this procedure and was compliant with all required EHS trainings.

While performing the orthotopic surgery, the Researcher prepared to implant murine pancreatic tumor cells into a mouse under isoflurane sedation. The tumor cells, derived from a mouse line containing $KRas^{G12D}$ and $Tp53^{R17H}$ mutations, had been engineered to expressed Cas9 and the puromycin selectable marker. After injecting the cells, the Researcher placed the syringe on the BSC surface to grab a cotton swab. While moving their hand to retrieve the cotton swab, their hand passed over the syringe and the needle on the syringe stuck their right thumb.

Following the incident, the Researcher immediately took off their gloves and squeezed the wound to allow it to bleed. The Researcher then washed the wound with soap and water for several minutes and immediately reported the incident to their Supervisor. The Researcher did not go to the University Employee Occupational Health Clinic (UEOHC) to be evaluated, believing the injury to be minor, however, they did submit an Employee Incident Report form to the UEOHC.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The IBC is aware of this incident and will review it at the next IBC meeting on 2/3/2021. |
| **Please describe the root cause of this incident:** | The root cause of the incident appears to be related to poor sharps safety and improper disposal of used syringes. |

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**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, and discuss the importance of appropriate sharps handling and safety. The PI must review "Preventing Cuts and Punctures" (https://ehs.unc.edu/files/2015/09/cuts_punctures.pdf) with their lab, which stresses that uncapped needles should never be stored on bench tops and should always be disposed of in appropriate sharps containers.

The PI will also be instructed to discuss with their lab the requirement for reporting all incidents and accidents in the laboratory to the University Employee Occupational Health Clinic (UEOHC), including the need to either i) directly call the UEOHC for evaluation and determination on whether an in-person evaluation is indicated, or ii) physically reporting to the UEOHC for medical evaluation by the clinical staff at UEOHC.

The expected date of completion for recommendations will be 2/5/2021.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Craigen, Amanda Doris <craigena@email.unc.edu>
**Sent:** Thursday, January 28, 2021 9:24 AM
**To:** NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.; Coulson, Garry Brian
**Subject:** NIH Incident Report- Final
**Attachments:** NIH Incident Report_01272021.pdf; NIH Incident Report_01282021.pdf

Dear NIH Office of Science Policy (OSP),

In fulfillment of our requirement for reporting incidents subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the OSP, please find enclosed two completed incident reports involving potential exposure to 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.

**Amanda Craigen**
Associate Biosafety Officer
Environment, Health and Safety | University of North Carolina at Chapel Hill
Chapel Hill, NC 27599
Phone | 919 962-5726
Email: craigena@email.unc.edu

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:31 PM
**To:** kumara1@mskcc.org; NIH guidelines
**Cc:** glickmam@MSKCC.ORG; cottinge@mskcc.org; schalled@mskcc.org; GibsonJ2@mskcc.org; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Full report- MSK rDNA exposure

Dear Dr. Asmita Kumar,

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:** kumara1@mskcc.org <kumara1@mskcc.org>
**Sent:** Tuesday, March 9, 2021 12:29 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** glickmam@MSKCC.ORG; cottinge@mskcc.org; schalled@mskcc.org; GibsonJ2@mskcc.org
**Subject:** Full report- MSK rDNA exposure

Good Afternoon,

Please find attached report on behalf of the IBC Chairman, Dr. Michael Glickman. This exposure was originally reported to the OSP on 2/8/21 as a pre-report.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

**Memorial Sloan Kettering Cancer Center**
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10017
C Redacted by agreement
kumara1@mskcc.org

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Memorial Sloan Kettering Cancer Center

March 9, 2021

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: rDNA exposure at Memorial Sloan Kettering Cancer Center

In accordance with the NIH guidelines, this report is a follow up of an initial incident report submitted to the NIH Office of Science Policy via email to NIHGuidelines@od.nih.gov on 2/9/2021.

A graduate student sustained a sharps injury involving recombinant nucleic acids while working as approved personnel under an approved IBC Registration. The student was handling a glass capillary needle loaded with plasmid with zebrafish DNA, sgRNAs against two zebrafish genes, recombinant Cas9 protein, and mRNA for the transposase tol2. While removing the glass capillary needle form the injector, the student's other hand accidently brushed up against the capillary needle and the tip of the needle broke off and pushed through the glove and got stuck in her left finger. She removed her glove and was able to pull out the glass easily. There was some bleeding and she washed her hand with soap and water for about 10 minutes. She contacted Employee Health and Wellness and was advised to monitor the skin for signs of infection and go in for an in-person evaluaton for further problems. There was a minor mark which was no longer visible by the next day.

The student was wearing the required PPE: gloves and gown, required for entry into the aquatics facility. She had completed the required training for handling zebrafish and procedure specific training by senior members of her laboratory. Our Biosafety Officer has counseled the employee on the safe use of sharps (completed 2/16/2021). The details of this incident were discussed at the IBC meeting on February 23, 2021. The IBC agreed that the retraining was appropriate and adequate.

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We believe that retraining will help reduce the recurrence of such issues. 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 email at: glickmam@mskcc.org.

Sincerely,

Redacted by agreement

Michael Glickman, MD
IBC Chairperson

Cc: Eric Cottington, PhD, 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

February 9, 2021

**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 potential exposure to guide RNAs targeting zebrafish sequences at our institution yesterday. We are gathering the necessary information for a full report, which will follow.

Our Evironmental Health and Safety department and the IBC are reviewing the incident and the laboratory worker has received appropriate medical attention.

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 646.888.1077 F 646.888.1120
www.mskcc.org

NCI-designated Comprehensive Cancer Center

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## Hunter, Renee (NIH/OD) [C]

**From:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Sent:** Thursday, March 11, 2021 11:36 AM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Glickman, Michael/Sloan Kettering Institute; Cottington, Eric M./Research and Technology Mgmt; Schaller-Demers, Debra S./Research and Technology Mgmt; Gibson, James H./Facilities Management
**Subject:** RE: Full report- MSK rDNA exposure

Good Morning Kathryn,
Hope you are doing well and staying healthy. This incident happened in a BSL-1 facility.
Please let me know if you have any additional questions.
Regards,
Asmita

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Wednesday, March 10, 2021 2:08 PM
**To:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Cc:** Glickman, Michael/Sloan Kettering Institute <glickmam@MSKCC.ORG>; Cottington, Eric M./Research and Technology Mgmt <cottinge@mskcc.org>; Schaller-Demers, Debra S./Research and Technology Mgmt <schalled@mskcc.org>; Gibson, James H./Facilities Management <GibsonJ2@mskcc.org>
**Subject:** [EXTERNAL] RE: Full report- MSK rDNA exposure

Hi Asmita:

Can you please confirm the Biosafety Level the incident occurred at?

Thanks,

Kathryn

---

**From:** kumara1@mskcc.org <kumara1@mskcc.org>
**Sent:** Tuesday, March 9, 2021 12:29 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** glickmam@MSKCC.ORG; cottinge@mskcc.org; schalled@mskcc.org; GibsonJ2@mskcc.org
**Subject:** Full report- MSK rDNA exposure

Good Afternoon,

Please find attached report on behalf of the IBC Chairman, Dr. Michael Glickman. This exposure was originally reported to the OSP on 2/8/21 as a pre-report.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

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kumara1@mskcc.org

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## Hunter, Renee (NIH/OD) [C]

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**To:** kumara1@mskcc.org
**Cc:** glickmam@MSKCC.ORG; cottinge@mskcc.org; schalled@mskcc.org; GibsonJ2@mskcc.org
**Subject:** RE: Full report- MSK rDNA exposure

Hi Asmita:

Can you please confirm the Biosafety Level the incident occurred at?

Thanks,

Kathryn

---

**From:** kumara1@mskcc.org <kumara1@mskcc.org>
**Sent:** Tuesday, March 9, 2021 12:29 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** glickmam@MSKCC.ORG; cottinge@mskcc.org; schalled@mskcc.org; GibsonJ2@mskcc.org
**Subject:** Full report- MSK rDNA exposure

Good Afternoon,

Please find attached report on behalf of the IBC Chairman, Dr. Michael Glickman. This exposure was originally reported to the OSP on 2/8/21 as a pre-report.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

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**To:** NIH guidelines
**Cc:** glickmam@MSKCC.ORG; cottinge@mskcc.org; schalled@mskcc.org; GibsonJ2@mskcc.org
**Subject:** Full report- MSK rDNA exposure
**Attachments:** rDNA Exposure report 2-08-2021.pdf

Good Afternoon,

Please find attached report on behalf of the IBC Chairman, Dr. Michael Glickman. This exposure was originally reported to the OSP on 2/8/21 as a pre-report.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

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## Hunter, Renee (NIH/OD) [C]

**From:** kumara1@mskcc.org
**Sent:** Tuesday, February 9, 2021 5:00 PM
**To:** NIH guidelines
**Cc:** glickmam@MSKCC.ORG; schalled@mskcc.org; cottinge@mskcc.org; GibsonJ2@mskcc.org
**Subject:** Preliminary Report- potential exposure
**Attachments:** MSKCC Exposure 2-8-2021.pdf

Good Afternoon,

Please see attached preliminary report on behalf of the IBC Chairman, Dr. Michael Glickman.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

**Memorial Sloan Kettering Cancer Center**
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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:47 PM
**To:** ANDREA N LADD; NIH guidelines
**Cc:** Kristen Bernard; STEPHANIE G KUTZ; CARRIE A ENSRUD; 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:** Friday, March 5, 2021 4:31 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>; CARRIE A ENSRUD <carrie.ensrud@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 potential exposure initially reported on 02/09/21 (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
- Carrie Ensrud, Animal Research Safety Manager
- 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:** Tuesday, February 9, 2021 3:48 PM
**To:** harriskath@mail.nih.gov; NIHGuidelines@od.nih.gov
**Cc:** Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; CARRIE A ENSRUD <carrie.ensrud@wisc.edu>
**Subject:** initial notification of incident

Kathryn or Whom It May Concern,

We were notified today of a potential exposure to a recombinant microbe from an animal bite in one of our ABSL2 laboratories. The employee received medical care.

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
- Carrie Ensrud, Animal Research Safety Manager

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

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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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## 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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Wisconsin-Madison |
| **Date of Report:** | 02/09/21 (initial email to OSP)<br>03/05/21 (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<br>30 East Campus Mall<br>Madison, WI 53715 |
| **Date of incident:** | 02/09/21 |
| **Name of Principal Investigator:** | David Evans |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 02/22/19 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☐BL2 ☐BL2+ ☒ABSL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-1-a, III-D-1-b |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA<br><br>Not applicable |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Recombinant SHIV (SIV engineered to have envelope of HIV), strain SHIV-AD8 EO |

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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.**

**Location:** barrier primate facility

**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:** bonnet, surgical mask, face shield, 2 pairs of nitrile gloves, shoe covers, and tyvek jumpsuit

**Event description:** An employee was placing a biscuit in the feeder box on the side of a macaque's cage. The employee did not reach into the cage, but the animal reached out of the cage and grabbed the employee's hand. As the employee pulled the hand away, the monkey bit the tip of one finger.

It may be noted that although the macaque involved in this incident had previously been infected with SHIV, viral loads of SHIV were below the limit of detection in plasma from this animal at the last two time points measured (26 and 28 weeks post-infection). The animal had also tested negative for Herpes B virus when last tested on 7/24/19. It is the SOP of this facility to treat all bites or scratches as exposures that could transmit infection.

**Immediate follow-up and medical follow-up:** The employee immediately stopped work, removed their gloves, and performed a 15 minute flush and scrub of the site with chlorhexidine. The employee notified the Primate Center's Safety Officer and went to University Health Services/Occupational Medicine for medical follow up. A report was submitted to the Office of Biological Safety, and the Biological Safety Officer reported the incident to NIH-OSP.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br>The IBC Chair was aware of the event upon initial report to OSP. The IBC was apprised of the incident at the next IBC meeting on March 3, 2021. |
| **Please describe the root cause of this incident:** | Root cause was the nature of the animal. Although this monkey is not known to be aggressive, there were recent changes in the housing room (e.g., animals moved in and out) that may have caused it to become stressed. |

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| | |
|---|---|
| | Inattention on the part of the employee (i.e., not noticing the animal had moved to that side of the cage) may have been a contributing factor. |

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 Safety Officer for the animal facility to discuss the incident and review the emergency follow-up.

The employee and supervisor followed the established emergency procedures as outlined in the IBC-approved biosafety protocol and facility SOPs. The Safety Officer discussed the incident with the employee. They reviewed the SOP for feeding macaques, and how stress can affect animal behavior. The importance of paying attention to the position of the animals at all times was emphasized.

- **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:** Friday, March 5, 2021 4:31 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Kristen Bernard; STEPHANIE G KUTZ; CARRIE A ENSRUD; Christopher Strang
**Subject:** Incident report attached
**Attachments:** Evans_020921_OSP Reportable.docx

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the potential exposure initially reported on 02/09/21 (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
- Carrie Ensrud, Animal Research Safety Manager
- 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
**Sent:** Tuesday, February 9, 2021 3:48 PM
**To:** harriskath@mail.nih.gov; NIHGuidelines@od.nih.gov
**Cc:** Kristen Bernard <kristen.bernard@wisc.edu>; STEPHANIE G KUTZ <stephanie.kutz@wisc.edu>; CARRIE A ENSRUD <carrie.ensrud@wisc.edu>
**Subject:** initial notification of incident

Kathryn or Whom It May Concern,

We were notified today of a potential exposure to a recombinant microbe from an animal bite in one of our ABSL2 laboratories. The employee received medical care.

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.

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Individuals included on this email:

- Kristen Bernard, Chair of IBC
- Stephanie Kutz, Assistant Biological Safety Officer
- Carrie Ensrud, Animal Research Safety Manager

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

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** ANDREA N LADD <andrea.ladd@wisc.edu>
**Sent:** Tuesday, February 9, 2021 4:48 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Kristen Bernard; STEPHANIE G KUTZ; CARRIE A ENSRUD
**Subject:** initial notification of incident

Kathryn or Whom It May Concern,

We were notified today of a potential exposure to a recombinant microbe from an animal bite in one of our ABSL2 laboratories. The employee received medical care.

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
- Carrie Ensrud, Animal Research Safety Manager

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

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 2, 2021 10:24 AM
**To:** Sherie L Donahue; NIH guidelines
**Cc:** Tran Phan; Ian Naftzger; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Noncompliance reports from UCR

Dear Sherie Donahue,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

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**From:** Sherie L Donahue <sherie.donahue@ucr.edu>
**Sent:** Friday, February 12, 2021 1:39 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Tran Phan <tran.phan@ucr.edu>; Ian Naftzger <ian.naftzger@ucr.edu>
**Subject:** Noncompliance reports from UCR

Dear Sir or Madam,

Attached are two noncompliance reports from UCR. In both cases, the noncompliance was a lapse in approval caused by failure to update training in a timely manner.

Please let me know if you need addition information.

Sincerely,

Sherie

*Sherie Donahue*
**Research Integrity Analyst – IBC/IACUC**
**Office of Research Integrity**
**University of California, Riverside**
**900 University Avenue**
**University Office Building, Suite 216 | Riverside, CA 92521**

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**951.827.4814 |** sherie.donahue@ucr.edu
**ORI Resources:** https://research.ucr.edu/ori/resources
**COVID-19 information for Researchers** https://keepresearching.ucr.edu and https://ehs.ucr.edu/coronavirus

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, Riverside |
| **Date of Report:** | February 12, 2021 |
| **Reporter name and position:** | Sherie Donahue<br>Research Integrity Analyst |
| **Telephone number:** | 951-827-4814 |
| **Email address:** | Sherie.donahue@ucr.edu |
| **Reporter mailing address:** | 900 University Ave.<br>University Office Building, Suite 216<br>Riverside, CA 92521 |
| **Date of incident:** | December 10, 2020 |
| **Name of Principal Investigator:** | Isgouhi Kaloshian |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other (please describe): Lapse in IBC approval |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: December 17, 2020 |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | NIH Guidelines III-E-2-a |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☒FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | CRISPR/CAS-9 or viral or bacterial vectors will be used to study the genes that regulate immunity against pests and pathogens. Silencing constructs are also used. |

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:

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- 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)**

The University of California, Riverside (UCR), in accordance with the NIH Guidelines for The University of California, Riverside (UCR), in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), provides this report of noncompliance regarding the failure to obtain approval for BSL1 research activities (experiments involving the CRISPR/CAS-9 or viral or bacterial vectors to study the genes that regulate immunity against pests and pathogens in tomato, Arabidopsis, cowpea or N. benthamiana) in the protocol entitled, "*Interactions of plants with aphids and nematodes*."

The investigator originally submitted the renewal BUA protocol to the IBC on August 25, 2020 and it was reviewed at a convened meeting of the IBC on September 24, 2020. The committee voted to approve the protocol upon confirmation that the training was completed. The approval process at UCR requires that all training be up to date before the BUA can be approved by the IBC. The protocol expired on October 25, 2020.

The non-compliance was discovered when reviewing the IBC records for the final committee meeting of the year. All required training was completed by December 17, 2020 and the renewal BUA was approved on December 17, 2020.

The noncompliance was reviewed at a convened meeting of the IBC on January 28, 2021.

| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
|---|---|
| | Due to the pandemic, all research was shut down on |

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| **Please describe the root cause of this incident:** | campus. Research was allowed to restart on a case-by-case basis once specific criteria had been met, however that was a separate process from the IBC approval. The PI was reminded of the lab training several times with the expectation that the training would be completed before the current protocol expired.<br><br>Staff have also been working remotely since March 2020 and that has made it difficult to monitor which labs are active and need to be up to date and which have paused experiments. |

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):

After the lapse in training non-compliance was reviewed at the convened IBC meeting on January 28,2021. It was agreed that the chair would send a letter to the faculty member outlining the noncompliance and a reminder that training must be kept current. This will be completed by the end of February 2021.

In addition, the offices of Research Integrity and Environmental Health & Safety have implemented more frequent communication to keep this scenario from occurring again.

- **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:** Sherie L Donahue <sherie.donahue@ucr.edu>
**Sent:** Friday, February 12, 2021 1:39 PM
**To:** NIH guidelines
**Cc:** Tran Phan; Ian Naftzger
**Subject:** Noncompliance reports from UCR
**Attachments:** NIH Incident Reporting - Kaloshian-final.pdf; NIH Incident Reporting - Cheloufi - final.pdf

Dear Sir or Madam,

Attached are two noncompliance reports from UCR. In both cases, the noncompliance was a lapse in approval caused by failure to update training in a timely manner.

Please let me know if you need addition information.

Sincerely,

Sherie

*Sherie Donahue*
**Research Integrity Analyst – IBC/IACUC**
**Office of Research Integrity**
**University of California, Riverside**
**900 University Avenue**
**University Office Building, Suite 216 | Riverside, CA 92521**
**951.827.4814 |** sherie.donahue@ucr.edu
**ORI Resources:** https://research.ucr.edu/ori/resources
**COVID-19 information for Researchers** https://keepresearching.ucr.edu and https://ehs.ucr.edu/coronavirus

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 2, 2021 10:24 AM
**To:** Sherie L Donahue; NIH guidelines
**Cc:** Tran Phan; Ian Naftzger; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Noncompliance reports from UCR

Dear Sherie Donahue,

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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

---

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**Sent:** Friday, February 12, 2021 1:39 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Tran Phan <tran.phan@ucr.edu>; Ian Naftzger <ian.naftzger@ucr.edu>
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Sincerely,

Sherie

*Sherie Donahue*
**Research Integrity Analyst – IBC/IACUC**
**Office of Research Integrity**
**University of California, Riverside**
**900 University Avenue**
**University Office Building, Suite 216 | Riverside, CA 92521**

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**951.827.4814 |** sherie.donahue@ucr.edu
**ORI Resources:** https://research.ucr.edu/ori/resources
**COVID-19 information for Researchers** https://keepresearching.ucr.edu and https://ehs.ucr.edu/coronavirus

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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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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, Riverside |
| **Date of Report:** | February 12, 2021 |
| **Reporter name and position:** | Sherie Donahue<br>Research Integrity Analyst |
| **Telephone number:** | 951-827-4814 |
| **Email address:** | Sherie.donahue@ucr.edu |
| **Reporter mailing address:** | 900 University Ave.<br>University Office Building, Suite 216<br>Riverside, CA 92521 |
| **Date of incident:** | December 10, 2020 |
| **Name of Principal Investigator:** | Sihem Cheloufi |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other (please describe): Lapse in IBC approval |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: December 15, 2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | NIH Guidelines III-D-1-a, III-E-3 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Replication incompetent vectors [ranging from non-viral expression plasmids to Retrovirus, lentivirus, and adeno-associated virus (AAV)] used to express chromatin factors, transcription factors, short hairpin RNAs or guide RNAs in mouse primary & established lines and in human established lines. |

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?

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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)**

- 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)**

The University of California, Riverside (UCR), in accordance with the NIH Guidelines for The University of California, Riverside (UCR), in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), provides this report of noncompliance regarding the failure to obtain approval for BSL2 research activities (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) involving mouse and human cell lines in a Principal Investigator's (PI) protocol entitled, "*Investigating the impact of chromatin organ on cellular plasticity*."

The investigator originally submitted the renewal BUA protocol to the IBC on August 7, 2020 and it was reviewed at a convened meeting of the IBC on August 27, 2020. The committee comments were sent to the PI, one of which was that 'all lab members must complete mandatory training.' The approval process at UCR requires that all training be up to date before the BUA can be approved by the IBC. As the lab was undergoing personnel changes, the training requirement could not be cleared immediately. Several communications from the Acting BSO were sent to the investigator to follow up on the training.

The non-compliance was discovered when reviewing the IBC records for the final committee meeting of the year. On December 11, 2020, the PI clarified that though all experiments had stopped with the COVID campus shut down in March 2020, the lab became active again during the research ramp up in the late summer. All required training was completed by December 15, 2020and the renewal BUA was approved on December 15, 2020.

The noncompliance was reviewed at a convened meeting of the IBC on January 28, 2021.

| | |
|---|---|
| **Has the IBC reviewed this** | ☒YES ☐NO |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **incident?** | |
| **Please describe the root cause of this incident:** | Due to the pandemic, all research was shut down on campus. Research was allowed to restart on a case-by-case basis once specific criteria had been met, however that was a separate process from the IBC approval. The PI was reminded of the lab training several times with the expectation that the training would be completed before the current protocol expired.<br><br>Staff have also been working remotely since March 2020 and that has made it difficult to monitor which labs are active and need to be up to date and which have paused experiments. |

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):

After the lapse in training non-compliance was reviewed at the convened IBC meeting on January 28, 2021. It was agreed that the chair would send a letter to the faculty member outlining the noncompliance and a reminder that training must be kept current. This will be completed by the end of February 2021.

In addition, the offices of Research Integrity and Environmental Health & Safety have implemented more frequent communication to keep this scenario from occurring again.

- **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:** Sherie L Donahue <sherie.donahue@ucr.edu>
**Sent:** Friday, February 12, 2021 1:39 PM
**To:** NIH guidelines
**Cc:** Tran Phan; Ian Naftzger
**Subject:** Noncompliance reports from UCR
**Attachments:** NIH Incident Reporting - Kaloshian-final.pdf; NIH Incident Reporting - Cheloufi - final.pdf

Dear Sir or Madam,

Attached are two noncompliance reports from UCR. In both cases, the noncompliance was a lapse in approval caused by failure to update training in a timely manner.

Please let me know if you need addition information.

Sincerely,

Sherie

*Sherie Donahue*
**Research Integrity Analyst – IBC/IACUC**
**Office of Research Integrity**
**University of California, Riverside**
**900 University Avenue**
**University Office Building, Suite 216 | Riverside, CA 92521**
**951.827.4814 |** sherie.donahue@ucr.edu
**ORI Resources:** https://research.ucr.edu/ori/resources
**COVID-19 information for Researchers** https://keepresearching.ucr.edu and https://ehs.ucr.edu/coronavirus

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:07 PM
**To:** Johnson,Christine; NIH guidelines
**Cc:** Rudolph,Alan; Dobos,Karen; Moritz,Rebecca; Chen,Chaoping; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Final Incident Report-CSU 021021

Dear Christine Johnson,

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

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**From:** Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Sent:** Tuesday, March 2, 2021 5:16 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Rudolph,Alan <Alan.Rudolph@colostate.edu>; Dobos,Karen <Karen.Dobos@colostate.edu>; Moritz,Rebecca <Rebecca.Moritz@colostate.edu>; Chen,Chaoping <Chaoping.Chen@colostate.edu>; Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Subject:** Final Incident Report-CSU 021021

Dear Dr. Harris,

In follow up to the initial incident report emailed on 2/10/21 regarding recombinant DNA work involving plant pathogens (Risk Group 1 agents) being conducted without IBC approval, please see attached the final incident report. Let me know if you have any questions.

Thank you,
Christy

**Christine M. Johnson, MS, RBP**
Senior IBC Coordinator
Research Integrity & Compliance Review Office

Obtained via FOIA by Judicial Watch Inc.

2011 Campus Delivery | Fort Collins, CO 80523-2011
200D University Services Center | Colorado State University
Office: (970) 491-1553 | Direct: (970) 491-8690 | https://www.research.colostate.edu/ricro/ibc/

*"We must find time to stop and thank the people who make a difference in our lives."*
**–John F. Kennedy**

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Colorado State University |
| **Date of Report:** | Initial report emailed on 2/12/21; final report date: 3/2/21 |
| **Reporter name and position:** | Christine Johnson<br>Senior IBC Coordinator |
| **Telephone number:** | 970-491-8690 |
| **Email address:** | Christine.johnson@colostate.edu |
| **Reporter mailing address:** | Christine Johnson<br>Colorado State University<br>Campus Delivery 2011<br>Fort Collins, CO 80523-2011 |
| **Date of incident:** | 02/10/21 (when confirmation was received that recombinant work in plant pathogens was being done without IBC approval) |
| **Name of Principal Investigator:** | Vamsi Nalam, PhD<br>Assistant Professor<br>Department of Agricultural Biology<br>Colorado State University |
| **Is this an NIH-funded project?** | ☐YES X NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>X Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X-YES ☐NO<br><br>If yes, date of approval: 2/26/21 |
| **What was the approved biosafety level of the research?** | X BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Recombinant of Potato Virus Y and Potato Mop-top virus constructed by assembling fragments of each virus in E. coli using standard molecular biology techniques. Recombinant strains of the viruses will be cloned along with a visual marker (Rosea1 transcription factor from snapdragon) and a fluorescent protein (mCherry) to track viral movement in plants (Tobacco and Potato). |

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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)**

On 2/9/21 one of the Biosafety Officers noted a discrepancy between notes taken during a lab audit and the Project Approval Request Form (PARF) currently under review, which suggested additional recombinant was being conducted without IBC approval. On 2/10/21, the Biosafety Director contacted the PI, who confirmed that additional recombinant was being conducted. The Biosafety Director instructed the PI to stop recombinant work, and to submit the appropriate Agent Approval Request Forms (AARF) and PARFs to the IBC for review. The IBC was informed on 2/10/21 about the work being done without IBC approval and the forthcoming NIH Incident Report.

The PI submitted the IBC forms on 2/10/21, which further confirmed the lab was cloning Potato Virus Y and Potato Mop-top virus by attempting to assemble fragments of each virus in E. coli using standard molecular biology techniques. Recombinant strains of the viruses will be cloned along with a visual marker (Rosea1 transcription factor from snapdragon) and a fluorescent protein (mCherry) to track viral movement in plants (Tobacco and Potato). The PARF also confirmed that the work is performed under BSL1 and BSL2 conditions and falls under sections III-E-1 of the NIH Guidelines.

During an incident review meeting on 2/22/21, the PI indicated that the lab has not been successful in making the recombinant clones yet. And confirmed that no recombinant viruses have been introduced into plants.

On 2/24/21, the IBC reviewed the AARFs and PARFs, and the project was approved with minor modifications. The AARFs and PARFs have been modified and final approval granted on 2/26/21. The PI is now in compliance with the IBC.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO<br>IBC reviewed the incident on 2/24/21 |
| **Please describe the root cause of this incident:** | The PI believed the work to be exempt and was unaware that IBC approval was required. However, upon request he was very responsive in submitting the appropriate forms. |

**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):**

- On 2/10/21, the PI was instructed to stop recombinant work, and to submit the appropriate Agent Approval Request Forms (AARF) and PARFs to the IBC for review.
- On 2/22/21, an incident review meeting was held to inform the PI of the incident reporting process and to clarify items on the AARFs and PARFs.
- On 2/24/21, the IBC held a special meeting to review the AARFs and PARFs, and the incident. The AARFs and PARFs were approved with minor modifications. The AARFs and PARFs have been modified and final approval granted on 2/26/21.
- The PI will be given additional training and reference material regarding the use of rDNA and plants. Additional education/outreach opportunities are being discussed.

- **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:** Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Sent:** Tuesday, March 2, 2021 5:16 PM
**To:** NIH guidelines; Harris, Kathryn (NIH/OD) [C]
**Cc:** Rudolph,Alan; Dobos,Karen; Moritz,Rebecca; Chen,Chaoping; Johnson,Christine
**Subject:** Final Incident Report-CSU 021021
**Attachments:** FINAL OSP_Incident Report_CSU021021.pdf

Dear Dr. Harris,

In follow up to the initial incident report emailed on 2/10/21 regarding recombinant DNA work involving plant pathogens (Risk Group 1 agents) being conducted without IBC approval, please see attached the final incident report. Let me know if you have any questions.

Thank you,
Christy

**Christine M. Johnson, MS, RBP**
Senior IBC Coordinator
Research Integrity & Compliance Review Office
2011 Campus Delivery | Fort Collins, CO 80523-2011
200D University Services Center | Colorado State University
Office: (970) 491-1553 | Direct: (970) 491-8690 | https://www.research.colostate.edu/ricro/ibc/

*"We must find time to stop and thank the people who make a difference in our lives."*
**–John F. Kennedy**

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Sent:** Friday, February 12, 2021 11:31 AM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Johnson,Christine; Chen,Chaoping; Dobos,Karen; Moritz,Rebecca
**Subject:** initial incident report-CSU 021021

Dear Dr. Harris,

I hope that you are well. On February 10, 2021, our office became aware of recombinant DNA work involving plant pathogens (Risk Group 1 agents) being conducted without IBC approval. I am submitting this email as an initial report as we are still gathering the information needed to fill out the Template for Reporting Incidents Subject to the NIH Guidelines. I will submit the full report as soon as possible.

Best regards,
Christy

**Christine M. Johnson, MS, RBP**
Senior IBC Coordinator
Research Integrity & Compliance Review Office
2011 Campus Delivery | Fort Collins, CO 80523-2011
200D University Services Center | Colorado State University
Office: (970) 491-1553 | Direct: (970) 491-8690 | https://www.research.colostate.edu/ricro/ibc/

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 2, 2021 11:17 AM
**To:** Harding, Beverly; NIH guidelines
**Cc:** IBO; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Clarifications for incident reports for University of Pittsburgh

Dear Beverly Harding,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

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**From:** Harding, Beverly <beverlyh@pitt.edu>
**Sent:** Thursday, February 18, 2021 5:56 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** IBO <ibo@pitt.edu>
**Subject:** Clarifications for incident reports for University of Pittsburgh

Hi Dr. Harris,

As per our conversation on Thursday, February 18, 2021, the following update is provided for the two incidents recently reported from the University of Pittsburgh:

The mouse bite incident (IR-21-02), described a bite from a mouse previously exposed to a recombinant and attenuated viral strain under Biosafety Level 2. The bite injury was treated in the emergency clinic and there were no adverse events from the mouse bite. The supervisor conducted re-training for the handling of mice exposed to the recombinant virus. The committee determined that the incident did not require any additional actions as the incident was an accident and re-training had already occurred by the supervisor. The incident was correspondingly reported to appropriate agencies.

To clarify the non-compliance incident (IR-21-01), the University of Pittsburgh's IBC required the investigator to complete training relevant to Section *IV-B-2-b-(7)* of the *NIH Guidelines* and provided information regarding the responsibilities of investigators as detailed on the IBC website. The investigator submitted an application for research that describes work that falls under the *NIH Guidelines* Exemption, but the University of Pittsburgh

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requires that *all* investigators working with recombinant or synthetic nucleic acid molecules must register their work with the IBC. This is above the requirements indicated in the *NIH Guidelines*, but is the standard practice at the University of Pittsburgh. The IBC recognizes that this incident does not fall under the requirement to report to NIH OSP, however the committee determined that since additional training was necessary for the investigator that the incident should be reported as a non-compliance incident. As indicated, the investigator has completed the required training and has registered the NIH Exempt research with the University of Pittsburgh Institutional Biosafety Division, Office of Research Protections.

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, February 18, 2021 5:56 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** IBO
**Subject:** Clarifications for incident reports for University of Pittsburgh

Hi Dr. Harris,

As per our conversation on Thursday, February 18, 2021, the following update is provided for the two incidents recently reported from the University of Pittsburgh:

The mouse bite incident (IR-21-02), described a bite from a mouse previously exposed to a recombinant and attenuated viral strain under Biosafety Level 2. The bite injury was treated in the emergency clinic and there were no adverse events from the mouse bite. The supervisor conducted re-training for the handling of mice exposed to the recombinant virus. The committee determined that the incident did not require any additional actions as the incident was an accident and re-training had already occurred by the supervisor. The incident was correspondingly reported to appropriate agencies.

To clarify the non-compliance incident (IR-21-01), the University of Pittsburgh's IBC required the investigator to complete training relevant to Section *IV-B-2-b-(7)* of the *NIH Guidelines* and provided information regarding the responsibilities of investigators as detailed on the IBC website. The investigator submitted an application for research that describes work that falls under the *NIH Guidelines* Exemption, but the University of Pittsburgh requires that *all* investigators working with recombinant or synthetic nucleic acid molecules must register their work with the IBC. This is above the requirements indicated in the *NIH Guidelines*, but is the standard practice at the University of Pittsburgh. The IBC recognizes that this incident does not fall under the requirement to report to NIH OSP, however the committee determined that since additional training was necessary for the investigator that the incident should be reported as a non-compliance incident. As indicated, the investigator has completed the required training and has registered the NIH Exempt research with the University of Pittsburgh Institutional Biosafety Division, Office of Research Protections.

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.

# 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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Pittsburgh |
| **Date of Report:** | 1/15/2020 |
| **Reporter name and position:** | Beverly Harding<br>Institutional Biosafety Division<br>Office of Research Protections |
| **Telephone number:** | 412-373-1766 |
| **Email address:** | ibo@pitt.edu or beverlyh@pitt.edu |
| **Reporter mailing address:** | Suite 200 Hieber Building<br>3500 Fifth Avenue<br>Pittsburgh, PA 15213 |
| **Date of incident:** | 1/6/2020 |
| **Name of Principal Investigator:** | Ossama Kashlan |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:R01 DK125439 01*<br>*NIH funding institute or center:NIDDK*<br>*NIH program officer (name, email address): Chris Ketchum, ketchumc@extra.niddk.nih.gov* |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other (please describe): Failure to register work with the IBC in accordance with University Policy |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐YES ☒NO<br><br>If yes, date of approval: Work described in the subsequent registration document qualifies as NIH Exemption |
| **What was the approved biosafety level of the research?** | ☒BL1 – Registration with IBC only<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-F |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | plasmids that encode mouse and human proteins suitable for expression in mammalian cells and for *in vitro* transcription of RNA. |

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

Obtained via FOIA by Judicial Watch Inc.

- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

I had been promoted within the Department. I had been working with plasmids for expression of mouse and human proteins in either cultured mammalian cells or oocytes isolated from the African clawed frog (Xenopus). When I moved into my own lab space nearby, that work continued. Upon my initial inspection, the inspector had told me that I would need to obtain my own IBC protocol. Unfortunately, I failed to follow up and it fell completely off my radar. While recently meeting with an Environmental Health and Safety (EHS) inspector regarding upgrading our lab from BSL-1 to BSL-2, he informed me that we needed to have an IBC protocol for our work.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br>February 8, 2021 – determination to report to the NIH due to non-compliance with University policy |
| **Please describe the root cause of this incident:** | Investigator error and not reporting research activities. |

**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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- ***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.



February 10, 2021

Dear Dr. Harris/NIH OSP Incident Reporting,

The attached two incident reports are to inform the NIH OSP of the IBC deliberation of incidents under the *NIH Guidelines* Sections *IV-B-2-a-(5)*, *IV-B-2-b-(4)* and reporting under Section *IV-B-2-b-(7)*.

The incidents were reviewed at the February 8, 2021 IBC meeting. The initial reporting forms were reviewed by the committee.

To summarize the mouse bite incident (IR-21-02), the new incident report was in the Pre-Submission state in the online system at the time of the January meeting, and had not yet been submitted by the investigator for IBC review. The incident had since been submitted and points from the IBC were clarified. The IBC reviewed the incident details at the February meeting, and determined that the incident required reporting to the NIH OSP per the *NIH Guidelines*. The incident involved a bite from a mouse previously exposed to a recombinant and attenuated viral strain. The bite injury was treated in the emergency clinic and there were no expected adverse events from the mouse bite. The supervisor conducted re-training for handling of mice exposed to the recombinant virus. The committee determined that the incident did not require any additional actions.

To summarize the non-compliance incident (IR-21-01), the University of Pittsburgh's IBC became aware that the investigator failed to apply for IBC review. An incident inquiry was sent to the investigator upon IBC Staff notification on January 6th, but as there was no response from the investigator in advance of the meeting, the incident discussion was deferred. The investigator has since submitted the incident form and an IBC application to cover the work described. The work described the criteria for NIH Exemption/IBC Registration, and a Registration letter was sent to the investigator for the research. There were no further actions required by the IBC from the investigator.

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:** Friday, February 12, 2021 10:03 AM
**To:** NIH guidelines
**Cc:** Harding, Beverly
**Subject:** Attention - Incident Reporting for IBCs
**Attachments:** 21-01 Kashlan February non-compliance report.pdf; INC-21-02 McElroy 02-08-21.pdf; OSP Summary for IR-21-01 and IR-21-02 Reports 2-11-21.doc

Dear OSP staff,

Hope you are all doing well. Attached please find two incident reports reviewed by the University of Pittsburgh IBC at the February IBC meeting.

Thank you,
Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
beverlyh@pitt.edu
ibo@pitt.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 2, 2021 11:17 AM
**To:** Harding, Beverly; NIH guidelines
**Cc:** IBO; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Clarifications for incident reports for University of Pittsburgh

Dear Beverly Harding,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Harding, Beverly <beverlyh@pitt.edu>
**Sent:** Thursday, February 18, 2021 5:56 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** IBO <ibo@pitt.edu>
**Subject:** Clarifications for incident reports for University of Pittsburgh

Hi Dr. Harris,

As per our conversation on Thursday, February 18, 2021, the following update is provided for the two incidents recently reported from the University of Pittsburgh:

The mouse bite incident (IR-21-02), described a bite from a mouse previously exposed to a recombinant and attenuated viral strain under Biosafety Level 2. The bite injury was treated in the emergency clinic and there were no adverse events from the mouse bite. The supervisor conducted re-training for the handling of mice exposed to the recombinant virus. The committee determined that the incident did not require any additional actions as the incident was an accident and re-training had already occurred by the supervisor. The incident was correspondingly reported to appropriate agencies.

To clarify the non-compliance incident (IR-21-01), the University of Pittsburgh's IBC required the investigator to complete training relevant to Section *IV-B-2-b-(7)* of the *NIH Guidelines* and provided information regarding the responsibilities of investigators as detailed on the IBC website. The investigator submitted an application for research that describes work that falls under the *NIH Guidelines* Exemption, but the University of Pittsburgh

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requires that *all* investigators working with recombinant or synthetic nucleic acid molecules must register their work with the IBC. This is above the requirements indicated in the *NIH Guidelines*, but is the standard practice at the University of Pittsburgh. The IBC recognizes that this incident does not fall under the requirement to report to NIH OSP, however the committee determined that since additional training was necessary for the investigator that the incident should be reported as a non-compliance incident. As indicated, the investigator has completed the required training and has registered the NIH Exempt research with the University of Pittsburgh Institutional Biosafety Division, Office of Research Protections.

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.

**University of Pittsburgh INC-21-02**

**Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules***

## 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.

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**

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | Yes |
| **Institution Name:** | University of Pittsburgh |

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| | |
|---|---|
| **Date of Report:** | 2/8/2021 1:24 PM |
| **Reporter name and position:** | Beverly Harding<br><br>U of Pgh \| Institutional Biosafety Division, Office of Research Protections |
| **Email address:** | ibo@pitt.edu or beverlyh@pitt.edu |
| **Date of incident:** | 1/2/2021 |
| **Protocol Information:** | Investigator: Anita McElroy<br><br>Recombinant Nucleic Acids<br>Viable genetically-modified (with recombinant or synthetic nucleic acids) microorganisms tested in whole animals<br>Exempt Experiments<br>Human or animal pathogens used as host-vector systems<br>Human or animal pathogen DNA cloned into a non-pathogenic prokaryote or lower eukaryote<br>Experiments that Require Institutional Biosafety Committee Approval Before Initiation<br>Infectious animal or plant DNA or RNA viruses in tissue culture or defective viruses in the presence of a helper virus |
| **Is this an NIH-funded project?** | No |

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| | |
|---|---|
| **What was the nature of the incident?** | Personnel exposure due to animal bite |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | Yes |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | DelNSs RVFV generated via reverse genetics. Highly attenuated since it is missing the main virulence factor, NSs protein, which is an interferon antagonist. |

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

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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
- 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:**

It was reported to the investigator by the DLAR RBL Manager that a DLAR animal care technician who was handling the mice was bitten by one of them. The mouse had been infected with DelNSs RVFV on 12/28/20. This is a highly attenuated strain of the virus that we use as a vaccine. The technician reported that she immediately washed the wound and then reported to Presbyterian ED for evaluation.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | Yes, it was determined that no additional actions were required from the investigator<br><br>2/8/2021 |
| **Please describe the root cause of this incident:** | Animals are unpredictable.<br>DLAR staff are required by DLAR to wear chainmail link gloves when handling Select Agent mice and she had taken the glove off after handling the mice and was replacing the lid on the cage when the bite occurred (per the DLAR supervisor). |

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**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):** DLAR staff have been reminded by their supervisor that they are required to wear the chainmail link gloves when handling Select Agent mice and should not take them off until the animals are secured.

- ***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 <u>NOT</u> 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.



February 10, 2021

Dear Dr. Harris/NIH OSP Incident Reporting,

The attached two incident reports are to inform the NIH OSP of the IBC deliberation of incidents under the *NIH Guidelines* Sections *IV-B-2-a-(5)*, *IV-B-2-b-(4)* and reporting under Section *IV-B-2-b-(7)*.

The incidents were reviewed at the February 8, 2021 IBC meeting. The initial reporting forms were reviewed by the committee.

To summarize the mouse bite incident (IR-21-02), the new incident report was in the Pre-Submission state in the online system at the time of the January meeting, and had not yet been submitted by the investigator for IBC review. The incident had since been submitted and points from the IBC were clarified. The IBC reviewed the incident details at the February meeting, and determined that the incident required reporting to the NIH OSP per the *NIH Guidelines*. The incident involved a bite from a mouse previously exposed to a recombinant and attenuated viral strain. The bite injury was treated in the emergency clinic and there were no expected adverse events from the mouse bite. The supervisor conducted re-training for handling of mice exposed to the recombinant virus. The committee determined that the incident did not require any additional actions.

To summarize the non-compliance incident (IR-21-01), the University of Pittsburgh's IBC became aware that the investigator failed to apply for IBC review. An incident inquiry was sent to the investigator upon IBC Staff notification on January 6th, but as there was no response from the investigator in advance of the meeting, the incident discussion was deferred. The investigator has since submitted the incident form and an IBC application to cover the work described. The work described the criteria for NIH Exemption/IBC Registration, and a Registration letter was sent to the investigator for the research. There were no further actions required by the IBC from the investigator.

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, February 18, 2021 5:56 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** IBO
**Subject:** Clarifications for incident reports for University of Pittsburgh

Hi Dr. Harris,

As per our conversation on Thursday, February 18, 2021, the following update is provided for the two incidents recently reported from the University of Pittsburgh:

The mouse bite incident (IR-21-02), described a bite from a mouse previously exposed to a recombinant and attenuated viral strain under Biosafety Level 2. The bite injury was treated in the emergency clinic and there were no adverse events from the mouse bite. The supervisor conducted re-training for the handling of mice exposed to the recombinant virus. The committee determined that the incident did not require any additional actions as the incident was an accident and re-training had already occurred by the supervisor. The incident was correspondingly reported to appropriate agencies.

To clarify the non-compliance incident (IR-21-01), the University of Pittsburgh's IBC required the investigator to complete training relevant to Section *IV-B-2-b-(7)* of the *NIH Guidelines* and provided information regarding the responsibilities of investigators as detailed on the IBC website. The investigator submitted an application for research that describes work that falls under the *NIH Guidelines* Exemption, but the University of Pittsburgh requires that *all* investigators working with recombinant or synthetic nucleic acid molecules must register their work with the IBC. This is above the requirements indicated in the *NIH Guidelines*, but is the standard practice at the University of Pittsburgh. The IBC recognizes that this incident does not fall under the requirement to report to NIH OSP, however the committee determined that since additional training was necessary for the investigator that the incident should be reported as a non-compliance incident. As indicated, the investigator has completed the required training and has registered the NIH Exempt research with the University of Pittsburgh Institutional Biosafety Division, Office of Research Protections.

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:** Friday, February 12, 2021 10:03 AM
**To:** NIH guidelines
**Cc:** Harding, Beverly
**Subject:** Attention - Incident Reporting for IBCs
**Attachments:** 21-01 Kashlan February non-compliance report.pdf; INC-21-02 McElroy 02-08-21.pdf; OSP Summary for IR-21-01 and IR-21-02 Reports 2-11-21.doc

Dear OSP staff,

Hope you are all doing well. Attached please find two incident reports reviewed by the University of Pittsburgh IBC at the February IBC meeting.

Thank you,
Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
beverlyh@pitt.edu
ibo@pitt.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 2, 2021 11:19 AM
**To:** Branum, Jennifer Dawn (jmw4qs); NIH guidelines
**Cc:** Leonard, Tom (rtl5p); Mann, Barbara J (bjm2r); Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Report of Exposure - University of Virginia

Dear Jennifer Branum,

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:** Branum, Jennifer Dawn (jmw4qs) <jmw4qs@virginia.edu>
**Sent:** Friday, February 12, 2021 5:29 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Leonard, Tom (rtl5p) <rtl5p@virginia.edu>; Mann, Barbara J (bjm2r) <bjm2r@virginia.edu>
**Subject:** Report of Exposure - University of Virginia

Dear OSP,
Please find the attached completed report for an incident that occurred involving modified human lung fibroblast cell line at the University of Virginia.

Regards,
Jenni

**Jennifer Branum, MBA, MT, RBP, CBSP**
*Biosafety Officer*
*Environmental Health & Safety*

**E** jbranum@virginia.edu
**P** 434.982.4989
**F** 434.243.1735

UNIVERSITY of VIRGINIA

Obtained via FOIA by Judicial Watch Inc.

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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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Virginia |
| **Date of Report:** | February 12, 2021 |
| **Reporter name and position:** | Jennifer Branum, Biosafety Officer |
| **Telephone number:** | 434-982-4989 |
| **Email address:** | Jmw4qs@virginia.edu |
| **Reporter mailing address:** | Environmental Health & Safety<br>P.O. Box 400333<br>Charlottesville, VA 22904 |
| **Date of incident:** | January 29, 2021 |
| **Name of Principal Investigator:** | Thomas Barker |
| **Is this an NIH-funded project?** | ☐YES √NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>√Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ √YES ☐NO<br>If yes, date of approval: 01/05/2021 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>√BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Human lung fibroblast cell line obtained from ABM modified using CRISPR to knockout expression of cell surface protein, SEMA7a |

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT:

A graduate student was working in a biosafety cabinet in an approved BSL2 laboratory while wearing gloves and lab coat, but no safety glasses. After removing media from the petri dishes containing human lung fibroblast cell lines with a glass Pasteur pipette, he proceeded to remove the glass Pasteur pipette from the vacuum line to dispose into the red sharps container (see picture below) located under the biosafety cabinet. As the glass pipette was placed into the sharps container, the pipette shattered (see picture of point where glass pipette shattered) as it hit one of the pieces of plastic in the top liner of the sharps container. A small piece of glass from the pipette flew into his lower right eye, after which he experienced moderate pain. Immediately, he flushed his eyes for three minutes at the eyewash located in the lab and was able to flush the piece of glass out of his eye and there was no more pain. He proceeded to the Emergency Room concerned that there could be smaller pieces of glass in his eye. The Emergency Room confirmed no remaining pieces of glass were present in the eye. The Emergency Room prescribed antibiotic eye drops and advised a follow-up call to Ophthalmology. During this time, while waiting in the Emergency Room, he informed his supervisor about the incident. The laboratory supervisor informed the biosafety office via email of the incident on Monday, February 1, 2021 at 9:34am.

The biosafety office asked the graduate student to follow up with the UVA occupational health provider, WorkMed. The graduate student met with the UVA WorkMed on 2/2/2021 and was provided a pair of safety goggles during his visit. UVA WorkMed collected initial blood work to test for HIV, HBV, and HCV, which results were negative. This bloodwork will be collected again at 3 months, 6 months, and 1 year. The graduate student called Ophthalmology, who did not recommend evaluation unless any complications arise (vision problems, swelling, irritation, etc.).

During the investigation, it was noted that the PI's IBC registration had not been updated to include the graduate student as having potential exposure to human derived materials, which the lab supervisor updated immediately. Although the graduate student had completed the Bloodborne Pathogens and Biosafety Training for Research Personnel on 8/27/2018, he had not completed the Bloodborne Pathogen annual retraining within the last year. Annual Bloodborne Pathogens training was completed on 2/1/2021.

Originally, the graduate student informed the biosafety office that no recombinant DNA work was performed. Upon further investigation, the graduate student noted that the human lung fibroblast cell line had been modified using CRISPR to knockout the expression of a cell surface protein, SEMA7a.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☑NO<br>Incident will be reviewed during the next IBC meeting on March 2, 2021 |
| **Please describe the root cause of this incident:** | The root cause of this incident was the use of glass Pasteur pipettes instead of a plastic alternative and the position of the sharps container. |

Obtained via FOIA by Judicial Watch Inc.

Describe measures taken by the institution to mitigate any problems identified:

During the investigation, the sharps container was observed as positioned too far under the biosafety cabinet for safe disposal of the glass Pasteur pipette and safety glasses were not worn when working with glass Pasteur pipettes.

The laboratory manager was advised to ensure that personnel are accurately reflected in PI IBC registration. The graduate student was informed via email on 2/1/2021 to complete Bloodborne pathogen annual re-training, which completed the same day. In addition, the graduate student was asked to call WorkMed to inform them of the accident even though he had reported immediately to the ER on the date of the incident. Lab personnel were recommended to wear safety glasses when working with glass Pasteur pipettes and UVA WorkMed provided the graduate student a pair of safety glasses during his visit on 2/2/21. Additionally, plastic aspiration pipettes were suggested as plastic alternatives are recommended over glass Pasteur pipettes, which the lab supervisor will look into ordering plastic aspiration pipettes for the lab. Lastly, since the sharps container was located under the biosafety cabinet, it was suggested that the sharps container be moved out from under the BSC when placing the pipettes into the sharps container in order to provide immediate direct access without creating potential of sharps injury during disposal.



Red sharps container under biosafety cabinet



Plastic top liner of sharps container

Obtained via FOIA by Judicial Watch Inc.



Indicates where glass Pasteur pipette shattered as being placed into the sharps container

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Branum, Jennifer Dawn (jmw4qs) <jmw4qs@virginia.edu>
**Sent:** Friday, February 12, 2021 5:29 PM
**To:** NIH guidelines
**Cc:** Leonard, Tom (rtl5p); Mann, Barbara J (bjm2r)
**Subject:** Report of Exposure - University of Virginia
**Attachments:** NIH Incident-Miller 2-3-21.docx

Dear OSP,
Please find the attached completed report for an incident that occurred involving modified human lung fibroblast cell line at the University of Virginia.

Regards,
Jenni

**Jennifer Branum, MBA, MT, RBP, CBSP**
*Biosafety Officer*
*Environmental Health & Safety*

**E** jbranum@virginia.edu
**P** 434.982.4989
**F** 434.243.1735

UNIVERSITY of VIRGINIA

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 2:58 PM
**To:** Gomez-Saladin, Eduardo (CDC/DDPHSS/OLSS/OD); NIH guidelines
**Cc:** Monroe, Steve (CDC/DDPHSS/OLSS/OD); Owen, Sherry M. (Michele) (CDC/DDID/NCHHSTP/OD); Carroll, Serena (CDC/DDID/NCEZID/OD); Kools, John J. (CDC/DDID/NCEZID/OD); IBC (CDC); Garcia-Lerma, Gerardo (CDC/DDID/NCHHSTP/DHP); Powell, Nathaniel (CDC/DDID/NCEZID/DSR); Hatcher, Brandon (CDC/DDPHSS/OLSS/OLS); Stevens, James (CDC/DDID/NCIRD/ID); Tansey, Cassandra (CDC/DDID/NCEZID/DSR); Dobard, Charles W. (CDC/DDID/NCHHSTP/DHP); Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: FINAL REPORT REC NA INCIDENT FEB 12

Dear Dr. Eduardo Gomez,

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:** Gomez-Saladin, Eduardo (CDC/DDPHSS/OLSS/OD) <gqo9@cdc.gov>
**Sent:** Tuesday, March 2, 2021 2:44 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Monroe, Steve (CDC/DDPHSS/OLSS/OD) <stm2@CDC.GOV>; Owen, Sherry M. (Michele) (CDC/DDID/NCHHSTP/OD) <smo2@CDC.GOV>; Carroll, Serena (CDC/DDID/NCEZID/OD) <awx6@CDC.GOV>; Kools, John J. (CDC/DDID/NCEZID/OD) <czk7@CDC.GOV>; IBC (CDC) <ibc@cdc.gov>; Garcia-Lerma, Gerardo (CDC/DDID/NCHHSTP/DHP) <jng5@CDC.GOV>; Powell, Nathaniel (CDC/DDID/NCEZID/DSR) <czn5@CDC.GOV>; Hatcher, Brandon (CDC/DDPHSS/OLSS/OLS) <qaw7@cdc.gov>; Stevens, James (CDC/DDID/NCIRD/ID) <fwb4@CDC.GOV>; Tansey, Cassandra (CDC/DDID/NCEZID/DSR) <kuo2@cdc.gov>; Dobard, Charles W. (CDC/DDID/NCHHSTP/DHP) <gok5@CDC.GOV>
**Subject:** FINAL REPORT REC NA INCIDENT FEB 12
**Importance:** High

Dear OSP,
In compliance with Appendix G-II-B-2-k of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and on the behalf of the Centers for Disease Control and Prevention (CDC) Institutional Biosafety Committee (IBC), I am submitting the final report concerning a potential exposure to recombinant Simian Human Immunodeficiency virus (SHIV).
Please find attached the final report.

Obtained via FOIA by Judicial Watch Inc.

Please let me know if you have any questions or if there is any other additional information that you require.
Sincerely,
Eduardo Gomez, Ph.D.
CDC IBC Biosafety Officer

*Eduardo Gomez, PhD, SM, RBP, CBSP*
*CDR USPHS*
*Senior Scientist, Office of Laboratory Science and Safety*
*Centers for Disease Control and Prevention*
*Office: (404) 639-0782, FAX: (404)235-4916,*
*blackberry:* Redacted by *Email: GQO9@cdc.gov*

OLSS Office of Laboratory Science and Safety
*Strengthening the culture of laboratory science and safety at CDC*

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | CENTERS FOR DISEASE CONTROL AND PREVENTION |
| **Date of Report:** | March 19, 2021 |
| **Reporter name and position:** | EDUARDO GOMEZ<br>IBC BSO |
| **Telephone number:** | 404 639 0782 |
| **Email address:** | GQO9@CDC.GOV |
| **Reporter mailing address:** | 1600 CLIFTON ROAD NE<br>MS 21-2<br>ATLANTA, GA 30333 |
| **Date of incident:** | FEBRUARY 12, 2021 |
| **Name of Principal Investigator:** | |
| **Is this an NIH-funded project?** | ☐YES xNO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | XYES ☐NO If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐BL2 ☐BL2+<br>☐ BL3 ☐BL3+<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-1-a/b; III-D-4 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Simian-Human Immunodeficiency 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)

**NOTE: We are sending this report being cautious/thorough with our response even though there is no evidence of a failure in PPE. May turn out to be a near miss.**

**Employee Type:** Contractor, Veterinary Technician

**Type of Injury:** Possible SHIV/Herpes B exposure at macaque colony

**Date of Injury:** 02/12/2021

**Time of Injury:** Approximately 1030 am.

**Location of Injury:** CDC Roybal campus

**Cause of Injury:** Unknown: After technician finished dispensing oral medications administered to macaques in medicine cups, he left to wash his hands, dried them, applied hand sanitizer, which began to sting. He noticed a small abrasion on his right hand, 5th finger on the lateral side.

**Source of Injury:** Unknown as he did not have any physical contact with any of the macaques that he dispensed medication to. Possibly a cage or the injury may have occurred outside of work.

**Lab-Related?** Y

**Treatment/Management: HIV post-exposure prophylaxis, herpes B post exposure prophylaxis for 5 days was dispensed. Waiting to hear from the Comparative Medicine Branch on the SHIV status of the macaques. Contracting company has been notified. Contractor will pick up remaining medications at contracting company pharmacy. He will RTC on 2/16/2021 for follow-up and for further laboratory testing on weeks 2, 4, 6, and 12 post-exposure. Baseline serum was drawn today. Td vaccine is current.**

| | |
|---|---|
| **Has the IBC reviewed this incident?** | YES NO |
| **Please describe the root cause of this incident:** | pending |

Obtained via FOIA by Judicial Watch Inc.

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):

- **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.

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*?** | XYES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | CENTERS FOR DISEASE CONTROL AND PREVENTION |
| **Date of Report:** | March 19, 2021 |
| **Reporter name and position:** | EDUARDO GOMEZ<br>IBC BSO |
| **Telephone number:** | 404 639 0782 |
| **Email address:** | GQO9@CDC.GOV |
| **Reporter mailing address:** | 1600 CLIFTON ROAD NE<br>MS 21-2<br>ATLANTA, GA 30333 |
| **Date of incident:** | FEBRUARY 12, 2021 |
| **Name of Principal Investigator:** | GERARDO GARCIA-LERMA |
| **Is this an NIH-funded project?** | ☐YES xNO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | XYES ☐NO<br><br>If yes, date of approval: 6/19/2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>XABSL2 ☐BL2+<br>☐ BL3 ☐BL3+<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-1-a/b; III-D-4 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Simian-Human Immunodeficiency 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.**

On February 12, 2021 a veterinary technician noted a minor dermal abrasion on their right index finger after passing out morning medications to multiple rooms of nonhuman primates housed in conventional caging within a vivarium. The rooms entered are all ABSL-2 areas. The technician was wearing a hair bonnet, a PAPR, disposable coveralls, two pairs of nitrile gloves, facility scrubs, and facility shoes, as required by SOP. Outer gloves were changed between each room and no tear was noted at any point, nor did they notice any specific incident to make them believe there was potentially a breach of PPE. After all medications were given out, the technician doffed their PPE, washed their hands, and then applied hand sanitizer, at which point the technician felt a burning sensation and noticed the abrasion.

The technician began scrubbing the wound with chlorhexidine scrub solution and water for 15 minutes, as required by SOP but failed to notify their supervisor after the scrub was complete. A short time later, their supervisor saw the technician wearing a glove in a non-animal area while doing other tasks. When questioned, the technician told their supervisor about the incident. To ensure that the 15 minute scrub was done to a high standard (as there were no witnesses previously), the supervisor had the technician scrub the dermal abrasion again for 15 minutes, then escorted them to the Occupational Health Clinic for medical evaluation and treatment. The Occupational Health Clinic performed an evaluation, drew samples for baseline tests, and prescribed medications for HIV and Herpes B prophylaxis.

A description of:

- The incident/violation location: **Animal biosafety level 2 rooms in the vivarium**
- Who was involved in the incident/violation, including others present at the incident location? **A contractor Veterinary technician**

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event: **: HIV post-exposure prophylaxis, herpes B post exposure prophylaxis for 5 days was dispensed. Contacted the Comparative Medicine Branch with regards to the SHIV status of the macaques. Contracting company has been notified. Contractor will pick up remaining medications at contracting company pharmacy. He will RTC on 2/16/2021 for follow-up and for further laboratory testing on weeks 2, 4, 6, and 12 post-exposure. Baseline serum was drawn. Td vaccine is current.**

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

    - **Personal Protective Equipment, 29 JAN 2021**
    - **Bloodborne Pathogens, 1 FEB 2021**
    - **NIH's Working Safely with NHPs, 29 JAN 2021**
    - **First Aid, 29 JAN 2021**
    - **Herpes B Virus Training, 11 FEB 2021**

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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: **Standard operating procedures (SOPs) following a potential exposure to infectious material in ABSL-2 areas dictate that the exposed person begins flushing and scrubbing the wound immediately for 15 minutes with chlorhexidine and water. Additional personnel, if available, perform supporting tasks, including securing the animal, informing the supervisor, and collecting pertinent medical records or samples from the animal. If the exposed person is alone, that person informs the supervisor immediately following the scrubbing. The exposed person is then assessed at the Occupational Health Clinic. A minor deviation from the SOP occurred when the technician did not immediately seek out their supervisor to inform them of the potential exposure after completion of the wound scrub. There was no deviation from the containment level or other IBC approval conditions 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: **No deviations noted. Approved protocols were in use IBC 2020.275 AND 2020.276**

- The personal protective equipment in use at the time of the incident/violation: **hair bonnet, a PAPR, disposable coveralls, two pairs of nitrile gloves, facility scrubs, and facility shoes, as required by SOP.**

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

  **All personnel involved in research in the vivarium must participate in the CDC's *Animal Area Access* Medical program, which entails the following at enrollment:**
  - **Hepatitis A titer and/ or hepatitis A primary series**
  - **Hepatitis B titer and/ or hepatitis B primary series**
  - **MMR vaccination**
  - **Varicella infection history, positive varicella titer, or varicella vaccination series**
  - **Tetanus- diphtheria (Td) vaccination**
  - **Rabies primary series**
  - **Audiogram**
  - **Respirator clearance exam and spirometry**
  - **Two-step TB skin test, or TB screening if positive by history**
  - **Hepatitis C titer**
  - **Initial animal allergy questionnaire**
  - **Immunocompromising condition (including pregnancy) questionnaire and discussion**

  **After enrollment, personnel receive tuberculosis screening for all personnel working in the animal areas every six months as well as the following services annually:**
  - **Hepatitis B and C titer checks**
  - **Rabies titer or vaccine as appropriate**
  - **Audiogram to monitor hearing damage**

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- **Pulmonary function test for respirator clearance**
- **Respirator fit testing**

- Any medical surveillance provided or recommended after the incident: **In this instance, HIV post-exposure prophylaxis and Herpes B post-exposure prophylaxis for 5 days was dispensed on the day of exposure by the Occupational Health Clinic, with additional prescriptions extending the treatment to 2 weeks for Herpes B and 4 weeks for SHIV/HIV prophylaxis after confirmation that animals within the rooms are SHIV positive. The technician will have further laboratory testing on weeks 2, 4, 6, and 12 post-exposure. Baseline serum was drawn the day of the incident. Tetanus and diphtheria vaccine is current.**
- Any injury or illness associated with the incident: **right hand, 5th finger on the lateral side; abrasion, source unknown.**
  - **Cause of Injury:** Unknown: After technician finished dispensing oral medications administered to macaques in medicine cups, the technician left to wash hands, dried them, applied hand sanitizer, which began to sting. The individual noticed a small abrasion on the right hand, 5th finger on the lateral side.
  - **Source of Injury:** Unknown as the technician did not have any physical contact with any of the macaques to which medication was dispensed. Possibly a cage or the injury may have occurred outside of work.
- Equipment failures: **None noted**

It is unknown if the nitrile gloves failed. If the gloves failed, it is unknown if the failure was due to trauma or faulty manufacturing. There is no indication that remaining gloves in the various rooms are faulty. No other equipment failures are associated with this incident.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | **xYES** NO |
| **Please describe the root cause of this incident:** | Undetermined, as it is not known whether an incident has indeed occurred in the animal rooms or if the abrasion occurred outside the workplace |

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):

Recommendations from incident investigation report:
Continue employee`s training on working with NHP. Advise employee to be attentive to surroundings and follow standard universal precautions while around NHPs. Advise employee to inspect gloves while changing between rooms and at the final doffing procedures. Continue cage inspections upon each washing cycle, identify broken and/or sharp-edged cages and repair them promptly.

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:** Gomez-Saladin, Eduardo (CDC/DDPHSS/OLSS/OD) <gqo9@cdc.gov>
**Sent:** Tuesday, March 2, 2021 2:44 PM
**To:** NIH guidelines
**Cc:** Monroe, Steve (CDC/DDPHSS/OLSS/OD); Owen, Sherry M. (Michele) (CDC/DDID/NCHHSTP/OD); Carroll, Serena (CDC/DDID/NCEZID/OD); Kools, John J. (CDC/DDID/NCEZID/OD); IBC (CDC); Garcia-Lerma, Gerardo (CDC/DDID/NCHHSTP/DHP); Powell, Nathaniel (CDC/DDID/NCEZID/DSR); Hatcher, Brandon (CDC/DDPHSS/OLSS/OLS); Stevens, James (CDC/DDID/NCIRD/ID); Tansey, Cassandra (CDC/DDID/NCEZID/DSR); Dobard, Charles W. (CDC/DDID/NCHHSTP/DHP)
**Subject:** FINAL REPORT REC NA INCIDENT FEB 12
**Attachments:** REC NA INCIDENT report SHIV Feb 2021.docx; NOTIFICATION OF INCIDENT INVOLVING REC NA

**Importance:** High

Dear OSP,
In compliance with Appendix G-II-B-2-k of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and on the behalf of the Centers for Disease Control and Prevention (CDC) Institutional Biosafety Committee (IBC), I am submitting the final report concerning a potential exposure to recombinant Simian Human Immunodeficiency virus (SHIV).
Please find attached the final report.
Please let me know if you have any questions or if there is any other additional information that you require.
Sincerely,
Eduardo Gomez, Ph.D.
CDC IBC Biosafety Officer

*Eduardo Gomez, PhD, SM, RBP, CBSP*
*CDR USPHS*
*Senior Scientist, Office of Laboratory Science and Safety*
*Centers for Disease Control and Prevention*
*Office: (404) 639-0782, FAX: (404)235-4916,*
*blackberry:* Redacted by agreement *Email: GQO9@cdc.gov*
OLSS Office of Laboratory Science and Safety
Strengthening the culture of laboratory science and safety at CDC

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Gomez-Saladin, Eduardo (CDC/DDPHSS/OLSS/OD) <gqo9@cdc.gov>
**Sent:** Saturday, February 13, 2021 9:35 PM
**To:** NIH guidelines
**Cc:** IBC (CDC); Stevens, James (CDC/DDID/NCIRD/ID); Olson, Victoria (CDC/DDID/NCEZID/DHCPP); Hatcher, Brandon (CDC/DDPHSS/OLSS/OLS)
**Subject:** NOTIFICATION OF INCIDENT INVOLVING REC NA
**Attachments:** preliminary report SHIV Feb 2021.docx

**Importance:** High

Good evening,

This is a notification that yesterday (FEB12) a potential exposure has occurred at a CDC laboratory involving *Simian-Human Immunodeficiency virus*.

A full report will be submitted within 30 days.

Thanks,

*In Officio Salutis,*
*Eduardo Gomez, PhD, SM, RBP, CBSP*
*CDR USPHS*
*Senior Scientist, Office of Laboratory Science and Safety*
*Centers for Disease Control and Prevention*
*Office: (404) 639-0782*
*mobile:* Redacted by agreement *Email: GQO9@cdc.gov*
OLSS Office of Laboratory Science and Safety
Strengthening the culture of laboratory science and safety at CDC

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 2:56 PM
**To:** Fernandez, Javier; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident report involving human subject

Dear Javier Fernandez,

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

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**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Monday, March 15, 2021 6:49 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Re: Incident report involving human subject

Dear Dr. Harris,

Attached is the Incident Report form and a separate file with a detailed description of the incident, including Corrective and Preventive Actions.

The report submission has been delayed beyond the 30-day requirement as the incident was reported and investigated internally.

Please let me know if you need additional information.

Regards,

Javier

Obtained via FOIA by Judicial Watch Inc.

Javier P. Fernandez, MS, RAC, CSP, CBSP
Biosafety Officer, Environmental Health and Safety
Javier.Fernandez@cshs.org

Cedars-Sinai
8700 Beverly Boulevard, TSB-190 : Los Angeles CA 90048
office 310-423-4336 : cedars-sinai.org



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**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Tuesday, February 16, 2021 7:11 AM
**To:** NIHGuidelines@od.nih.gov <NIHGuidelines@od.nih.gov>
**Subject:** Incident report involving human subject

Dear Dr. Harris,

Our IBC was recently notified of an incident associated with a clinical research protocol conducted at one of our affiliated clinical sites which involves the administration of a personalized mRNA cancer vaccine; we are currently in the process of gathering information to generate the repot to NIH.

The incident involved a Pharmacy error that resulted in a human subject participant receiving a dose from a personalized mRNA cancer vaccine manufactured and intended for a different study participant. The participant who received the dose in error reported feeling fatigued, feverish and had aches after receiving the vaccine dose, and felt better after taking NSAID; these issues resolved completely after 36 hours, and she will continue to be monitored closely.

The clinical site where this incident happened has begun to implement corrective and preventive measures in collaboration with various groups at the main medical center, including the Main Pharmacy.

Again, we are gathering additional information and putting together the report to NIH, which we will be submitting as soon as possible.

In the meanwhile, please let me know if you require additional information.

Regards,

Javier P. Fernandez, MS, RAC, CSP, CBSP
Biosafety Officer, Environmental Health and Safety
Javier.Fernandez@cshs.org

Cedars-Sinai
8700 Beverly Boulevard, TSB-190 : Los Angeles CA 90048
office 310-423-4336 : cedars-sinai.org



Obtained via FOIA by Judicial Watch Inc.

IMPORTANT WARNING: This message is intended for the use of the person or entity to which it is addressed and may contain information that is privileged and confidential, the disclosure of which is governed by applicable law. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this information is strictly prohibited. Thank you for your cooperation.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ▣ YES ☐ NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Cedars-Sinai Medical Center |
| **Date of Report:** | 2021/03/15 |
| **Reporter name and position:** | Javier P. Fernandez (Biosafety Officer) |
| **Telephone number:** | (310) 423-4336 |
| **Email address:** | Javier.Fernandez@cshs.org |
| **Reporter mailing address:** | 8700 Beverly Boulevard<br>TSB-190<br>Los Angeles, CA 90048 |
| **Date of incident:** | 2021/01/12 |
| **Name of Principal Investigator:** | Mark Faries, M.D. |
| **Is this an NIH-funded project?** | ☐ YES ▣ NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>▣ Other (please describe): Dosing error with presonalized mRNA cancer vaccine |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ▣ YES ☐ NO<br>If yes, date of approval: 2019/04/16 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>▣ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐ State or local Public Health<br>▣ FDA ☐ Law enforcement<br>☐ EPA ▣ Other (please describe): WIRB<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Personalized mRNA cancer vaccine |

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 filing of this incident report with NIH has been delayed and could not be submitted within the required 30 days due to the following factors:

- The incident was discovered during a review of documentation several weeks after the date of the incident.
- Several institutional departments had to gather required information from the clinical site involved to help assess the incident and determine the necessary corrective and preventive measures.

Please see attached description of incident (**Description_of_Incident_Cedars_Sinai_Dosing_Error_mRNA_Cancer_Vaccine**).

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | Scheduling, Pharmacy, and Infusion errors described in attached file (**Description_of_Incident_Cedars_Sinai_Dosing_** |

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 see the attached file, which includes a description of the CAPA measures taken by the institutions to correct and prevent the problems identified (**Description_of_Incident_Cedars_Sinai_Dosing_Error_mRNA_Cancer_Vaccine**).

- **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.

# Description of the incident

This incident was a dosing error. A research patient (subject-A below) was on a protocol where they would receive a personalized mRNA vaccine for cancer treatment. This vaccine is custom manufactured for a single subject only. This incident: Subject-A received a vaccine dose made for a different subject (Subject-B below). No serious adverse events occurred as a result of this dosing error.

**The incident/violation location**:
Pharmacy and Infusion Areas at The Angeles Clinic and Research Institute (Cedars-Sinai Affiliate).

**The training received by the individual(s) involved and the date(s) the training was conducted**:
In addition to Pharmacy and Protocol related Standard Operating Procedure (SOP) training indicated in Corrective and Preventive Action (CAPA) report below, this is a list ofthe Bloodborne Pathogen (BBP) Standard and Safe Handling of Hazardous Medication training by individuals listed in the CAPA report:

| Individual Role | Bloodborne Pathogens Training Date of Completion | Safe Handling of Hazardous Medications for Clinicians Training- Date of Completion |
|---|---|---|
| Research Pharmacist | 01/07/2021 | 12/11/2019 |
| Research Coordinator | 12/22/2020 | 12/11/2019 |
| Infusion Nurse | 01/20/2021 | 12/13/2019 |
| Head Pharmacist | 02/22/2021 | 12/31/2019 |
| Principal Investigator | 01/12/2021 | 04/09/2020 |
| Site Research Director and Sub-Investigator | 02/16/2021 | 03/01/2021 |
| Subject's Physician and Sub-Investigator | 02/16/2021 | 03/01/2021 |

**Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation**: No deviations from containment level or other IBC approval conditions.

**The personal protective equipment in use at the time of the incident/violation**: Pharmacy personnel: Chemo gown, chemo gloves, head cap, and shoe covers. Infusion personnel: Chemo gown, chemo gloves, face mask, and safety goggles.

**Any injury or illness associated with the incident**: No personnel injury. Subject involved did not experience any Serious Adverse Event; only mild symptoms consistent with post-vaccination.

**Equipment failures**: None

## Corrective and Preventive Action Plan

**RE:** mRNA-4157 Vaccine Dosing Error

**Note:** Subject-A was seen for her Cycle 3 Day 1 visit on January 12, 2021. The subject is randomized to the combination therapy of mRNA-4157 plus pembrolizumab. Upon approval to treat, the Research Pharmacist retrieved 2 vials of the mRNA-4157 from a vaccine kit located in the -70 °C and prepared them for administration. The subject was dosed with both study drugs, mRNA-4157 vaccine was given first followed immediately by the administration of pembrolizumab, per protocol.

**Summary of Issue:**

During a monitoring visit at our site on January 21, 2021, our site designated Clinical Research

Obtained via FOIA by Judicial Watch Inc.

# Description of the incident

Associate (CRA) noticed that the dose preparation and administration worksheets for Subject-A were labelled with the vaccine label from Subject-B's vaccine kit. CRA reviewed the used mRNA-4157 vaccine for Subject-A and discovered that the vaccine box and vials were labelled for Subject-B.

Upon review of the current supply of mRNA-4157 for all subjects, the CRA noted that Subject-A had 10 unopened boxes of vaccine kits containing 2 vials each, which confirmed that no vaccine designated for Subject-A had been physically dispensed to date; although the Interactive Response Technology (IRT) transaction for this patient was processed for their planned visit on 12 Jan 2021.

CRA immediately notified the Head Pharmacist of the error. Head Pharmacist reviewed the dose preparation and administration worksheets, the used mRNA-4157 vaccine box and vials, and the unused supply of the mRNA-4157 vaccine for Subject-A. Head Pharmacist confirmed that Subject-A had 10 unopened boxes and that subject 415720US2030503 was missing one box containing 2 vials; concluding Subject-A was dosed with Subject-B's mRNA-4157 vaccine.

Head Pharmacist and Research Supervisor informed Site Research Director and sub-investigator on January 21, 2021 of the event that Subject-A had been dosed with Subject-B's manufactured vaccine. Site Research Director (and Sub-Investigator) then notified Principal Investigator (PI) and another Sub-Investigatorof the dosing error on January 22, 2021. Subject-B was not impacted by this dosing error as subject was permanently discontinued from study and had adequate supply for treatment while on study.

On January 22, 2021 Site Research Director discussed the incident with the Moderna Medical Monitor, who tentatively approved for Subject-A to continue on the study pending review of the Root Cause and CAPA. At the subject's next visit, Cycle 5 Day 1, the patients designated vaccine dose will be administered under direct supervision of the site CRA, and the patient can receive all of the personalized vaccine designed for her; for a total of 9 doses of the subjects own personalized cancer vaccine. The Principal Investigator, the two Sub-Investigators, and the Moderna Medical Monitor are all in agreement with this course of action.

The subject's physician (and Sub-Investigator) contacted Subject-A on January 23, 2021 via phone call discussion. The subject reported feeling fatigued, feverish, and had aches after the mRNA-4157 and pembrolizumab administration and felt better after taking Nonsteroidal anti-inflammatory drugs (NSAIDs) and that these issues resolved completely after 36 hrs. Her physician informed the subject that the wrong mRNA-4157 vaccine was inadvertently administered and that it was not expected for there to be any acute or chronic issues relatedto this synthetic vaccine. The subject's physician assured the subject that there was no risk of transmissionof blood borne pathogen, such as HIV, HBV, or HCV. The subject reported feeling the same as she felt prior to injection with IP. Her physician instructed the subject to contact him if there were any changes and to come in for a follow-up visit on January 27, 2021 for labs and a safety assessment to be performedby the Principal Investigator and him. On January 27, 2021 both the Principal Investigator and the subject'sphysician, upon examination and review of the subject's safety labs deemed the subject stable.

**Root cause(s):**

- Subject Scheduling:
    - Research Coordinator processed PPD IRT Subject Visit and Vial Re-Supply notification prior to confirming that IP was on site for Subject-A. The subject's dose was not physically on-site at the time of IP administration and appropriate communication between Research Coordinator/Research Pharmacist to assure inventory was present for dose did not occur.

Obtained via FOIA by Judicial Watch Inc.

# Description of the incident

- Dispensation/Preparation (SOP deficiency):
  - Research Pharmacist did not follow Step 1 in the provided mRNA-4157 dose preparation worksheet (Step 1 = confirmation of subject i.d number) against the IRT notification and the mRNA-4157 IP Label located on the vaccine kit; as only one mRNA-4157 product was present in the 70°C freezer; and Research Pharmacist assumed this was the appropriate dose.
  - Research Pharmacist did not follow Step 2 of the worksheet (Step 2 = Remove kit of required subject i.d. number) because she did not record subject i.d number on the worksheet before applying the additional duplicate IP Label, which serves as an additional cross-check.
  - Head Pharmacist did not perform a verification of the mRNA-4157 dose preparation worksheet because Step 1 was not followed. In performing a verification, checking Research Pharmacist's work requires verification and adherence to each step of the worksheet.
  - An independent confirmation of subject i.d. number was not specified within Site SOP #303.00 (Research Drug Accountability); which is attributed as a cause for this breakdown in dispensation/preparation.
- Administration/Verification (SOP deficiency):
  - Infusion Nurse did not perform identification of the administered medication required by Step 1 in the study-provided mRNA-4157 Dose Administration Worksheet.
  - An independent confirmation of subject i.d. was not specified within Site SOP #303.00 (Research Drug Accountability); which is attributed as a cause for this breakdown during administration.
- Pharmacy Manual- Documentation Deficiency
  - Original Protocol training was completed on the dates shown below.:
    - Research Pharmacist was trained on the protocol October 5, 2020; and started preparing drug for the trial in December of 2020; however, she was not delegated this task on the Delegation of Authority log until January 29, 2021.
    - Infusion Nurse was trained on the protocol September 26, 2019; and has been administering study medication since study start.
  - The following team members reviewed the Pharmacy Manual 1.0 during Site Initiation Visit (SIV) training.
    - Head Pharmacist was trained on the protocol July 26, 2019.
  - Pharmacy Manual v2.0 was received at the site on May 1, 2020. Training/self-review of manual 2.0 was not documented by the site.

**Corrective Actions:**

- Subject-A was informed of this dosing error on January 23, 2021 and seen by Principal Investigator and her physician (and Sub-Investigator) for examination and review of her safety labs and deemed stable, as described in the summary.
- Protocol deviation was reported to both Cedars-Sinai Medical Center (CSMC) Institutional Review Board (IRB) and to Western Institutional Review Board (WIRB) on January 29, 2021, as the PI, and the Moderna Medical Monitor deemed this to be a reportable event in which there is a possibility that this raises a safety concern for the subject, despite no identifiable changes in subject's health status. The subject will continue to be monitored closely.
- The issue was entered into PPD's electronic Protocol Inquiry Platform (ePIP) by site Clinical Research Coordinator to document the deviation; and summarize Site Research Director/Moderna Medical

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# Description of the incident

Monitor's discussion on January 22, 2021 with acknowledgement of the ePIP from Moderna received January 25, 2021.

- Head Pharmacist has verified that Subject-A vaccine kit is on site and available for continued dosing.

**Preventive Actions:**

- Investigational Product (IP) will be stored separately in a designated bin labeled clearly with protocol number and subjectinitials.
- Study coordinator will confirm with research pharmacy that IP is available for dispensation prior to releasing Subject Visit and Vial Re-Supply notification.
    - Study coordinators re-trained by Head Pharmacist on proper release of Subject Visit and Vial Re-Supply notification on February 9, 2021.
        - Research pharmacist will proceed with IP dispensation upon receiving IRT confirmation and document this confirmation appropriately.
- Pharmacy Staff was re-trained by Head Pharmacist on IRT dose preparation worksheet and Dose Administration Worksheet to be utilized as a source document and checklist to confirm compliance on February 5, 2021. Documentation will be provided at next monitoring visit.
    - Research pharmacist will be retrained to verify subject i.d. number with IP label upon retrieving IP from storage and prior to preparation.
- Pharmacy Manual training for the current version (version 2.0) was conducted and documented by 26 Feb 2021.
- Two independent checks by pharmacy staff (e.g research pharmacist) will be required to ensure correct IP prior to preparation. Minimum of two subject identifiers such as initials and subject ID number will be used to verify subject identity.
- Infusion Nurses were re-trained on the study-provided mRNA-4157 Dose Administration Worksheet to utilize as a source document and checklist to confirm compliance, per protocol by Head Pharmacist on February 10, 2021. Documentation will be provided at next monitoring visit.
- PPD's Clinical Research Associate will observe any new or current subjects dosed, upon request and contingent on lifting enrollment hold.
- P3D1 (third pembrolizumab dose in combination with first dose of mRNA-4157) will be scheduled by the study coordinator according to the expected vaccine delivery date noted in the IRT Notification of Estimated Vaccine Delivery Date and/or contacting the PPD/Modernastudy team for clarification.
    - Current study coordinator has had training documented on this CAPA for awareness of this requirement by Head Pharmacist by February 19, 2021
    - Any future study coordinator will have training on the CAPA to assure awareness of scheduling requirements.
    - Planned P3D1 dates and estimated vaccine delivery dates will be communicated to the Head Pharmacist, and Research Pharmacist responsible for dose preparation via email.
- Completion of dose administration worksheet will be verified by site staff (e.g. research pharmacist or infusion nurse) prior to administering IP to the subject.
- Quality Assurance Specialist has been assigned to oversee the development of new and/or the revision of existing SOP's, as appropriate, and assure best practices for research pharmacy.
    - Revision to Site SOP #303.00 (Research Drug Accountability) has been done in order to mandate a source documented secondary check by research pharmacy (time of dispensation, upon preparation, and prior to administration) on February 12, 2021. Delegated staff were trained on this policy before February 12, 2021.

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  - Quality Assurance Specialist will verify adherence to revised SOP #303.01 (Research Drug Accountability and Dispensation) following the next scheduled mRNA-4157 dose and communicate verification with PI and Site Research Director.
- Pharmacy Supervisor will observe all remaining dispensations, preparations, and administrations to ensure that the study specific mRNA-4157 Dose Preparation Worksheet and mRNA-4157 Dose Administration Worksheet are all adhered.
- It is acknowledged that the Pharmacy Supervisor, will ensure timely conduct of Pharmacy Manual amendment training and report completion directly to the Principal Investigator.
- Principal Investigator has conducted a documented review of the training/re-training records described in this CAPA to assure adequate training has been completed; and all site staff have been appropriately documented on the Delegation of Authority log by 1 Mar 2021.

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## Hunter, Renee (NIH/OD) [C]

**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Tuesday, February 16, 2021 10:12 AM
**To:** NIH guidelines
**Subject:** Incident report involving human subject

Dear Dr. Harris,

Our IBC was recently notified of an incident associated with a clinical research protocol conducted at one of our affiliated clinical sites which involves the administration of a personalized mRNA cancer vaccine; we are currently in the process of gathering information to generate the repot to NIH.

The incident involved a Pharmacy error that resulted in a human subject participant receiving a dose from a personalized mRNA cancer vaccine manufactured and intended for a different study participant. The participant who received the dose in error reported feeling fatigued, feverish and had aches after receiving the vaccine dose, and felt better after taking NSAID; these issues resolved completely after 36 hours, and she will continue to be monitored closely.

The clinical site where this incident happened has begun to implement corrective and preventive measures in collaboration with various groups at the main medical center, including the Main Pharmacy.

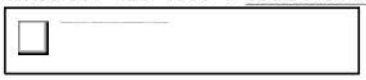
Again, we are gathering additional information and putting together the report to NIH, which we will be submitting as soon as possible.

In the meanwhile, please let me know if you require additional information.

Regards,

Javier P. Fernandez, MS, RAC, CSP, CBSP
Biosafety Officer, Environmental Health and Safety
Javier.Fernandez@cshs.org

Cedars-Sinai
8700 Beverly Boulevard, TSB-190 : Los Angeles CA 90048
office 310-423-4336 : cedars-sinai.org



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## Hunter, Renee (NIH/OD) [C]

**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Monday, March 15, 2021 6:49 PM
**To:** NIH guidelines
**Subject:** Re: Incident report involving human subject
**Attachments:** Description_of_Incident_Cedars-Sinai_Dosing_Error_Personalized_mRNA_Cancer_Vaccine.pdf; NIH_Incident_Report_Cedars-Sinai_Dosing_Error_Personalized_mRNA_Cancer_Vaccine.pdf

Dear Dr. Harris,

Attached is the Incident Report form and a separate file with a detailed description of the incident, including Corrective and Preventive Actions.

The report submission has been delayed beyond the 30-day requirement as the incident was reported and investigated internally.

Please let me know if you need additional information.

Regards,

Javier

Javier P. Fernandez, MS, RAC, CSP, CBSP
Biosafety Officer, Environmental Health and Safety
Javier.Fernandez@cshs.org

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---

**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Tuesday, February 16, 2021 7:11 AM
**To:** NIHGuidelines@od.nih.gov <NIHGuidelines@od.nih.gov>
**Subject:** Incident report involving human subject

Dear Dr. Harris,

Our IBC was recently notified of an incident associated with a clinical research protocol conducted at one of our affiliated clinical sites which involves the administration of a personalized mRNA cancer vaccine; we are currently in the process of gathering information to generate the repot to NIH.

The incident involved a Pharmacy error that resulted in a human subject participant receiving a dose from a personalized mRNA cancer vaccine manufactured and intended for a different study participant. The participant who received the dose in error reported feeling fatigued, feverish and had aches after receiving

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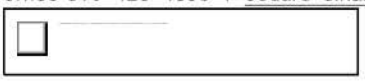
Again, we are gathering additional information and putting together the report to NIH, which we will be submitting as soon as possible.

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## Hunter, Renee (NIH/OD) [C]

**From:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Tuesday, February 16, 2021 2:22 PM
**To:** Desevilla, Liesl
**Subject:** RE: Incident Reporting Question

Dear Liesl:

Thank you for your email. If the research was not exempt from the *NIH Guidelines*, the incident would be reportable. If the mouse was exempt and no further recombinant or synthetic nucleic acid molecules were involved, the incident would not be reportable.

Basically, was the mouse purchased or transferred or generated by breeding (exempt under Appendix C-VII or C-VII) or was it generated in house (covered under III-E-3)?

Regards,

Dr. Kathryn Harris

---

**From:** Desevilla, Liesl <LDESEVIL@augusta.edu>
**Sent:** Tuesday, February 16, 2021 1:54 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident Reporting Question

Good afternoon,

We had an incident at our campus involving a mouse bite. Here are the details:

A lab worker was ear tagging a mouse when the mouse bit the worker on one of the fingers. The mouse is transgenic, with the following background - https://www.genecards.org/cgi-bin/carddisp.pl?gene=ATF3
The mouse is housed at ABSL1 containment. Mouse is healthy, no hazards were administered at the time of the incident, and the mouse does not have any significant genotypes.

Please indicate whether this is an NIH reportable event.

Your prompt response is greatly appreciated.

Kind regards,

*Liesl De Sevilla, MS*
Manager, BioSafety Programs
Environmental Health and Safety Division
Augusta University
1405 Goss Lane, CI-1003
Augusta, GA 30912
t. (706) 721-9201
f. (706) 721-9844
ldesevil@augusta.edu

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## Hunter, Renee (NIH/OD) [C]

**From:** Desevilla, Liesl <LDESEVIL@augusta.edu>
**Sent:** Tuesday, February 16, 2021 2:29 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: [EXTERNAL] RE: Incident Reporting Question

Hello,

Mouse obtained from a collaborator, not generated in house.

We will prepare our internal Incident Report and mention that this particular incident is exempt from the NIH Guidelines.

Many thanks!

Liesl

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Tuesday, February 16, 2021 2:22 PM
**To:** Desevilla, Liesl <LDESEVIL@augusta.edu>
**Subject:** [EXTERNAL] RE: Incident Reporting Question

**CAUTION: EXTERNAL SENDER**

**This email originated from an external source. Please exercise caution before opening attachments, clicking links, replying, or providing information to the sender. If you believe it to be fraudulent, contact the AU Cybersecurity Hotline at 72-CYBER (2-9237 / 706-722-9237) or 72CYBER@augusta.edu.**

---

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Dr. Kathryn Harris

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**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident Reporting Question

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ldesevil@augusta.edu

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 2, 2021 12:03 PM
**To:** Buissereth, Landau; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report - Icahn School of Medicine at Mount Sinai

Dear Landau Buissereth,

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. However, we note that the incident was not immediately reported and medical evaluation was not sought until the day after the incident. We recommend reminding employees 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Buissereth, Landau <landau.buissereth@mssm.edu>
**Sent:** Tuesday, February 16, 2021 7:38 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident Report - Icahn School of Medicine at Mount Sinai

Good Morning,

To follow-up on my phone call/voicemail report on Friday afternoon (2/12/20), please see the attached a written incident report for full details.

The incident involved a personnel exposure to a transduced human cell line via splash to the eye. The human cell line was transduced with a lentiviral vector approximately 40 days prior to the exposure, and was passage 3.

Thanks,
Landau



Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 2, 2021 12:03 PM
**To:** Buissereth, Landau; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
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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

---

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**To:** NIH guidelines <NIHguidelines@od.nih.gov>
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Landau

Mount Sinai

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**Landau Buissereth, RBP, MS**
**Associate Director, Biosafety Program**
**Biological Safety Officer (BSO)**
Mount Sinai Health System
One Gustave L. Levy Place
New York, NY 10029
Office: 212-241-3761
Mobile: Redacted by agreement
E-mail: landau.buissereth@mssm.edu
Website: https://icahn.mssm.edu/research/institutional-biosafety
SECTOR: https://labcliq.com/l/mount_sinai/

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Icahn School of Medicine at Mount Sinai |
| **Date of Report:** | 1/12/21 (date incident reported by exposed laboratory personnel) |
| **Reporter name and position:** | Landau Buissereth<br>Associate Director, Biosafety Program<br>Biological Safety Officer (BSO) |
| **Telephone number:** | 212-241-3761 |
| **Email address:** | landau.buissereth@mssm.edu |
| **Reporter mailing address:** | 1 Gustave L. Levy Place<br>New York, NY 10029-6574 |
| **Date of incident:** | 1/11/21 |
| **Name of Principal Investigator:** | Ramon Parsons, MD, PhD |
| **Is this an NIH-funded project?** | ☐ YES ☐ NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>▣ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ▣ NO<br><br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | For the specific incident, personnel was exposed to a human cell line transduced by replication defective viral vector. The work with viral vector system would apply to Section III-D-1 and potentially Section III-E-1. |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Human cell line transduced by lentivirus approximately 40 days prior to exposure. The lentivirus was made from psPAX2 (Addgene ID 12260), a 2nd generation packaging plasmid that contains Gag, Pol, Rev, and Tat and can be used with 2nd and 3rd generation transfer plasmids. The vector contained a doxycycline-inducible construct. https://www.addgene.org/12260/ |

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 1/11/21 at approximately 5:00 PM, the personnel (PhD student) was exposed to a cell suspension containing a human breast cancer cell line through a small splash of liquid in her left eye while in her laboratory (a BSL-2 area). She approximates that the volume was around 10-20 ul (a small droplet). She was performing tissue culture work and was splitting the MDA-MB-468 (ATCC HTB-132) human cell line. While working, she felt some of the cell suspension splashed into her left eye. She immediately washed her eye out with water in the bathroom. The splash occurred when the personnel was disposing of the serological pipette that she had used to transfer the cell suspension. The tip of the pipette got stuck in the metal grate in the front of the biosafety cabinet where the air flows out from and some of the liquid on the pipette tip splashed into her eye.

The cell suspension contained DMEM (Dulbecco's Modified Eagle Medium) with 10% FBS (fetal bovine serum), 1% Pen/Strep (Penicillin Streptomycin) and also contained 0.25% trypsin (5 ml media to 1 ml trypsin total) and the cell density of the suspension was 1.13x10^3 cells/ul. Per the safety data sheet (attachment available) on ATCC for the cell line, its states "This cell line is not known to cause disease in healthy adult humans. These cells have not been screened for Hepatitis B, human immunodeficiency viruses or other adventitious agents, unless otherwise reported on the Certificate of Analysis." The cells were from a common lab stock. The personnel does not have the lot number for the cells that she was growing and therefore could not download the Certificate of Analysis. She was able to find a COA for a recent stock of MDA-MB-468 cells that was recently ordered from ATCC as a representative document (attachment available).

The cells that the personnel was working with were previously transduced on 12/1/20 (approximately 40 days before the exposure incident) with a lentiviral vector containing a doxycycline-inducible construct; the cells had undergone antibiotic selection and were now passage 3. She has saved the rest of the original cell suspension in two 2 ml aliquots stored at 4*C and -80*C in case the samples can be tested for the presence of any infectious agents.

The incident was reported by the exposed personnel via e-mail to the Environmental Health & Safety e-mail address on 1/12/21 at 12:07 AM. It was forwarded in the morning to the Biosafety Program and Employee Health Services Deputy Medical Director. Employee Health Services advised the employee that her case will be assessed under Mount Sinai's BBFE (Blood or Body Fluid* Exposure) protocol and will monitor her for any infectious disease exposures, and advise her to visit their office for clinical evaluation. The employee made an appointment for 1:30 PM on this same date (1/12/21) for clinical evaluation.

The Biosafety Program Director asked the employee to provide more information about the lentiviral vector that was utilized. The personnel stated that it was 2nd generation lentiviral system from Addgene that was not replicative and had been modified for laboratory use. She made the vector using a transfer plasmid (psPAX2), which is listed as a 2nd generation plasmid. Per Addgene literature, "For safety reasons, transfer plasmids are all replication incompetent and may contain an additional deletion in the 3'LTR, rendering the virus “self-inactivating” (SIN) after integration." Additionally, "Unless recombination occurs between the packaging, envelope, and transfer vectors, and the resulting construct is packaged into a viral particle, it is not possible for viruses normally produced from these systems to replicate and produce more

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ▣ NO |
| **Please describe the root cause of this incident:** | When disposing of the serological pipette that was had used to transfer the cell suspension, the tip of the pipette got stuck in the metal grate in the front of the biosafety cabinet where the air flows out from and some of the liquid on the pipette tip splashed into her eye. |

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):

- Recommend personnel wear eye protection as an additional precaution.

- Advise personnel to complete Bloodborne Pathogens Training and to do so annually moving forward.

- Since the personnel stated that she washed out her her eye in the bathroom: 1) advise personnel on the location of the nearest eyewash and 2) assess location to determine if additional measures are needed (e.g. signage for eyewash location).

- **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:** Buissereth, Landau <landau.buissereth@mssm.edu>
**Sent:** Tuesday, March 2, 2021 10:03 PM
**To:** McKinney, Michelle (NIH/OD) [E]; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report - Icahn School of Medicine at Mount Sinai

Hi Michelle,

Thank you, we'll reach out to our personnel to remind them to immediately report incidents and seek medical evaluation after an exposure incident. I'll discuss with our IBC and applicable officials.

Best,
Landau




**Landau Buissereth, RBP, MS**
**Associate Director, Biosafety Program**
**Biological Safety Officer (BSO)**
Mount Sinai Health System
One Gustave L. Levy Place
New York, NY 10029
Office: 212-241-3761
Mobile: Redacted by agreement
E-mail: landau.buissereth@mssm.edu
Website: https://icahn.mssm.edu/research/institutional-biosafety
SECTOR: https://labcliq.com/l/mount_sinai/

---

**From:** McKinney, Michelle (NIH/OD) [E] <michelle.mckinney@nih.gov>
**Sent:** Tuesday, March 02, 2021 12:03 PM
**To:** Buissereth, Landau <landau.buissereth@mssm.edu>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Subject:** RE: Incident Report - Icahn School of Medicine at Mount Sinai

USE CAUTION: External Message.

Dear Landau Buissereth,

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. However, we note that the incident was not immediately reported and medical evaluation was not sought until the day after the incident. We recommend reminding employees 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.

Obtained via FOIA by Judicial Watch Inc.

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

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**From:** Buissereth, Landau <landau.buissereth@mssm.edu>
**Sent:** Tuesday, February 16, 2021 7:38 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident Report - Icahn School of Medicine at Mount Sinai

Good Morning,

To follow-up on my phone call/voicemail report on Friday afternoon (2/12/20), please see the attached a written incident report for full details.

The incident involved a personnel exposure to a transduced human cell line via splash to the eye. The human cell line was transduced with a lentiviral vector approximately 40 days prior to the exposure, and was passage 3.

Thanks,
Landau

**Landau Buissereth, RBP, MS**
**Associate Director, Biosafety Program**
**Biological Safety Officer (BSO)**
Mount Sinai Health System
One Gustave L. Levy Place
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**From:** Buissereth, Landau <landau.buissereth@mssm.edu>
**Sent:** Tuesday, February 16, 2021 7:38 AM
**To:** NIH guidelines
**Subject:** Incident Report - Icahn School of Medicine at Mount Sinai
**Attachments:** Incident Report_IcahnSchoolofMedicineatMountSinai.pdf

Good Morning,

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The incident involved a personnel exposure to a transduced human cell line via splash to the eye. The human cell line was transduced with a lentiviral vector approximately 40 days prior to the exposure, and was passage 3.

Thanks,
Landau

**Landau Buissereth, RBP, MS**
**Associate Director, Biosafety Program**
**Biological Safety Officer (BSO)**
Mount Sinai Health System
One Gustave L. Levy Place
New York, NY 10029
Office: 212-241-3761
Mobile: Redacted by agreement
E-mail: landau.buissereth@mssm.edu
Website: https://icahn.mssm.edu/research/institutional-biosafety
SECTOR: https://labcliq.com/l/mount_sinai/

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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Cedars-Sinai Medical Center |
| **Date of Report:** | 2021/03/15 |
| **Reporter name and position:** | Javier P. Fernandez (Biosafety Officer) |
| **Telephone number:** | (310) 423-4336 |
| **Email address:** | Javier.Fernandez@cshs.org |
| **Reporter mailing address:** | 8700 Beverly Boulevard<br>TSB-190<br>Los Angeles, CA 90048 |
| **Date of incident:** | 2021/01/12 |
| **Name of Principal Investigator:** | Mark Faries, M.D. |
| **Is this an NIH-funded project?** | ☐YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☒ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ☐ NO<br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☒ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐ State or local Public Health<br>☒ FDA ☐ Law enforcement<br>☐ EPA ☒ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Personalized mRNA cancer vaccine |

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 1/11/21 at approximately 5:00 PM, the personnel (PhD student) was exposed to a cell suspension containing a human breast cancer cell line through a small splash of liquid in her left eye while in her laboratory (a BSL-2 area). She approximates that the volume was around 10-20 ul (a small droplet). She was performing tissue culture work and was splitting the MDA-MB-468 (ATCC HTB-132) human cell line. While working, she felt some of the cell suspension splashed into her left eye. She immediately washed her eye out with water in the bathroom. The splash occurred when the personnel was disposing of the serological pipette that she had used to transfer the cell suspension. The tip of the pipette got stuck in the metal grate in the front of the biosafety cabinet where the air flows out from and some of the liquid on the pipette tip splashed into her eye.

The cell suspension contained DMEM (Dulbecco's Modified Eagle Medium) with 10% FBS (fetal bovine serum), 1% Pen/Strep (Penicillin Streptomycin) and also contained 0.25% trypsin (5 ml media to 1 ml trypsin total) and the cell density of the suspension was 1.13x10^3 cells/ul. Per the safety data sheet (attachment available) on ATCC for the cell line, its states "This cell line is not known to cause disease in healthy adult humans. These cells have not been screened for Hepatitis B, human immunodeficiency viruses or other adventitious agents, unless otherwise reported on the Certificate of Analysis." The cells were from a common lab stock. The personnel does not have the lot number for the cells that she was growing and therefore could not download the Certificate of Analysis. She was able to find a COA for a recent stock of MDA-MB-468 cells that was recently ordered from ATCC as a representative document (attachment available).

The cells that the personnel was working with were previously transduced on 12/1/20 (approximately 40 days before the exposure incident) with a lentiviral vector containing a doxycycline-inducible construct; the cells had undergone antibiotic selection and were now passage 3. She has saved the rest of the original cell suspension in two 2 ml aliquots stored at 4*C and -80*C in case the samples can be tested for the presence of any infectious agents.

The incident was reported by the exposed personnel via e-mail to the Environmental Health & Safety e-mail address on 1/12/21 at 12:07 AM. It was forwarded in the morning to the Biosafety Program and Employee Health Services Deputy Medical Director. Employee Health Services advised the employee that her case will be assessed under Mount Sinai's BBFE (Blood or Body Fluid* Exposure) protocol and will monitor her for any infectious disease exposures, and advise her to visit their office for clinical evaluation. The employee made an appointment for 1:30 PM on this same date (1/12/21) for clinical evaluation.

The Biosafety Program Director asked the employee to provide more information about the lentiviral vector that was utilized. The personnel stated that it was 2nd generation lentiviral system from Addgene that was not replicative and had been modified for laboratory use. She made the vector using a transfer plasmid (psPAX2), which is listed as a 2nd generation plasmid. Per Addgene literature, "For safety reasons, transfer plasmids are all replication incompetent and may contain an additional deletion in the 3'LTR, rendering the virus “self-inactivating” (SIN) after integration." Additionally, "Unless recombination occurs between the packaging, envelope, and transfer vectors, and the resulting construct is packaged into a viral particle, it is not possible for viruses normally produced from these systems to replicate and produce more

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ▣ NO |
| **Please describe the root cause of this incident:** | When disposing of the serological pipette that was had used to transfer the cell suspension, the tip of the pipette got stuck in the metal grate in the front of the biosafety cabinet where the air flows out from and some of the liquid on the pipette tip splashed into her eye. |

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):

- Recommend personnel wear eye protection as an additional precaution.

- Advise personnel to complete Bloodborne Pathogens Training and to do so annually moving forward.

- Since the personnel stated that she washed out her her eye in the bathroom: 1) advise personnel on the location of the nearest eyewash and 2) assess location to determine if additional measures are needed (e.g. signage for eyewash location).

- **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:** Buissereth, Landau <landau.buissereth@mssm.edu>
**Sent:** Tuesday, March 2, 2021 10:03 PM
**To:** McKinney, Michelle (NIH/OD) [E]; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report - Icahn School of Medicine at Mount Sinai

Hi Michelle,

Thank you, we'll reach out to our personnel to remind them to immediately report incidents and seek medical evaluation after an exposure incident. I'll discuss with our IBC and applicable officials.

Best,
Landau




**Landau Buissereth, RBP, MS**
**Associate Director, Biosafety Program**
**Biological Safety Officer (BSO)**
Mount Sinai Health System
One Gustave L. Levy Place
New York, NY 10029
Office: 212-241-3761
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E-mail: landau.buissereth@mssm.edu
Website: https://icahn.mssm.edu/research/institutional-biosafety
SECTOR: https://labcliq.com/l/mount_sinai/

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**Sent:** Tuesday, March 02, 2021 12:03 PM
**To:** Buissereth, Landau <landau.buissereth@mssm.edu>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Subject:** RE: Incident Report - Icahn School of Medicine at Mount Sinai

USE CAUTION: External Message.

Dear Landau Buissereth,

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. However, we note that the incident was not immediately reported and medical evaluation was not sought until the day after the incident. We recommend reminding employees 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.

Obtained via FOIA by Judicial Watch Inc.

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:** Buissereth, Landau <landau.buissereth@mssm.edu>
**Sent:** Tuesday, February 16, 2021 7:38 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident Report - Icahn School of Medicine at Mount Sinai

Good Morning,

To follow-up on my phone call/voicemail report on Friday afternoon (2/12/20), please see the attached a written incident report for full details.

The incident involved a personnel exposure to a transduced human cell line via splash to the eye. The human cell line was transduced with a lentiviral vector approximately 40 days prior to the exposure, and was passage 3.

Thanks,
Landau




**Landau Buissereth, RBP, MS**
**Associate Director, Biosafety Program**
**Biological Safety Officer (BSO)**
Mount Sinai Health System
One Gustave L. Levy Place
New York, NY 10029
Office: 212-241-3761
Mobile: Redacted by agreement
E-mail: landau.buissereth@mssm.edu
Website: https://icahn.mssm.edu/research/institutional-biosafety
SECTOR: https://labcliq.com/l/mount_sinai/

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

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**Sent:** Tuesday, February 16, 2021 7:38 AM
**To:** NIH guidelines
**Subject:** Incident Report - Icahn School of Medicine at Mount Sinai
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One Gustave L. Levy Place
New York, NY 10029
Office: 212-241-3761
Mobile: Redacted by agreement
E-mail: landau.buissereth@mssm.edu
Website: https://icahn.mssm.edu/research/institutional-biosafety
SECTOR: https://labcliq.com/l/mount_sinai/

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 2, 2021 10:19 AM
**To:** Indiana University IBC; NIH guidelines
**Cc:** Biosafety Program at IUPUI; Baumann, John R; Vidal, Ruben; Dong, X Charlie; Jones, Stephanie; Winters, Emily Jean; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: IUPUI IBC - 30 Day Report
**Signed By:** michelle.mckinney@nih.gov

Dear Holly Moore,

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:** Indiana University IBC <ibc@iu.edu>
**Sent:** Friday, February 19, 2021 10:05 AM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Biosafety Program at IUPUI <ehsbio@iupui.edu>; Baumann, John R <baumannj@iu.edu>; Vidal, Ruben <rvidal@iupui.edu>; Dong, X Charlie <xcdong@iupui.edu>; Jones, Stephanie <strrober@iu.edu>; Winters, Emily Jean <ejwinter@iu.edu>
**Subject:** RE: IUPUI IBC - 30 Day Report

Good morning Dr. Harris,

Thank you for talking with me yesterday. Below, please find the IUPUI IBC follow-up to the 30 day report for Dr. Frank Yang.

Dr. Yang is approved to conduct the *B. burgdorferi* membrane implantation experiments in rats in a LARC BL-2 facility. Dr. Yang is required to notify LARC staff 3 days before beginning the experiments to allow LARC time to update signage and make staff aware of the infected animals. He is required to house infected animals in LARC and is not allowed to house them in his lab. Instead of conducting the experiment in the LARC BL-2 space, Dr. Yang removed his rats from LARC and conducted the experiments in an unapproved (for rat experimentation) BL-2 lab, following BL-2 containment requirements. In this space, lab members wear disposable gowns, splash goggles, and a mask when performing rat implantation experiments. The dialysis tubing containing the bacteria is prepared in another approved location inside of a biosafety cabinet and transported inside of a closed secondary container to the implantation room. All waste is

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collected at the end of the implantation surgery and removed from the room to be autoclaved. Surfaces are decontaminated with 70% ethanol or fresh 10% bleach. Dr. Yang is approved to use that particular BL-2 lab space for the same experiments in mice at BL-2, however mice & rats must return to the LARC BL-2 facility for housing after implantation and infection. Dr. Yang housed the infected rats in his unapproved BL-2 lab for 2 days before returning them to LARC and did not notify LARC that the infected rats were being returned.

After gathering these details about the incident, the IBC further discussed the appropriate follow-up actions to Dr. Yang's non-compliance. The IBC and IACUC are drafting a letter to Dr. Yang and his laboratory informing him that further non-compliance from his lab may result in the suspension of his research. The IBC will also require that the PI and is lab members re-take animal housing training. The PI has updated his IBC protocol to include the rat experiment in the BL-2 lab.

Please let me know if further detail is needed. We are happy to help!

*Holly*

**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
Indiana University
**Phone:** 812.855.0656
**Email:** holmoore@iu.edu
**Web:** https://research.iu.edu/compliance/

**Click here see upcoming IBC meeting dates and deadlines.**

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, February 18, 2021 3:44 PM
**To:** Indiana University IBC <ibc@iu.edu>
**Subject:** [External] RE: IUPUI IBC - 30 Day Report

Hi Holly:

Thank for your report. I have a few quick follow up questions. Is there a good time and number to reach you?

Regards,

Dr. Kathryn Harris

---

**From:** Indiana University IBC <ibc@iu.edu>
**Sent:** Wednesday, February 17, 2021 12:05 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Yang, Frank <xfyang@iu.edu>; Biosafety Program at IUPUI <ehsbio@iupui.edu>; Baumann, John R <baumannj@iu.edu>; Vidal, Ruben <rvidal@iupui.edu>; Dong, X Charlie <xcdong@iupui.edu>; Swank, Eric D. <edswank@iu.edu>; Jones, Stephanie <strrober@iu.edu>; Winters, Emily Jean <ejwinter@iu.edu>
**Subject:** IUPUI IBC - 30 Day Report

Dear NIH OSP:

Obtained via FOIA by Judicial Watch Inc.

Please find below the details of an incident involving recombinant DNA from the Indiana University–Purdue University Indianapolis (IUPUI) IBC.

**Date of Incident:** Confirmed on January 21, 2021. Experiments performed from 1/12/2021-1/15/2021
**Name of PI:** Frank Yang
**Nature of Incident:** Failure to follow approved containment conditions; Failure to obtain IBC approval

**Nature of recombinant or synthetic material involved:** Modified *Borrelia burgdorferi*, expressing bacterial transcriptional regulators, not known to be oncogenic or toxic.

**Description:** The PI has IBC approval to use a rat implantation model to study mutant gene expression by implanting a 1.5-inch length of dialysis membrane containing 5 mL of modified *B. burgdorferi* into the peritoneal cavity of a rat. The PI was approved for this experiment, but only within a designated LARC space. In November 2020, the PI notified LARC staff that the rats were not infected, so the animals were housed as non-infected animals. On Tuesday, January 12, the animals were gone from their housing room in LARC. The animals were not present through January 14, and LARC received no notice of this from the PI. On January 15, the animals were returned to LARC, infected with *B. burgdorferi*. The PI failed to notify LARC that the animals had been infected. LARC requires 3 days' notice prior to surgery, which is essential to protect LARC personnel from ABSL-2 agents. LARC had to quickly update the signage and checklists for LARC staff going into the holiday weekend.

Additionally, this assay is not covered in the PI's IACUC protocol and it is not known what biosafety measures were taken in the PI's lab.

**Cause:** Lack of communication from the PI regarding schedule of experiments; Not following the requirements of the IU IBC, which requires that PIs update their protocols to include all lab spaces and the activities performed therein; PI not following approved IBC and IACUC protocols

**Actions Taken:** The IUPUI IBC reviewed the incident at the January 21 meeting, before a clear timeline and all experimental details were available. The IBC recommended a letter be sent to the PI reiterating the policies and procedures required for work involving recombinant agents with animals and that the PI submit an amendment to the IBC before continuing this work.

If you have any questions regarding the incident, please feel welcome to contact the IUPUI IBC Office at IBC@iu.edu.

*Holly*

**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
Indiana University
**Phone:** 812.855.0656
**Email:** holmoore@iu.edu
**Web:** https://research.iu.edu/compliance/

**Click here see upcoming IBC meeting dates and deadlines.**

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## Hunter, Renee (NIH/OD) [C]

**From:** Indiana University IBC <ibc@iu.edu>
**Sent:** Friday, February 19, 2021 10:05 AM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Biosafety Program at IUPUI; Baumann, John R; Vidal, Ruben; Dong, X Charlie; Jones, Stephanie; Winters, Emily Jean
**Subject:** RE: IUPUI IBC - 30 Day Report
**Signed By:** ibc@iu.edu

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Thank you for talking with me yesterday. Below, please find the IUPUI IBC follow-up to the 30 day report for Dr. Frank Yang.

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After gathering these details about the incident, the IBC further discussed the appropriate follow-up actions to Dr. Yang's non-compliance. The IBC and IACUC are drafting a letter to Dr. Yang and his laboratory informing him that further non-compliance from his lab may result in the suspension of his research. The IBC will also require that the PI and is lab members re-take animal housing training. The PI has updated his IBC protocol to include the rat experiment in the BL-2 lab.

Please let me know if further detail is needed. We are happy to help!

*Holly*

**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
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**Phone:** 812.855.0656
**Email:** holmoore@iu.edu
**Web:** https://research.iu.edu/compliance/

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**Sent:** Thursday, February 18, 2021 3:44 PM
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Regards,

Dr. Kathryn Harris

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**Actions Taken:** The IUPUI IBC reviewed the incident at the January 21 meeting, before a clear timeline and all experimental details were available. The IBC recommended a letter be sent to the PI reiterating the policies and procedures required for work involving recombinant agents with animals and that the PI submit an amendment to the IBC before continuing this work.

If you have any questions regarding the incident, please feel welcome to contact the IUPUI IBC Office at IBC@iu.edu.

*Holly*



**Holly A. Moore**
Pronouns: *she, her, hers*
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IUPUI Radiation Safety Committees
Office of Research Compliance
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**Click here see upcoming IBC meeting dates and deadlines.**

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

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**Sent:** Wednesday, February 17, 2021 12:05 PM
**To:** NIH guidelines
**Cc:** Yang, Frank; Biosafety Program at IUPUI; Baumann, John R; Vidal, Ruben; Dong, X Charlie; Swank, Eric D.; Jones, Stephanie; Winters, Emily Jean
**Subject:** IUPUI IBC - 30 Day Report
**Signed By:** ibc@iu.edu

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Holly

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**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
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**Web:** https://research.iu.edu/compliance/

**Click here see upcoming IBC meeting dates and deadlines.**

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Shannon Reynolds <shannonr@alleninstitute.org>
**Sent:** Thursday, April 1, 2021 12:42 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Hongkui Zeng; Rebecca Hodge
**Subject:** RE: Reportable Exposure
**Attachments:** Incident-Report Risk Group 2 Exposure (4-1-2021)_Final.docx

Hi Kathryn,

Thank you for the reminder. The report was nearly complete, pending confirmation of whether or not this exposure was related to an NIH award. I was able to confirm that information this morning and the final report is attached for your review.

We had a similar exposure in 2016 due to exposure from a glass pipette tip. The tip of the pipettes are pulled until they are very thin and hard to see. If you have any additional recommendations related to this type of exposure we would appreciate your feedback.

I have cc'd the PI for this grant and our IBC Chair for visibility.

*Thanks,*

**Shannon Reynolds**
Program Manager, Research Compliance
(she / her)
T: 206.548.8443
M: Redacted by agreement
E: shannonr@alleninstitute.org

ALLEN INSTITUTE

alleninstitute.org

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, April 1, 2021 6:37 AM
**To:** Shannon Reynolds <shannonr@alleninstitute.org>
**Subject:** RE: Reportable Exposure

**CAUTION:** This email originated from outside the Allen Institute. Please do not click links or open attachments unless you've validated the sender and know the content is safe.

Dear Shannon:

Just following up to see if a final report was available yet (I apologize if we missed it coming in).

Regards,

Obtained via FOIA by Judicial Watch Inc.

Dr. Kathryn Harris

---

**From:** Shannon Reynolds <shannonr@alleninstitute.org>
**Sent:** Friday, February 19, 2021 7:19 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Reportable Exposure

Good afternoon,

I am writing to provide an initial report of an employee exposure to a Risk Group 2 rDNA viral vector at our institution. I will submit a full report using the template on your website in the next few weeks.

This exposure involved a small cut by a glass pipette tip after it had been used to administer a G-deleted rabies vector to a transgenic mouse. The employee scrubbed the exposure and then sought medical evaluation. No follow-up care was needed and the wound itself was minor.

Please let me know if you need any additional details at this time.

*Thanks,*

**Shannon Reynolds**
Program Manager, Research Compliance
(she / her)
T: 206.548.8443
M: Redacted by agreement
E: shannonr@alleninstitute.org

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alleninstitute.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

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | X YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Allen Institute |
| **Date of Report:** | February 19, 2021 |
| **Reporter name and position:** | Shannon Reynolds, Research Compliance Program Manager |
| **Telephone number:** | (206) 229-8647 (remote) |
| **Email address:** | shannonr@alleninstitute.org |
| **Reporter mailing address:** | 615 Westlake Ave. N.<br>Seattle, WA 98109 |
| **Date of incident:** | January 27, 2021 |
| **Name of Principal Investigator:** | Hongkui Zeng |
| **Is this an NIH-funded project?** | X YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* 1U19MH114830<br>*NIH funding institute or center:* NIH (NIMH)<br>*NIH program officer (name, email address):* Yong Yao (yyao@mail.nih.gov) |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ X YES ☐NO<br><br>If yes, date of approval: August 9, 2019 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA – listed on OSHA 200 Log only |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | The virus is a modified Rabies (cSPBN (pSAD) backbone). It was generated as described in this paper (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6503322/). We have received the virus directly from the Wickersham lab.<br><br>This virus has the gene, "G" (NCBI symbol: RABVgp4), encoding the viral envelope glycoprotein, and the L gene (NCBI symbol: RABVgp5), encoding the viral polymerase, deleted from the genome. The glycoprotein is required for the final steps of the viral life cycle, this deletion prevents the virus |

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| | |
|---|---|
| | from spreading beyond initially infected cells, but it does not prevent the virus from completing the entirety of its replication cycle up to that point. The L gene encodes the viral polymerase, which is required both for transcription of viral genes and for replication of the viral genome.<br><br>Plasmid info from addgene: http://www.addgene.org/98039/ |

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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)

The exposure occurred in a Biosafety Level 2 laboratory room used for survival surgery. A Research Associate had performed a stereotaxic injection of the modified Rabies vector into a mouse using a pulled glass pipette. After the procedure was completed, the RA was switching from one micro-injection machine to another and organizing the wires beneath the pipette holder, when they lifted their hand up instead of out, and were cut by the sharp tip of the glass pipette that had been used to administer the viral solution to the mouse. Other surgeons were present but were not impacted by the exposure.

The RA was directed to wash the wound with soap and water for 15 minutes and then go to our Occupational Health Provider for consultation on the exposure and to ensure that there was no glass in the wound. Information on the viral vector was provided to the RA who took it with them and shared it with the physician. No further treatment was needed due to the engineered safety features of the viral tracer.

The RA completed Biosafety for Lab employees and Biosafety for employees working with rDNA (CITI Program) in January 2020 (at hire). Subsequently, hands on training on the surgical procedures and SOPs for performing tracer injections was completed in October 2020.

At the time of the incident, the RA had just completed performing a viral injection as described in SOP AF0111 (Injection of Viral Tracers by Nanoject). The incident occurred after the completion of the procedure and there was no SOP non-compliance associated with this incident.

There were no deviations from the IBC approval conditions or containment level at the time of the incident.

The personal protective equipment in use at the time of the incident were nitrile gloves, lab coat, and surgical mask.

All employees who work with Risk Group 2 materials are informed of the IBC approvals and related safety procedures at the time they are added to the IBC Registration. In addition, employees who work with animals receive training on biosafety hazards associated with animals, and occupational health hazards associated with working in the vivarium.

There was no medical treatment or surveillance recommended after the incident. The only injury associated with the exposure was the soft tissue damage (cut and bruising) to the person's hand.

This exposure did not involve any equipment failures, but occurred due to the long, very thin tip of the pulled glass pipette being difficult to visualize while reaching below the equipment and the accidental upward movement of the person's hand when they were removing it.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO |
| **Please describe the root cause of this incident:** | Accidental injury due to human error. |

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 employee's supervisor said that surgeons will be instructed to remove the pipette from the equipment before reaching beneath it to make adjustments whenever possible. This is not always possible because sometimes multiple injections are performed using the same pipette, in these cases people will be instructed to remain very aware of their hands and the sharps hazard when making adjustments while the pipette is still mounted to the equipment.

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, April 14, 2021 2:31 PM
**To:** Shannon Reynolds; NIH guidelines
**Cc:** Hongkui Zeng; Rebecca Hodge; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Reportable Exposure

Dear Shannon Reynolds,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). No further information is required at this time.

However, we note that the incident occurred on January 27, 2021, and was not reported to NIH OSP until February 19, 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Shannon Reynolds <shannonr@alleninstitute.org>
**Sent:** Thursday, April 1, 2021 12:42 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Hongkui Zeng <HongkuiZ@alleninstitute.org>; Rebecca Hodge <rebeccah@alleninstitute.org>
**Subject:** RE: Reportable Exposure

Hi Kathryn,

Thank you for the reminder. The report was nearly complete, pending confirmation of whether or not this exposure was related to an NIH award. I was able to confirm that information this morning and the final report is attached for your review.

We had a similar exposure in 2016 due to exposure from a glass pipette tip. The tip of the pipettes are pulled until they are very thin and hard to see. If you have any additional recommendations related to this type of exposure we would appreciate your feedback.

I have cc'd the PI for this grant and our IBC Chair for visibility.

*Thanks,*

Obtained via FOIA by Judicial Watch Inc.

**Shannon Reynolds**
Program Manager, Research Compliance
(she / her)
T: 206.548.8443
M: Redacted by agreement
E: shannonr@alleninstitute.org

ALLEN INSTITUTE

alleninstitute.org

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, April 1, 2021 6:37 AM
**To:** Shannon Reynolds <shannonr@alleninstitute.org>
**Subject:** RE: Reportable Exposure

**CAUTION:** This email originated from outside the Allen Institute. Please do not click links or open attachments unless you've validated the sender and know the content is safe.

---

Dear Shannon:

Just following up to see if a final report was available yet (I apologize if we missed it coming in).

Regards,

Dr. Kathryn Harris

---

**From:** Shannon Reynolds <shannonr@alleninstitute.org>
**Sent:** Friday, February 19, 2021 7:19 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Reportable Exposure

Good afternoon,

I am writing to provide an initial report of an employee exposure to a Risk Group 2 rDNA viral vector at our institution. I will submit a full report using the template on your website in the next few weeks.

This exposure involved a small cut by a glass pipette tip after it had been used to administer a G-deleted rabies vector to a transgenic mouse. The employee scrubbed the exposure and then sought medical evaluation. No follow-up care was needed and the wound itself was minor.

Please let me know if you need any additional details at this time.

*Thanks,*

**Shannon Reynolds**
Program Manager, Research Compliance
(she / her)
T: 206.548.8443

Obtained via FOIA by Judicial Watch Inc.

M: Redacted by agreement
E: shannonr@alleninstitute.org

ALLEN INSTITUTE

alleninstitute.org

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Shannon Reynolds <shannonr@alleninstitute.org>
**Sent:** Friday, February 19, 2021 7:19 PM
**To:** NIH guidelines
**Subject:** Reportable Exposure

Good afternoon,

I am writing to provide an initial report of an employee exposure to a Risk Group 2 rDNA viral vector at our institution. I will submit a full report using the template on your website in the next few weeks.

This exposure involved a small cut by a glass pipette tip after it had been used to administer a G-deleted rabies vector to a transgenic mouse. The employee scrubbed the exposure and then sought medical evaluation. No follow-up care was needed and the wound itself was minor.

Please let me know if you need any additional details at this time.

*Thanks,*

**Shannon Reynolds**
Program Manager, Research Compliance
(she / her)
T: 206.548.8443
M: Redacted by agreement
E: shannonr@alleninstitute.org

ALLEN INSTITUTE

alleninstitute.org

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Thursday, February 25, 2021 8:12 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Kara Drolet
**Subject:** Initial report of two incidents at OHSU

Dear Dr. Harris,

This email serves as the initial notification of two potential exposures that occurred at Oregon Health & Science University.

- It was reported to the IBC on 2/23/2021 that an animal technician was splashed in the eye while working with SHIV infected non-human primates
- It was reported to the IBC on 2/24/2021 that an animal technician cut their thumb while working with a nonhuman primate infected with recombinant RhCMV.

Complete reports of the incidents and follow up actions 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:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Tuesday, April 20, 2021 3:08 PM
**To:** Sarah Byers; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Initial report of two incidents at OHSU
**Attachments:** 02222021 OHSU Eye Splash final report.pdf

Hello Dr. Harris,
Here is the final report for the eye splash incident.
We are still gathering follow up information on the other incident at this time.
Thank you, and let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Pronouns: she/her/hers
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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

---

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Friday, April 2, 2021 10:54 AM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** RE: Initial report of two incidents at OHSU

Hello Dr. Harris,

OHSU is still doing follow up regarding one incident and will soon send the final report for the other incident.

Sarah

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, April 1, 2021 6:40 AM
**To:** Sarah Byers <byerssa@ohsu.edu>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** [EXTERNAL] RE: Initial report of two incidents at OHSU

Dear Dr. Byers:

Just following up to see if the final reports are available yet (I apologize if we missed them coming in).

Obtained via FOIA by Judicial Watch Inc.

Regards,

Dr. Kathryn Harris

---

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Thursday, February 25, 2021 8:12 PM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** Initial report of two incidents at OHSU

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Complete reports of the incidents and follow up actions 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:** Thursday, May 6, 2021 1:51 PM
**To:** Kara Drolet; Sarah Byers; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Initial report of two incidents at OHSU

Dear Dr. Kara Manning Drolet,

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:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Tuesday, April 20, 2021 3:08 PM
**To:** Sarah Byers <byerssa@ohsu.edu>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Subject:** RE: Initial report of two incidents at OHSU

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We are still gathering follow up information on the other incident at this time.
Thank you, and let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Pronouns: she/her/hers
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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Friday, April 2, 2021 10:54 AM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** RE: Initial report of two incidents at OHSU

Hello Dr. Harris,

OHSU is still doing follow up regarding one incident and will soon send the final report for the other incident.

Sarah

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**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, April 1, 2021 6:40 AM
**To:** Sarah Byers <byerssa@ohsu.edu>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** [EXTERNAL] RE: Initial report of two incidents at OHSU

Dear Dr. Byers:

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Regards,

Dr. Kathryn Harris

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**Sent:** Thursday, February 25, 2021 8:12 PM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** Initial report of two incidents at OHSU

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- It was reported to the IBC on 2/24/2021 that an animal technician cut their thumb while working with a nonhuman primate infected with recombinant RhCMV.

Complete reports of the incidents and follow up actions will be provided at a later date.

Sarah

Sarah A. Byers, PhD
IBC Program Manager
Research Integrity Office (ORIO)

Obtained via FOIA by Judicial Watch Inc.

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:** Thursday, May 6, 2021 1:52 PM
**To:** Kara Drolet; Sarah Byers; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Initial report of two incidents at OHSU

Dear Dr. Kara Manning Drolet,

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:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Monday, May 3, 2021 12:59 PM
**To:** Sarah Byers <byerssa@ohsu.edu>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Subject:** RE: Initial report of two incidents at OHSU

Hello Dr. Harris, please find the final report for the other incident initially reported below and let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Pronouns: she/her/hers
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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

**From:** Kara Drolet
**Sent:** Tuesday, April 20, 2021 12:08 PM
**To:** Sarah Byers <byerssa@ohsu.edu>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Subject:** RE: Initial report of two incidents at OHSU

Hello Dr. Harris,
Here is the final report for the eye splash incident.
We are still gathering follow up information on the other incident at this time.
Thank you, and let us know if you have any questions.
Best regards,
Kara

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:manningk@ohsu.edu
Executive Asst: Ann Trione | : trione@ohsu.edu
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---

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Friday, April 2, 2021 10:54 AM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** RE: Initial report of two incidents at OHSU

Hello Dr. Harris,

OHSU is still doing follow up regarding one incident and will soon send the final report for the other incident.

Sarah

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, April 1, 2021 6:40 AM
**To:** Sarah Byers <byerssa@ohsu.edu>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** [EXTERNAL] RE: Initial report of two incidents at OHSU

Dear Dr. Byers:

Just following up to see if the final reports are available yet (I apologize if we missed them coming in).

Regards,

Dr. Kathryn Harris

Obtained via FOIA by Judicial Watch Inc.

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Thursday, February 25, 2021 8:12 PM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** Initial report of two incidents at OHSU

Dear Dr. Harris,

This email serves as the initial notification of two potential exposures that occurred at Oregon Health & Science University.

- It was reported to the IBC on 2/23/2021 that an animal technician was splashed in the eye while working with SHIV infected non-human primates
- It was reported to the IBC on 2/24/2021 that an animal technician cut their thumb while working with a nonhuman primate infected with recombinant RhCMV.

Complete reports of the incidents and follow up actions 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.

OREGON HEALTH & SCIENCE UNIVERSITY

**Institutional Biosafety Committee**

Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
fax 503 346-6808
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

May 3, 2021

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

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 2/25/2021.

| | |
|---|---|
| OHSU IBC registration number | IBC-06-30 |
| OHSU project title | Virologic and immunologic parameters of Rhesus CMV infection and development of RhCMV vaccine vectors |
| Nature of the material | Replication competent RhCMV vaccine vector expressing SIV antigen |
| Risk Group | II |
| Containment level | ABSL-2 |
| Nature of the incident | Personnel Exposure |
| PPE in use | Scrubs, double gloves, face shield, hair bonnet, and safety glasses |

**Description of incident:**

A clinical veterinary technician was cleaning the teeth of a sedated non-human primate (NHP). During the cleaning procedure the sedation wore off and the NHP bit down on the technician's thumb causing an abrasion to their thumb through the double layer of gloves. The technician removed their gloves, washed their hands for 15 minutes with soap and water and reported to Occupational Health.

**Actions taken:**

After the incident the technician met with their supervisor to review the incident. The supervisor and technician discussed how standard procedures for sedation and use of Kevlar gloves may need to be revised based on the animal and its sedation history. The supervisor recommended the use of a more powerful sedative if the animal had a history of showing resistance to ketamine. They also discussed that while Kevlar gloves are typically only used for invasive dental procedures because they impact dexterity, the technician should consider using them when conducting routine dental work on males with larger teeth.

The incident was reviewed by the IBC admin group and the campus incident review committee. The biosafety officer conducted a follow up review of the incident with the technician and found changes in work practices recommended by the supervisor to be appropriate.

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,

Kara Drolet Digitally signed by Kara Drolet Date: 2021.05.03 09:54:51 -07'00'

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

cc: 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, May 3, 2021 12:59 PM
**To:** Sarah Byers; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Initial report of two incidents at OHSU
**Attachments:** 02242021 NHP RhCMV bite final report.pdf

Hello Dr. Harris, please find the final report for the other incident initially reported below and let us know if you have any questions.
Best regards,
Kara

Kara Manning Drolet, Ph.D.
Pronouns: she/her/hers
Associate Vice President
OHSU Research Integrity Office
Chair, Conflict of Interest in Research Committee
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:manningk@ohsu.edu
Executive Asst: Ann Trione | : trione@ohsu.edu
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**From:** Kara Drolet
**Sent:** Tuesday, April 20, 2021 12:08 PM
**To:** Sarah Byers <byerssa@ohsu.edu>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Subject:** RE: Initial report of two incidents at OHSU

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Kara

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Pronouns: she/her/hers
Associate Vice President
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**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
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Sarah

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**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, April 1, 2021 6:40 AM
**To:** Sarah Byers <byerssa@ohsu.edu>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** [EXTERNAL] RE: Initial report of two incidents at OHSU

Dear Dr. Byers:

Just following up to see if the final reports are available yet (I apologize if we missed them coming in).

Regards,

Dr. Kathryn Harris

---

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**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
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Complete reports of the incidents and follow up actions will be provided at a later date.

Sarah

Sarah A. Byers, PhD
IBC Program Manager
Research Integrity Office (ORIO)
Oregon Health & Science University

Obtained via FOIA by Judicial Watch Inc.

503-494-9763
byerssa@ohsu.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Thursday, February 25, 2021 8:12 PM
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**Cc:** Kara Drolet
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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:** Tuesday, March 16, 2021 2:42 PM
**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

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, March 3, 2021 10:16 AM
**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
**Importance:** High

Good Morning,

Attached is ASU's report of an incident that occurred on February 5, 2021. 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

Obtained via FOIA by Judicial Watch Inc.

*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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Arizona State University |
| **Date of Report:** | 3/3/2021 |
| **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<br>PO Box 876011<br>Tempe, AZ 85287-6111 |
| **Date of incident:** | 2/5/2021 |
| **Name of Principal Investigator:** | Audrone Lapinaite |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 11/12/2020 |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☒BL2 ☒BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-1 RG2, III-E, III-F-1, and III-F-8 Appendices C-I and C-II |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | DNA that was a PCR amplified fragment encoding part of the pETDuet plasmid and METTL3/METLL14 genes |

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A female graduate student in the Principal Investigator's BSL1 Lab was recapping a scalpel when they cut themselves on the palm of their hand with the scalpel. The cut was shallow. The scalpel was used to cut DNA (made by PCR) band from the agarose gel stained with SYBR Green I. The student notified their supervisor. They washed the wound with soap and water, applied an antibiotic solution from the first aid kit and applied a bandaid. The student was instructed by their supervisor to report to ASU Health Services for evaluation. The student reported to health services and was cleared for work with no follow-up needed. Personal Protective Equipment used by the student at the time of the incident included nitrile gloves, a lab coat, and goggles.

The student has completed the following trainings:

EHS Fire Safety Annual Training 2/11/2021

EHS NIH Guidelines Training 10/29/2020

EHS ASU Autoclave Training 10/29/2020

EHS ASU Biosafety and Bloodborne Pathogens Training 8/9/2020

EHS Hazardous Waste Management 8/8/2020

EHS Annual Laboratory Safety Refresher 8/8/2020

There was a deviation from the laboratory SOP on using needles and sharps as the SOP did not address recapping sharps (scalpels) at the time of the incident. There was no equipment failure at the time of the incident. There was no deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | Incident occurred while recapping a sharp (scalpel) which was not addressed in the lab-specific SOP on using needles and sharps at the time of the incident. |

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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):

To avoid these types of incidents in the future, the laboratory specific SOP on using needles and sharps was updated to include scalpels and address recapping, and the student was re-trained in these procedures.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Nancy Henderson <Nancy.J.Henderson@asu.edu>
**Sent:** Wednesday, March 3, 2021 10:16 AM
**To:** NIH guidelines
**Cc:** Jacobs, Bertram; Debra Murphy; ibc@asu.edu
**Subject:** Arizona State University Incident Report
**Attachments:** Arizona State University Incident Report (Lapinaite) 03032021.pdf

**Importance:** High

Good Morning,

Attached is ASU's report of an incident that occurred on February 5, 2021. 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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:19 PM
**To:** Melissa Ly; NIH guidelines
**Cc:** David Hall; Mitchell Kronenberg; Christopher Benedict; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: NIH Incident Report

Dear Melissa Ly,

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:** Melissa Ly <mly@lji.org>
**Sent:** Wednesday, March 3, 2021 6:50 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** David Hall <davidh@lji.org>; Mitchell Kronenberg <mitch@lji.org>; Christopher Benedict <benedict@lji.org>
**Subject:** NIH Incident Report

Good afternoon, NIH OSP.

We had disposed of some waste that was not properly inactivated by autoclaving. The vivarium technicians had selected the incorrect autoclave cycle for the soiled waste from the vivarium. No laboratory researchers were involved in this incident. The full report is attached to this email with the details surrounding the incident.

If you have any questions, you can reach me by email at mly@lji.org, or by phone at 858-229-3850.

Warm regards,
Melissa

Melissa Ly
Biosafety Officer
**La Jolla Institute for Immunology**
Environment, Health, & Safety
9420 Athena Circle | La Jolla, CA 92037 | United States of America
E-mail: mly@lji.org | Office: (858) 752-6981 | Mobile: 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

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | X YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | La Jolla Institute for Immunology |
| **Date of Report:** | 3/2/2021 |
| **Reporter name and position:** | Melissa Ly<br>Biosafety Officer |
| **Telephone number:** | (858) 752-6981 |
| **Email address:** | mly@lji.org |
| **Reporter mailing address:** | 9420 Athena Circle<br>La Jolla, CA 92037 |
| **Date of incident:** | 1/21/2021 |
| **Name of Principal Investigator:** | Dr. Mitchell Kronenberg<br>Dr. Chris Benedict |
| **Is this an NIH-funded project?** | X YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number: AI125955, R01 AI101423, R01 AI139749*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>X Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br>If yes, date of approval: 4/13/2020 and 12/1/2020. |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA x Other (please describe): County of San Diego Department of Environmental Health, Hazardous Materials Division<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Salmonella enterica* serovar typhimurium expressing mCherry<br>Mouse cytomegalovirus (MCMV) (Smith WT, K181 WT, K181 m166STOP, K181 M09S, K181 Δm157-104bp, and K181 Δm157-104bp-m166STOP) |

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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)

  ABSL-2 vivarium autoclave

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

  Vivarium technician (male), senior vivarium supervisor (male)

  **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

  County of San Diego Department of Environmental Health, Hazardous Materials Division was notified upon discovery of improper autoclave treatment of biological materials.

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

  All autoclave users were re-trained on proper autoclave SOP on January 21, 2021.

- 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

  Institutional SOP for autoclaving waste disposal:
  1. Upon completion of the autoclave cycle, carefully remove the bags from the machine.
  2. Verify the autoclave cycle by checking the run log (temperature and time) and the indicator on the bag.
  3. Dispose of waste in secure dumpster.

  Verification of the autoclave cycle by checking run log was not performed.

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

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No deviation from IBC approved containment level or IBC approval conditions.

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

  Heat resistant gloves, disposable gown.

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

  Vivarium personnel are required to have a pre-placement physical exam upon hire, participate in the allergen assessment program, and are offered vaccinations/testing for agents that are approved for use at ABSL-2.
  No laboratory personnel involved in research were involved in this incident.

- Any medical surveillance provided or recommended after the incident

  N/A

- Any injury or illness associated with the incident

  No injury or illness associated with the incident.

- Equipment failures

  N/A

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

On January 21, 2021, a vivarium supervisor noticed that the autoclave was set to the incorrect cycle run when he pulled out biohazard waste from the autoclave. When he followed up with the history of the autoclave runs, he found out that a total of 6 bags of waste containing animal bedding and small amounts of PPE were autoclaved on a short 3 minute sterilization cycle at 252 degrees F instead of 60 minutes sterilization cycle at 252 degrees F and had been discarded into the trash compactor. It was also discovered during this time that the post-autoclave verification checks were not being performed. The County of San Diego Department of Environmental Health, Hazardous Materials Division was notified. Upon a further in-depth investigation at the end of February on the materials that could be shed by the animals, it was discovered that genetically modified *Salmonella enterica* serovar typhimurium and genetically modified MCMV was administered to the mice during the duration that the wrong autoclave cycle was selected.

No laboratory researchers were involved with this incident.

After the incident was discovered, all autoclave operators were re-trained and a third party contractor was brought out to re-program all autoclaves on site to have the same cycle runs. Legends were also made and posted on each autoclave next to the control panel as a guidance document for what is to be run on each cycle. Additional personnel were incorporated into checking the autoclave print out log to ensure that the waste was run on the correct cycle prior to disposal into the trash compactor, so 2 technicians check the log before disposal of autoclaved waste, and the autoclave log book was modified to include all the parameters that need to be checked.

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| **Has the IBC reviewed this incident?** | X YES ☐NO |
| **Please describe the root cause of this incident:** | Vivarium technician operating the autoclave was not paying attention to the autoclave cycle, post-autoclave printed run log was not checked, and each autoclave had different cycles preset. |

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):

All autoclave operators were re-trained on proper autoclave operations, including pre- and post- autoclave run verifications. A third party vendor was brought out to re-program all on-site autoclaves to have the same pre-programmed run cycles. Autoclave cycle legend was created and posted next to each autoclave control panel as a guidance document on what materials should be run on which particular cycle. Autoclave printed run log is verified by multiple people prior to disposal of autoclaved waste. Autoclave run log book was modified to include all parameters that must be checked on the autoclave printed run log.

- **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:** Melissa Ly <mly@lji.org>
**Sent:** Wednesday, March 3, 2021 6:50 PM
**To:** NIH guidelines
**Cc:** David Hall; Mitchell Kronenberg; Christopher Benedict
**Subject:** NIH Incident Report
**Attachments:** 2021-03-02_OSP_Incident_Reporting DMH-ML-mk.docx

Good afternoon, NIH OSP.

We had disposed of some waste that was not properly inactivated by autoclaving. The vivarium technicians had selected the incorrect autoclave cycle for the soiled waste from the vivarium. No laboratory researchers were involved in this incident. The full report is attached to this email with the details surrounding the incident.

If you have any questions, you can reach me by email at mly@lji.org, or by phone at 858-229-3850.

Warm regards,
Melissa

Melissa Ly
Biosafety Officer
**La Jolla Institute for Immunology**
Environment, Health, & Safety
9420 Athena Circle | La Jolla, CA 92037 | United States of America
E-mail: mly@lji.org | Office: (858) 752-6981 | Mobile: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:27 PM
**To:** Sheldon, Rebecca; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: LOVELACE BIOMEDICAL RESEARCH INSTITUE - INCIDENT REPORTING

Dear Rebecca Sheldon,

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:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Wednesday, March 3, 2021 5:55 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** LOVELACE BIOMEDICAL RESEARCH INSTITUE - INCIDENT REPORTING

Biosafety Officer, Responsible Official, BS, MBA, RBSP
Lovelace Respiratory Research Institute
2425 Ridgecrest Drive
505-348-9533 Office
Redacted by agreement Cell
505-348-4980 Fax
505-331-0270 on call 24/7
rsheldon@lrri.org

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Lovelace Biomedical Research Institute |
| **Date of Report:** | March 3, 2021 |
| **Reporter name and position:** | Rebecca Sheldon<br>Biosafety Officer/Responsible Official |
| **Telephone number:** | 505-348-9533 |
| **Email address:** | rshledon@lovelacebiomedical.com |
| **Reporter mailing address:** | 2425 Ridgecrest Drive, SW<br>Albuquerque, NM 87108 |
| **Date of incident:** | February 2, 2021 |
| **Name of Principal Investigator:** | Dr. David Revelli |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 7/29/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☐BL2 ☐BL2+<br>☒BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Bacillus anthracis* UTA1 strain. This is an Ames mutant strain which was prepared by replacing coding sequences of the toxin genes, *cya*, *lef*, and *pagA*, respectively, with an omega-kanamycin resistance cassette into the Ames strain, using CP51-mediated transduction. |

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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)

Redacted by agreement

At approximately 11:30 a.m. on February 2, 2021 an animal technician entered the ABSL-3 Building [redacted] room [redacted] animal room in order to perform routine husbandry duties. Rabbits within the room were exposed to *Bacillus anthracis* UTA spores (Ames strain mutant which lacks the edema factor component of the toxin) on February 1, 2021. Animals were showing no signs of illness at the time of the incident. The employee was wearing a Tyvek jump suit, two pairs of shoe covers, two pairs of gloves, a Bullard PAPR respirator, and a waterproof apron when entering the animal room. The employee was within the room for approximately 10 minutes and had not handled animals or equipment exposed to select agents prior to the incident occurring. As the employee bent down to change the caging pan in a rabbit cage, the hose connecting to the PAPR hood disconnected. The employee immediately deconned out of the animal room removing apron, removing outer shoe covers, removing outer gloves, spraying inner gloves with 5% acidified bleach and entered into the decon room [redacted] While in the decon room the employee deconned out as normal following the steps below:

Redacted by agreement

- Spray all our portions of the PAPR hood with disinfectant, being sure to spray under the hose connection and under the chin.
- Spray the hose, belt, and motor-blower with disinfectant.
- Unclip and remove belt, reclip the belt, and hang belt on hook.
- Spray motor-blower, belt, and hose a second time with disinfectant.
- Remove tape from wrists and discard into the infectious waste container.
- Spray gloves thoroughly again with disinfectant and rub hands together.
- Unzip and remove Tyvek jumpsuit, taking care to peel the jumpsuit inside out and avoiding agitating movements that may shake contaminants off Tyvek and into the air. Discard into the infectious waste container.
- Remove gloves and discard into the infectious waste container.

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- Don a new pair of gloves.
- Pick up belt with motor-blower and walk to the yellow line on the floor.
- Pick up one foot, spray sole of shoe with disinfectant, and step over the yellow line into designated clean area. Spray away from the clean side of the yellow line, toward the dirty side of the yellow line. Repeat the same procedure with the other foot.
- Enter the PAPR room and place equipment away.

The PAPR hose was disconnected from the PAPR hood for approximately 4 minutes. The employee exited the ABSL-3 Facility as normal with a shower out and reported the incident to the RO and Facility Director immediately upon exiting the building. The employee was seen by the onsite Occupational Health Provider and prescribed 500 mg BID of Ciprofloxacin for 30 days. At the time of the incident the employee had two previous anthrax vaccinations- the initial and two week post vaccination. As to date, the employee has shown no signs of illness. CDC was immediately notified and a Form 3 was filed on February 2, 2021.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br><br>IBC meeting scheduled for March 12,2021 |
| **Please describe the root cause of this incident:** | At the time of the incident the employee used a "Visitor" PAPR hood and did not closely check the PPE. The PAPR hose was loosely attached to the PAPR hood. |

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 employee involved in the incident did not inspect the hose connection properly prior to entering the ABSL-3 Facility. At the time of the incident the employee was in a hurry and utilized a visitor hood, the hood was hanging with the hose connected to the hood and the employee did not check the hose connection to the hood prior to placing the hood on. The employee was re-

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trained on PPE inspection steps as described below:

Procedures for inspecting the PAPR hood and hose:

- Inspect the unit for damage. Ensure the white rubber gasket is in place in the breathing tube coupler on the blower unit.
- Inspect the Bullard breathing tube (white) for defects.
- Attach the breathing tube to the motor-blower unit. Turn on the motor-blower by pressing the ON/OFF switch for 1 to 2 seconds confirmed by a short beep. If the low battery alarm sounds at this time, the battery needs to be charged and should be returned to the charging unit and another battery connected to the motor-blower unit.
- Use the indicator provided by the manufacturer to test the airflow at the end of those and check the integrity of the breathing tube. The ball of the airflow indicator should be above the line indicated for the EVA unit.
- Select a Bullard PAPR hood and inspect for defects.
- Connect the hood to the breathing tube; check the integrity of the hood.

- **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:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Tuesday, March 9, 2021 9:23 AM
**To:** Harris, Kathryn (NIH/OD) [C]
**Subject:** Re: LOVELACE BIOMEDICAL INCIDENT REPORT

Hi Kathryn,
Yes, a Form 3 was submitted on February 4th.

Best regards,
Rebecca Sheldon

Sent from my iPhone

On Mar 9, 2021, at 7:20 AM, Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov> wrote:

> WARNING: This is an external email. Use Caution responding, opening attachments and following links.
>
> Hi Rebecca:
>
> I just wanted to check whether this incident was reported to CDC DSAT. The incident report indicates the CDC emergency number was called, but I am specifically checking whether it was reported to DSAT.
>
> Thanks,
>
> Kathryn
>
> ---
>
> **From:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
> **Sent:** Thursday, March 4, 2021 12:10 PM
> **To:** NIH guidelines <NIHguidelines@od.nih.gov>
> **Subject:** LOVELACE BIOMEDICAL INCIDENT REPORT

Biosafety Officer, Responsible Official, BS, MBA, RBSP
Lovelace Respiratory Research Institute
2425 Ridgecrest Drive
505-348-9533 Office
Redacted by agreement Cell
505-348-4980 Fax
505-331-0270 on call 24/7
rsheldon@lrri.org

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Tuesday, March 9, 2021 9:20 AM
**To:** Sheldon, Rebecca
**Subject:** RE: LOVELACE BIOMEDICAL INCIDENT REPORT

Hi Rebecca:

I just wanted to check whether this incident was reported to CDC DSAT. The incident report indicates the CDC emergency number was called, but I am specifically checking whether it was reported to DSAT.

Thanks,

Kathryn

---

**From:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Thursday, March 4, 2021 12:10 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** LOVELACE BIOMEDICAL INCIDENT REPORT

Biosafety Officer, Responsible Official, BS, MBA, RBSP
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505-331-0270 on call 24/7
rsheldon@lrri.org

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Wednesday, March 3, 2021 5:55 PM
**To:** NIH guidelines
**Subject:** LOVELACE BIOMEDICAL RESEARCH INSTITUE - INCIDENT REPORTING
**Attachments:** Incident Reporting Feb2,2021.docx

Biosafety Officer, Responsible Official, BS, MBA, RBSP
Lovelace Respiratory Research Institute
2425 Ridgecrest Drive
505-348-9533 Office
Redacted by agreement Cell
505-348-4980 Fax
505-331-0270 on call 24/7
rsheldon@lrri.org

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:27 PM
**To:** Sheldon, Rebecca; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: LOVELACE BIOMEDICAL INCIDENT REPORT

Dear Rebecca Sheldon,

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:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Thursday, March 4, 2021 12:10 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** LOVELACE BIOMEDICAL INCIDENT REPORT

Biosafety Officer, Responsible Official, BS, MBA, RBSP
Lovelace Respiratory Research Institute
2425 Ridgecrest Drive
505-348-9533 Office
Redacted by agreement Cell
505-348-4980 Fax
505-331-0270 on call 24/7
rsheldon@lrri.org

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Lovelace Biomedical Research Institute |
| **Date of Report:** | March 4, 2021 |
| **Reporter name and position:** | Rebecca Sheldon<br>Biosafety Officer/Responsible Official |
| **Telephone number:** | 505-348-9533 |
| **Email address:** | rshledon@lovelacebiomedical.com |
| **Reporter mailing address:** | 2425 Ridgecrest Drive, SW<br>Albuquerque, NM 87108 |
| **Date of incident:** | February 3, 2021 |
| **Name of Principal Investigator:** | Dr. David Revelli |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 7/29/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☐BL2 ☐BL2+<br>☒BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Bacillus anthracis* UTA1 strain. This is an Ames mutant strain which was prepared by replacing coding sequences of the toxin genes, *cya*, *lef*, and *pagA*, respectively, with an omega-kanamycin resistance cassette into the Ames strain, using CP51-mediated transduction. |

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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)

Redacted by agreement

On February 3, 2021 at approximately 10 p.m. MST a laboratory employee was stuck with a needle while restraining a rabbit within the ABSl-3 Facility room [redacted] The rabbit had been exposed to *Bacillus anthracis* UTA1 strain (Ames strain mutant which lacks the edema factor component of the toxin). The rabbit was a vehicle control animal and was not receiving drugs at the time of the incident. The rabbit was exposed to 2.3 x01^6 spores via aerosol on February 1, 2021. Two laboratory technicians were working together within the ABSL-3 Facility Technician 1 was performing blood draws with a butterfly needle, Technician 2 was restraining the rabbit let. The rabbit jumped when the needle entered its saphenous vein, the needle pulled out and struck Technician 2 on the right index finger. Technician 2 exited the facility and milked and washed the wound for 15 minutes while showering out the facility. Technician 1 contacted the ABSL-3 Facility Director who contacted the responsible Official while Technician 2 showered out to the ABSL-3 Facility.

The Responsible Official drove Technician 2 to UNM emergency room. While in the emergency room, Technician 2 was seen by a physician, given one dose of doxycycline, and received a blood draw. The physician did contact the NM Department of Health and contacted CDC via the CDC emergency number. The laboratory employee had received 2 Anthrax vaccinations prior to the incident, on 02Dec, 2020 and the second on 04Jan, 2021.

At the time of the incident, Technician 2 was wearing standard ABSL-3 PPE of Tyvek jump suit, two pairs of shoe covers, Bullard PAPR respirator, 2 pairs of nitrile and one pair of latex gloves.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br><br>IBC meeting scheduled for March 12,2021 |
| **Please describe the root cause of this incident:** | Hand position close to the needle when blood draw was occurring. |

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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):

Retraining with the employee relating to hand positioning while restraining. The rabbit was sedated and in a restrainer at the time of the incident. The rabbit blood draw SOP is currently under revision to include the use of hexarmor gloves by the employee restraining the rabbit.

- **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:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Tuesday, March 9, 2021 9:23 AM
**To:** Harris, Kathryn (NIH/OD) [C]
**Subject:** Re: LOVELACE BIOMEDICAL INCIDENT REPORT

Hi Kathryn,
Yes, a Form 3 was submitted on February 4th.

Best regards,
Rebecca Sheldon

Sent from my iPhone

On Mar 9, 2021, at 7:20 AM, Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov> wrote:

> WARNING: This is an external email. Use Caution responding, opening attachments and following links.
>
> Hi Rebecca:
>
> I just wanted to check whether this incident was reported to CDC DSAT. The incident report indicates the CDC emergency number was called, but I am specifically checking whether it was reported to DSAT.
>
> Thanks,
>
> Kathryn
>
> ---
>
> **From:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
> **Sent:** Thursday, March 4, 2021 12:10 PM
> **To:** NIH guidelines <NIHguidelines@od.nih.gov>
> **Subject:** LOVELACE BIOMEDICAL INCIDENT REPORT
>
> Biosafety Officer, Responsible Official, BS, MBA, RBSP
> Lovelace Respiratory Research Institute
> 2425 Ridgecrest Drive
> 505-348-9533 Office
> Redacted by agreement Cell
> 505-348-4980 Fax
> 505-331-0270 on call 24/7
> rsheldon@lrri.org

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Thursday, March 4, 2021 1:14 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: LOVELACE BIOMEDICAL INCIDENT REPORT

This is a new incident. One occurred the morning of Feb. 2 and one occurred on the evening of Feb. 3rd. The same study.

Best regards,
Rebecca Sheldon

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Thursday, March 4, 2021 11:10 AM
**To:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Subject:** RE: LOVELACE BIOMEDICAL INCIDENT REPORT

WARNING: This is an external email. Use Caution responding, opening attachments and following links.

Rebecca:

Is this a follow up from Yesterday's report or a new one?

Regards,

Kathryn

---

**From:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Thursday, March 4, 2021 12:10 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** LOVELACE BIOMEDICAL INCIDENT REPORT

Biosafety Officer, Responsible Official, BS, MBA, RBSP
Lovelace Respiratory Research Institute
2425 Ridgecrest Drive
505-348-9533 Office
Redacted by agreement Cell
505-348-4980 Fax
505-331-0270 on call 24/7
rsheldon@lrri.org

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Sheldon, Rebecca <rsheldon@lovelacebiomedical.org>
**Sent:** Thursday, March 4, 2021 12:10 PM
**To:** NIH guidelines
**Subject:** LOVELACE BIOMEDICAL INCIDENT REPORT
**Attachments:** Incident Reporting Feb3,2021 (2).docx

Biosafety Officer, Responsible Official, BS, MBA, RBSP
Lovelace Respiratory Research Institute
2425 Ridgecrest Drive
505-348-9533 Office
Redacted by agreement Cell
505-348-4980 Fax
505-331-0270 on call 24/7
rsheldon@lrri.org

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 4:07 PM
**To:** Theresa Siefkas; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Recombinant DNA exposure (BSL-1)

Dear Theresa Siefkas,

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. However, please note that exempt activities are not reportable.

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:** Theresa Siefkas <Theresa.Siefkas@Colorado.EDU>
**Sent:** Monday, March 15, 2021 1:55 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** RE: Recombinant DNA exposure (BSL-1)

Hello,

I have attached the report for this needle stick incident. Please let me know if you need any more information.

Thank you,

Theresa

Theresa Siefkas
Assistant Biosafety Officer
Environmental Health and Safety
Office (303) 492-7072
Cell Redacted by agreement

---

**From:** Theresa Siefkas
**Sent:** Friday, March 5, 2021 8:27 AM
**To:** NIHGuidelines@od.nih.gov
**Subject:** Recombinant DNA exposure (BSL-1)

Obtained via FOIA by Judicial Watch Inc.

Hello,

I am writing to inform NIH OSP that the biosafety office at the University of Colorado Boulder was informed of a BSL-1 exposure from a needlestick involving a transgenic mouse. We are currently getting more details from this lab about the incident, and completing an incident report that we will be submitting to your office promptly. Please let me know if you have any questions at this time.

Thank you,

Theresa

Theresa Siefkas
Assistant Biosafety Officer
Environmental Health and Safety
Office (303) 492-7072
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

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | X YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Colorado Boulder |
| **Date of Report:** | 3/11/21 |
| **Reporter name and position:** | Theresa Siefkas – Assistant Biosafety Officer |
| **Telephone number:** | 970-443-4557 |
| **Email address:** | Theresa.Siefkas@colorado.edu |
| **Reporter mailing address:** | Environmental Health & Safety<br>1000 Regent Drive<br>413 UCB<br>Boulder, CO 80309 |
| **Date of incident:** | 3/4/21 |
| **Name of Principal Investigator:** | Dr. David Root |
| **Is this an NIH-funded project?** | X YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br>If yes, date of approval: most recent addendum was approved 3/2/2021 (renewal application was approved 7/28/2020) |
| **What was the approved biosafety level of the research?** | X BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-F-8 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Transgenic mouse blood, strain VGaT-IRES::Cre homozygote. |

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 researcher was performing a surgery in the surgery suite. The surgery was on a transgenic mouse (VGaT-IRES::Cre homozygote) and the researcher accidentally pricked themselves with a needle tip. The needle did not have any viral vectors or drugs in it, but had been used to gently poke the injection site pre-injection to break through the dura mater underneath the mouse's skull. There was a small amount of mouse blood on the needle tip. It broke through their nitrile glove and skin enough to draw a small amount of their own blood. Immediately following the incident, they flushed the area with isopropyl alcohol and then washed thoroughly with soap and water. They were trained on these surgical methods in August of 2020 by their supervisor. The researcher contacted our occupational health specialist, who then contacted the biosafety officer and assistant biosafety officer. The researcher also submitted a report through University Risk Management.

Biosafety training: 8/6/2020
Occupational Health and Safety for Animal Research training: 8/4/2020

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES NO |
| **Please describe the root cause of this incident:** | Lack of care taken when handling sharp objects. |

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):

It was discussed that in the future, the researcher could use a new needle tip for each surgery. Then there would not be an exposed needle tip sitting out on the blue pad between uses.

- **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:** Theresa Siefkas <Theresa.Siefkas@Colorado.EDU>
**Sent:** Monday, March 15, 2021 1:55 PM
**To:** NIH guidelines
**Subject:** RE: Recombinant DNA exposure (BSL-1)
**Attachments:** IncidentReport03112021.docx

Hello,

I have attached the report for this needle stick incident. Please let me know if you need any more information.

Thank you,

Theresa

Theresa Siefkas
Assistant Biosafety Officer
Environmental Health and Safety
Office (303) 492-7072
Cell Redacted by agreement

---

**From:** Theresa Siefkas
**Sent:** Friday, March 5, 2021 8:27 AM
**To:** NIHGuidelines@od.nih.gov
**Subject:** Recombinant DNA exposure (BSL-1)

Hello,

I am writing to inform NIH OSP that the biosafety office at the University of Colorado Boulder was informed of a BSL-1 exposure from a needlestick involving a transgenic mouse. We are currently getting more details from this lab about the incident, and completing an incident report that we will be submitting to your office promptly. Please let me know if you have any questions at this time.

Thank you,

Theresa

Theresa Siefkas
Assistant Biosafety Officer
Environmental Health and Safety
Office (303) 492-7072
Cell Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Theresa Siefkas <Theresa.Siefkas@Colorado.EDU>
**Sent:** Friday, March 5, 2021 10:27 AM
**To:** NIH guidelines
**Subject:** Recombinant DNA exposure (BSL-1)

Hello,

I am writing to inform NIH OSP that the biosafety office at the University of Colorado Boulder was informed of a BSL-1 exposure from a needlestick involving a transgenic mouse. We are currently getting more details from this lab about the incident, and completing an incident report that we will be submitting to your office promptly. Please let me know if you have any questions at this time.

Thank you,

Theresa

Theresa Siefkas
Assistant Biosafety Officer
Environmental Health and Safety
Office (303) 492-7072
Cell Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:44 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Judge,Sharon <sjudge@ehs.ufl.edu>
**Sent:** Friday, March 5, 2021 7:53 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Gulig,Paul A <gulig@UFL.EDU>; RES-Operations <operations@research.ufl.edu>
**Subject:** Incident Report

Good morning Dr. Harris,

Attached is an incident report detailing the release of recombinant organisms without proper inactivation. Please let us know if you have any questions or require any additional information.

Thanks,
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

Obtained via FOIA by Judicial Watch Inc.

Email: sjudge@ehs.ufl.edu

Obtained via FOIA by Judicial Watch Inc.

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Business Affairs
Division of Environmental Health & Safety
Biological Safety Office

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

March 5, 2021

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 release of recombinant organisms. The incident occurred on February 10th when an Animal Care Staff (ACS) technician changed cages for animals that had been exposed to *Streptococcus mutans* via their oral cavity. Lab members (a postdoctoral associate and a research assistant professor) had mistakenly placed the biohazard cage sticker (indicating that the cages required autoclaving) behind the cage card so that it was no longer visible to ACS staff and as a result, the bedding was disposed of with regular trash without being autoclaved.

The rats received *S. mutans* UA159 (wild type strain), *S. mutans* OMZ175 (wild type strain) and *S. mutans* OMZ175-Δ*cnm* (recombinant strain lacking the *cnm* gene) on 2/8, 2/9 and 2/10 by having their mouths swabbed with bacterial broth culture (approximately $10^8$ CFU). There was a total of 6 cages, involving 34 rats; 10 of those animals received the recombinant *S. mutans*. The issue was not detected by senior ACS staff until the following day and they notified me late that afternoon via email. I read the email on the morning of 2/12 and asked whether there was any chance the bedding was still inside the facility and could be located for autoclaving, but it had already been sent to the dumpster.

The recombinant *S. mutans* involved is part of a project appropriately registered through the IBC. We had previously requested (and received) permission from NIH to lower containment for various *Streptococcus* species that are common oral commensals from BSL-2 to BSL-1. Given that, *in vivo* experiments were approved at ABSL-1i (the "i" is a UF designation for experiments that require inactivation of bedding prior to disposal) in September 2018 under section III-D-4 for experiments involving whole animals. The recombinant strain has a deletion in the *cnm* gene which renders it less virulent as *cnm* encodes for a surface protein that plays a major role in adherence to host cells.

Cage changes are performed in an animal transfer station by husbandry staff wearing disposable gowns, gloves and shoe covers and cage wash technicians dump bedding using a down draft dump station while wearing gown, gloves, N95, face shield and bouffant. Due to the practices and PPE used and the fact that *S. mutans* is primarily transmitted through saliva, we do not believe there was any risk of exposure to personnel. Per the PI, *S. mutans* does not survive on surfaces (including bedding) for more than a few minutes so the risk of environmental exposure is minimal.

The incident occurred due to the SOP not being properly followed. The biohazard sticker is supposed to be placed on the front of the cage card so that it is clearly visible. The sticker indicates the agent used and the date introduced and alerts ACS staff to the fact that the cages require special handling. In this

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instance, the biohazard sticker was placed on the “Special Care by PI” card and that card was then placed behind the cage card. All lab staff have been reminded that the biohazard sticker must be prominent on the cage card and not placed on the “Special Care” card. To avoid a future incident, the laboratory has changed their “Special Care by PI” instructions to indicate that lab members are now responsible for cage changes after animal infections and ensuring that cages are properly marked for autoclaving.

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
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E: sjudge@ehs.ufl.edu

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:44 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

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**To:** NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Gulig,Paul A <gulig@UFL.EDU>; RES-Operations <operations@research.ufl.edu>
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March 5, 2021

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

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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
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Gainesville, FL 32611
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## Hunter, Renee (NIH/OD) [C]

**From:** Judge,Sharon <sjudge@ehs.ufl.edu>
**Sent:** Friday, March 5, 2021 7:53 AM
**To:** NIH guidelines; Harris, Kathryn (NIH/OD) [C]
**Cc:** Gulig,Paul A; RES-Operations
**Subject:** Incident Report
**Attachments:** Reportable NIH Incident 2-10-21.pdf

Good morning Dr. Harris,

Attached is an incident report detailing the release of recombinant organisms without proper inactivation. Please let us know if you have any questions or require any additional information.

Thanks,
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:** Tuesday, March 16, 2021 3:15 PM
**To:** Indiana University IBC; NIH guidelines
**Cc:** BIOSAFETY; Hollenhorst, Peter C; Baumann, John R; Swank, Eric D.; Jones, Stephanie; Winters, Emily Jean; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: IUB IBC - 30 Day Report
**Signed By:** michelle.mckinney@nih.gov

Dear Holly Moore,

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:** Indiana University IBC <ibc@iu.edu>
**Sent:** Monday, March 8, 2021 4:01 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** BIOSAFETY <biosafe@indiana.edu>; Hollenhorst, Peter C <pchollen@indiana.edu>; Baumann, John R <baumannj@iu.edu>; Swank, Eric D. <edswank@iu.edu>; Jones, Stephanie <strrober@iu.edu>; Winters, Emily Jean <ejwinter@iu.edu>
**Subject:** IUB IBC - 30 Day Report

Dear NIH OSP:

Please find below the details of a 30 day incident report from the Indiana University Bloomington IBC.

Institution Name: Indiana University Bloomington
Date of Report: 03/08/2021
Reporter Name & Position: Holly Moore, IBC Administrator
Telephone Number: 812-855-0656
Email Address: holmoore@iu.edu
Reporter Mailing Address: Indiana University, Office of Research Compliance, 2218 North Dunn Street, Bloomington, Indiana 47408

Date of Incident: 02/20/2021

Obtained via FOIA by Judicial Watch Inc.

Name of PI: Peter Hollenhorst
NIH Funded: Yes
NIH grant of contract number: R01CA204121, R01CA224342
Nature of Incident: Personnel exposure
Reviewed by IBC? Yes Approval Date: 07/21/2020
Approved Biosafety Level: BL-2
Sections of *NIH Guidelines*: III-D, III-D-1, III-D-2, III-E, III-E-1, III-F, III-F-1, III-F-2, III-F-8 (Appx. C-I, C-II)

Nature of recombinant or synthetic material involved: Potentially oncogenic

Description: A graduate student in the Hollenhorst lab was manipulating a glass Pasteur pipette inside tubing. The glass pipette broke inside the tubing without the graduate student realizing. When the student went to place a new tube, their finger was cut on the broken pipette glass. The tubing contained human cell lines expressing EWSR1. The student was working at the appropriate containment level (BL-2), inside a biosafety cabinet, and was wearing gloves and a lab coat.

Cause: The incident was an accident but could have been prevented by using plastic aspirating pipettes or examining the tube more thoroughly.

Actions Taken: The student immediately addressed the cut by washing with soap and water and applying a band-aid. When reporting the incident to Environmental Health and Safety, they were given information on how to report to occupational health and seek medical treatment if they wished.

On 2/26/2021 both the Biological Safety Manager and the EHS Occupational Safety Manager visited the lab to discuss the incident and view the location. The Biosafety Manager sent information to the PI about plastic aspirating pipettes that could be used in place of glass. The BSO Manager also sent information on examining the condition of pipettes when placing them and removing them from tubing as well as information regarding the use of tweezers to remove any broken glass pieces, should a glass pipette break in tubing in the future. The PI agreed to use plastic aspirating pipettes.

The incident was reviewed by the full IBC on 03/04/2021. The committee felt that the follow up actions requested by the Biosafety Manager and taken by the lab were sufficient.

If you have any questions regarding the incident, please feel welcome to contact the Indiana University IBC Office at IBC@iu.edu.

*Holly*

**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
Indiana University
**Phone:** 812.855.0656
**Email:** holmoore@iu.edu
**Web:** https://research.iu.edu/compliance/

**Click here see upcoming IBC meeting dates and deadlines.**

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Indiana University IBC <ibc@iu.edu>
**Sent:** Monday, March 8, 2021 4:01 PM
**To:** NIH guidelines
**Cc:** BIOSAFETY; Hollenhorst, Peter C; Baumann, John R; Swank, Eric D.; Jones, Stephanie; Winters, Emily Jean
**Subject:** IUB IBC - 30 Day Report
**Signed By:** ibc@iu.edu

Dear NIH OSP:

Please find below the details of a 30 day incident report from the Indiana University Bloomington IBC.

Institution Name: Indiana University Bloomington
Date of Report: 03/08/2021
Reporter Name & Position: Holly Moore, IBC Administrator
Telephone Number: 812-855-0656
Email Address: holmoore@iu.edu
Reporter Mailing Address: Indiana University, Office of Research Compliance, 2218 North Dunn Street, Bloomington, Indiana 47408

Date of Incident: 02/20/2021
Name of PI: Peter Hollenhorst
NIH Funded: Yes
NIH grant of contract number: R01CA204121, R01CA224342
Nature of Incident: Personnel exposure
Reviewed by IBC? Yes Approval Date: 07/21/2020
Approved Biosafety Level: BL-2
Sections of *NIH Guidelines*: III-D, III-D-1, III-D-2, III-E, III-E-1, III-F, III-F-1, III-F-2, III-F-8 (Appx. C-I, C-II)

Nature of recombinant or synthetic material involved: Potentially oncogenic

Description: A graduate student in the Hollenhorst lab was manipulating a glass Pasteur pipette inside tubing. The glass pipette broke inside the tubing without the graduate student realizing. When the student went to place a new tube, their finger was cut on the broken pipette glass. The tubing contained human cell lines expressing EWSR1. The student was working at the appropriate containment level (BL-2), inside a biosafety cabinet, and was wearing gloves and a lab coat.

Cause: The incident was an accident but could have been prevented by using plastic aspirating pipettes or examining the tube more thoroughly.

Actions Taken: The student immediately addressed the cut by washing with soap and water and applying a band-aid. When reporting the incident to Environmental Health and Safety, they were given information on how to report to occupational health and seek medical treatment if they wished.

On 2/26/2021 both the Biological Safety Manager and the EHS Occupational Safety Manager visited the lab to discuss the incident and view the location. The Biosafety Manager sent information to the PI about plastic aspirating pipettes that could be used in place of glass. The BSO Manager also sent information on examining the condition of pipettes

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when placing them and removing them from tubing as well as information regarding the use of tweezers to remove any broken glass pieces, should a glass pipette break in tubing in the future. The PI agreed to use plastic aspirating pipettes.

The incident was reviewed by the full IBC on 03/04/2021. The committee felt that the follow up actions requested by the Biosafety Manager and taken by the lab were sufficient.

If you have any questions regarding the incident, please feel welcome to contact the Indiana University IBC Office at IBC@iu.edu.

*Holly*

**Holly A. Moore**
Pronouns: *she, her, hers*
*Research Compliance Consultant*
Institutional Biosafety Committees (IBC)
IUPUI Radiation Safety Committees
Office of Research Compliance
Indiana University
**Phone:** 812.855.0656
**Email:** holmoore@iu.edu
**Web:** https://research.iu.edu/compliance/

**Click here see upcoming IBC meeting dates and deadlines.**

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Tuesday, March 16, 2021 3:12 PM
**To:** Wilson, Zachary R; NIH guidelines
**Cc:** Finucane, Marcia; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: CU Anschutz Exposure Report

Dear Zachary Wilson,

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:** Wilson, Zachary R <ZACHARY.WILSON@CUANSCHUTZ.EDU>
**Sent:** Tuesday, March 9, 2021 6:31 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Finucane, Marcia <MARCIA.FINUCANE@CUANSCHUTZ.EDU>
**Subject:** CU Anschutz Exposure Report

Hello,
Please see the attached incident report concerning an exposure to supernatant from HeLa cells transduced with an HIV-1-based viral vector at the University of Colorado Anschutz Medical Campus. Please let us know if you have any questions or other comments.
Thank you,

**Zachary R. Wilson, MS, RBP(ABSA), CBSP(ABSA)**
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.

## 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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Colorado Denver \| Anschutz Medical Campus |
| **Date of Report:** | March 9th, 2021 |
| **Reporter name and position:** | Zachary Wilson, MS, RBP, CBSP<br>Assistant Biological Safety Officer |
| **Telephone number:** | 303-724-5954 |
| **Email address:** | Zachary.wilson@cuanschutz.edu |
| **Reporter mailing address:** | 1784 Racine Street<br>Mail Stop F484, Building 401<br>Aurora, CO 80045 |
| **Date of incident:** | January 31st, 2021 |
| **Name of Principal Investigator:** | Eric Poeschla |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* DP1DA043915 (Novel Approaches to Innate Immunity Against HIV-1 and other Co-infection Viruses)<br><br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: October 28th, 2019 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☒BL2+<br>☒BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | IIID4, IIID2, IIID1, IIIE1, IIIF AppC |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | **Viral vector: HIV-1 non replicative luciferase virus (Envelope and Vpr deleted). Cell line:HeLa** |

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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)

An MD Fellow was working in a certified BSC in a BSL2 lab, collecting HeLa cells transduced with a non-replicating HIV-1-based viral vector expressing luciferase. They were wearing disposable gloves and a lab coat. No eye protection was in use. After trypsin treatment and centrifugation they took out the supernatant and discarded the tip into a waste disposal tank outside of the BSC. The tip created a splash and one droplet of supernatant splashed on their face and potentially into their right eye. They used 70% ethanol and a tissue to remove the drop from their face and then used an eye wash device to clean their face and eyes for 10 minutes. They sought medical treatment/advice at the UCHealth Infectious Disease Clinic on our campus. The Clinic will check for HIV-1 antibodies at 6 weeks and 4 Months after exposure for a reference.

The individual is current on all EHS-required training (Lab Safety, Regulated Medical Waste, Bloodborne Pathogens, Chemical Waste) and up to date on Occupational Health medical surveillance requirements.

The individual was working in the IBC-approved containment level for this research. However, the approved procedures included use of eye protection and for aerosol or splash-generating procedures to be performed in the BSC. The individual was not wearing eye protection and the waste container was stored outside of the BSC.

The incident was not immediately reported to the biosafety office. The individual and the PI have been reminded about the requirement for immediate reporting of exposures to biological materials and recombinant DNA.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br><br>The Biosafety Office will present the incident during the next IBC meeting on March 22nd, 2021 |
| **Please describe the root cause of this incident:** | The individual should have been wearing eye protection. The waste container should have been stored in the BSC. The individual and PI should have been aware of the immediate reporting requirements. It is stated in the training courses they have taken. |

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 an email to the individual and the PI, the Biosafety Office re-stated the BSL2 lab requirements for PPE and use of BSCs, as well as the reporting requirements involving biological spills and exposures. The individual was asked to attend the BSC User Training course today (3/9/21). The course is a 1hr virtual course provided by the biosafety office which covers the safe use of BSCs, including spill and exposure response. This course is not a required course.

The incident was not immediately reported to the biosafety office. The individual and the PI have been reminded about the requirement for immediate reporting of exposures to biological materials and recombinant DNA.

- **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, March 9, 2021 6:31 PM
**To:** NIH guidelines
**Cc:** Finucane, Marcia
**Subject:** CU Anschutz Exposure Report
**Attachments:** CU Anschutz Incident Report 9Mar2021.docx

Hello,
Please see the attached incident report concerning an exposure to supernatant from HeLa cells transduced with an HIV-1-based viral vector at the University of Colorado Anschutz Medical Campus. Please let us know if you have any questions or other comments.
Thank you,

**Zachary R. Wilson, MS, RBP(ABSA), CBSP(ABSA)**
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:** Tuesday, March 16, 2021 2:47 PM
**To:** Desevilla, Liesl; NIH guidelines; Young, Philip
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Reportable Event Augusta University 3/5/2021
**Attachments:** NIH Incident Report Follow-Up

Dear Liesl De Sevilla,

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:** Desevilla, Liesl <LDESEVIL@augusta.edu>
**Sent:** Tuesday, March 9, 2021 12:20 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>; Young, Philip <PHYOUNG@augusta.edu>
**Subject:** Reportable Event Augusta University 3/5/2021

A campus researcher initiated an experiment with replication-incompetent, recombinant DNA material without IBC approval. A report of that incident is attached for you review.

Please let me know if you need any additional information.

Regards,

*Liesl De Sevilla, MS*
Manager, BioSafety Programs
Environmental Health and Safety Division
Augusta University
1405 Goss Lane, CI-1003
Augusta, GA 30912
t. (706) 721-9201
f. (706) 721-9844
ldesevil@augusta.edu

Obtained via FOIA by Judicial Watch Inc.

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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Augusta University |
| **Date of Report:** | 3/5/2021 |
| **Reporter name and position:** | Liesl De Sevilla<br>Biosafety Officer and Manager, Biosafety Programs |
| **Telephone number:** | 706-721-9201 |
| **Email address:** | ldesevil@augusta.edu |
| **Reporter mailing address:** | Augusta University<br>Environmental Health and Safety, CI-1007<br>1405 Goss Lane<br>Augusta, GA 30912 |
| **Date of incident:** | February 25th, 2021 |
| **Name of Principal Investigator:** | Sergei A. Kirov |
| **Is this an NIH-funded project?** | ☐YES X NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>X Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES X NO<br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | X BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Retrovirus expressing NeuroD1 |

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

At the beginning of a new collaborative study, the PI's Post-Doctoral Fellow obtained one microliter of replication-incompetent retroviral vector for a pilot study from a Collaborator. Their Collaborator has IBC approval for the use of replication-incompetent retroviral vectors for both in-vitro and in-vivo experiments. The PI has IBC approval for the use of adeno-associated viral plasmids (AAV) in-vivo and is interested to see if retroviral constructs would work as well as AAV. The decision was made for the PI's Post-Doctoral Fellow to perform the surgery. The Post-Doctoral Fellow performed the stereotactic injection of retroviral plasmid into one mouse in their BSL2 laboratory. He was wearing adequate PPE: lab coat, gloves and safety glasses. The PI did not realize at the time of the experiment that IBC approval was required if he intended to work with retroviral constructs.

The Post-Doctoral Fellow is compliant with training requirements:

- Initial Biosafety and Bloodborne Pathogen Training 9/25/2008
- 2020-2021 Biosafety and Bloodborne Pathogen Refresher Training 10/23/2020
- NIH Guidelines Training: 7/1/2016

Once the Biosafety Office received notification of the incident, the BSO reached out to the PI to discuss IBC compliance. PI and his Collaborator agreed best to add the PI and his Post-Doctoral Fellow to the Collaborator's IBC approved biosafety protocol, since the PI and staff have years of experience performing stereotactic injections and the Collaborator has the plasmids at hand.

This incident will be reviewed at the next IBC Meeting.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES X NO |
| **Please describe the root cause of this incident:** | 1. The PI initiated experiment without IBC approval. This was a one-time oversight when the Post-Doctoral Fellow injected a replication-incompetent retroviral vector without required approval. |

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):

1. Collaborator who currently has IBC approval for the use of retroviral plasmids have added the PI and his Post-Doctoral Fellow to the Collaborator's biosafety and Animal Use Protocols.

   *Status: Completed.*

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:** Desevilla, Liesl <LDESEVIL@augusta.edu>
**Sent:** Friday, March 12, 2021 9:16 AM
**To:** Harris, Kathryn (NIH/OD) [C]
**Subject:** NIH Incident Report Follow-Up

Hello Dr. Harris,

Apologies for the late reply and many thanks for the call. Hope you received my voice mail message.

To follow-up:

1. The PI, as well as the Post-Doctoral Fellow, is compliant with training requirements, which cover requirements to work with recombinant DNA material:
   - Initial Biosafety and Bloodborne Pathogen Training 8/1/2003
   - 2020-2021 Biosafety and Bloodborne Pathogen Refresher Training 10/30/2020
   - NIH Guidelines Training 8/2/2016
2. In addition, when I spoke with him about this incident, I had with me a copy of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and showed/reviewed with him Section III-D. I reminded the PI that Institutional Biosafety Committee approval for the use of recombinant DNA is specific to the vector, insert, target cell, etc. , and any deviation from the approved material requires an amendment. The PI must register the material and that registration involves review and approval from the Institutional Biosafety Committee. In this case, the Collaborator (rather than the PI) amended his BSP to include the PI and his staff member.
3. If additional training is recommended, I will be glad to schedule an in-person or virtual session to review the NIH Guidelines. I can send you a note when training is completed.

Let me know if you have additional questions or concerns.

Regards,
Liesl

*Liesl De Sevilla, MS*
Manager, BioSafety Programs
Environmental Health and Safety Division
Augusta University
1405 Goss Lane, CI-1003
Augusta, GA 30912
t. (706) 721-9201
f. (706) 721-9844
ldesevil@augusta.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Desevilla, Liesl <LDESEVIL@augusta.edu>
**Sent:** Tuesday, March 9, 2021 12:20 PM
**To:** NIH guidelines; Young, Philip
**Subject:** Reportable Event Augusta University 3/5/2021
**Attachments:** AU NIH Report 2021.3.5.docx

A campus researcher initiated an experiment with replication-incompetent, recombinant DNA material without IBC approval. A report of that incident is attached for you review.

Please let me know if you need any additional information.

Regards,

*Liesl De Sevilla, MS*
Manager, BioSafety Programs
Environmental Health and Safety Division
Augusta University
1405 Goss Lane, CI-1003
Augusta, GA 30912
t. (706) 721-9201
f. (706) 721-9844
ldesevil@augusta.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 5:18 PM
**To:** Kathryn Obrien; NIH guidelines
**Cc:** Ekaterina Semenyuk; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report for University of Southern California

Dear Dr. Kate O'Brien,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). No further information is required at this time.

However, we note that the incident occurred on February 25, 2021, and was not reported to NIH OSP until March 12, 2021. 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
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:** Kathryn Obrien <kathryno@usc.edu>
**Sent:** Friday, March 12, 2021 1:17 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Ekaterina Semenyuk <semenyuk@usc.edu>
**Subject:** Incident Report for University of Southern California

Hello,

Please, find attached an incident report involving a researcher that was bitten by a transgenic mouse.

Please, let me know if you need anything else.

Thank you,
Kate

Obtained via FOIA by Judicial Watch Inc.

**Kate O'Brien, PhD, RBP (ABSA)**| Biosafety Officer & High Containment Officer
Environmental Health & Safety
kathryno@usc.edu
Desk: 323-442-2204
Cell: Redacted by agreement

USC University of Southern California

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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Southern California, Los Angeles |
| **Date of Report:** | 3/10/2021 |
| **Reporter name and position:** | Ekaterina Semenyuk, Safety Specialist I |
| **Telephone number:** | 323-229-4733 |
| **Email address:** | semenyuk@usc.edu |
| **Reporter mailing address:** | 2001 N Soto Street, SBA #329<br>Los Angeles, CA 90032 |
| **Date of incident:** | 02/25/2021 |
| **Name of Principal Investigator:** | Dr. Unmesh Jadhav |
| **Is this an NIH-funded project?** | ■YES ☐NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:* K01DK113067<br>*NIH funding institute or center:* National Institute of Diabetes & Digestive & Kidney Diseases<br>*NIH program officer (name, email address):*<br>SASLOWSKY, DAVID E<br>*david.saslowsky@nih.gov* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>■Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ■YES ☐NO If yes, date of approval: 02/27/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>■BL2 ☐BL2+ (describe specific enhancement in report)<br>☐BL3 ☐BL3+ (describe specific enhancement in report)<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | **Section III** |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Transgenic mouse containing Eed gene Floxed (Eed Fl). Designed to delete Eed gene activity upon induction with 4-OH tamoxifen in presence of a CreER producing allele (e.g. Vil-CreER), causing aberrant activation of its target 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)

The Postdoctoral researcher trained by USC Department of Animal Research on animal techniques was performing an IP injection of Tamoxifen (2mg/ml) to C57BL/6 mouse in the vivarium. He was wearing a disposable gown, face mask and gloves. The researcher was alone in the animal room. The animal line that he was using had been genetically modified to carry Eed Flox and Villi Cre. The day before the incident, the mouse had received the first injection of Tamoxifen and the researcher was performing the second one. The mouse had been manually restrained. This restrain method has been approved by USC IBC and IACUC. The researcher states that he accidentally loosened his grip and the mouse bit him. He removed the glove, washed the wound with soap and water for about ten minutes, and cleaned with alcohol. He went to the USC approved medical facility where he received tetanus shot and was offered a follow up appointment for the upcoming week.

The list of training received by the researcher:

**10/2020** 18th EDITION OF THE GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS (2011); A2 - INTRO TO ANIMAL CARE LAWS, REG; ASEPTIC TECHNIQUE FOR RODENT SURVIVAL SURGERY; MOUSE; RAT; NON SURG-REQ. ANESTHESIA; COMMON COMPLIANCE ISSUES (e-learning)

**11/1/2020** Basic lab animal care and use training (e-learning and hands –on); Rodent Reproduction and Colony Management (e-learning); Techniques Training ((e-learning and hands –on); Anesthesia, Analgesia, surgical skills, and aseptic technique (e-learning).

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ■YES ☐NO |
| **Please describe the root cause of this incident:** | Incorrect handling of the 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):

The researcher will wear double gloves. The researcher is going to receive a refresher training on using manual restraints on the transgenic mice.

- **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:** Kathryn Obrien <kathryno@usc.edu>
**Sent:** Friday, March 12, 2021 1:17 PM
**To:** NIH guidelines
**Cc:** Ekaterina Semenyuk
**Subject:** Incident Report for University of Southern California
**Attachments:** Incident-Reporting-USC 10mar21.pdf

Hello,

Please, find attached an incident report involving a researcher that was bitten by a transgenic mouse.

Please, let me know if you need anything else.

Thank you,
Kate

**Kate O'Brien, PhD, RBP (ABSA)**| Biosafety Officer & High Containment Officer
Environmental Health & Safety
kathryno@usc.edu
Desk: 323-442-2204
Cell: Redacted by agreement

USC University of Southern California

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, May 6, 2021 1:47 PM
**To:** Spurbeck, Rachel (US); NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Battelle rDNA Incident 3-15-2021

Dear Dr. Rachel Spurbeck,

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:** Spurbeck, Rachel (US) <spurbeck@battelle.org>
**Sent:** Thursday, April 15, 2021 5:50 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** RE: Battelle rDNA Incident 3-15-2021

NIH/OSP,

Attached is the incident report for the accidental environmental release that we initially notified the NIH/OSP about on 3/15/21. Please contact me if you have any questions.

Sincerely,

**Rachel R. Spurbeck, PhD**
*Senior Genomics Research Scientist*
Health Outcomes and Biotechnology Solutions
Office: 614.424.7838
spurbeck@battelle.org

**Battelle**
505 King Ave
Columbus, OH 43201
http://www.battelle.org

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**From:** Spurbeck, Rachel (US)
**Sent:** Monday, March 15, 2021 10:28 PM
**To:** NIHGuidelines@od.nih.gov
**Subject:** Battelle rDNA Incident 3-15-2021

NIH/OSP,

This email serves as an initial notification of a possible accidental environmental release of recombinant VSV that the IBC was notified about today. Bedding from mice that had been inoculated with recombinant VSV-GP (biosafety level 2 recombinant virus) were disposed of without first decontaminating the material. All technicians handling the material wore PPE including a papr with full face mask, tyvex, lab coat, gloves, and booties. The research was previously reviewed and approved by the IBC and had proper SOPs for bedding and waste disposal. A full incident investigation is underway and an incident report will be submitted to NIH/OSP in a timely manner.

Please contact me with any questions.

Sincerely,

**Rachel R. Spurbeck, PhD**
*Senior Genomics Research Scientist*
Health Outcomes and Biotechnology Solutions
Office: 614.424.7838
spurbeck@battelle.org

**Battelle**
505 King Ave
Columbus, OH 43201
http://www.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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Battelle Memorial Institute |
| **Date of Report:** | 4/15/2021 |
| **Reporter name and position:** | Rachel R. Spurbeck, IBC Chair |
| **Telephone number:** | (614) 424-7838 |
| **Email address:** | spurbeck@battelle.org |
| **Reporter mailing address:** | 505 King Ave<br>Columbus, OH 43201 |
| **Date of incident:** | 3/15/21 |
| **Name of Principal Investigators:** | Tessa Moir-Savitz<br>Jeff Wallery |
| **Is this an NIH-funded project?** | ☐YES X NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| **What was the nature of the incident?** | X Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>X Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO If yes, date of approval: 1/20/21 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-D-1<br>Section III-D-3 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA X State or local Public Health<br>☐ FDA ☐Law enforcement<br>X EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | **Recombinant Material #1:** replication competent vesicular stomatitis virus vector pseudotyped with the glycoprotein of lymphocytic choriomeningitis virus<br><br>**Recombinant Material #2:** replication competent vesicular stomatitis virus vector pseudotyped with the glycoprotein of lymphocytic choriomeningitis virus and a human chemokine gene.<br><br>Vesicular stomatitis virus (VSV) normally does not cause disease in humans. However, both VSV vectors, were modified to make it even less likely to cause disease in humans and other animals. The modification includes the removal of a VSV gene that allows the virus |

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| | to infect neurons (nervous system tissue) and replacement with a gene from another virus that allows the newly modified VSV to still infect other cell types. |

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)

Redacted by agreement

Redacted by agreement

On March 15, 2021, it came to the attention of study directors that animal bedding and waste from two studies involving the same recombinant VSV (BSL-2 recombinant organisms) test articles had been disposed of as non-hazardous material. The first study took place in building JM10 Floor 1 room [redacted] and the second study took place in JM10 Floor 1 room [redacted] This was a deviation from the IBC-approved containment level as all waste was supposed to be decontaminated and sent to Stericycle for disposal as infectious waste. The deviation was in violation of SOP GEN7-005 Title: DISPOSAL OF LABORATORY WASTE. The pre-study training meetings conducted by the building safety officer covered waste disposal methods and were conducted on 1/13/21 and 1/20/21 for the respective studies.

At the time of incident discovery, a total of six bags of bedding waste from mice which had been inoculated with the recombinant VSV test materials were placed in a regular dumpster that was subsequently taken to a landfill without decontamination prior to disposal. The recombinant organisms in question are risk group 2 organisms and, as such, the bedding from the inoculated animals should have been tagged as biohazard, emptied from the cage into Stericycle containers, and disposed of as biohazardous waste. All staff handling the material were wearing PPE including safety glasses with side shields, scrubs, fully body Tyvek, two pairs of disposable gloves, shoe covers, head cover, and an N95 respirator at a minimum (staff were encouraged to wear a full-face or PAPR due to worldwide PPE shortage). Vivarium technicians working with the mice, as well as the cage wash staff for the two studies, were involved in the incident. Immediately upon identification of the issue, the study directors, facility management, biosafety officers, and the IBC chair were notified. Immediate actions taken included updating door signs to cover steps for disinfecting bedding and proper disposal. An email communication was sent to the entire staff for both studies specifying the proper procedures. The lead technician and study director followed up to ensure the appropriate disinfecting items are available in the room. Items that leave the room are now all labeled with biohazard labels. Instructions for disinfecting also were placed in the room's logbook. The second study officially ended before the incident was identified. The animals from that study are no longer in the room, cages disinfected by ethanol were removed, and bedding was then dumped into Stericycle bins for disposal. Upon identification of the issue, procedures were adjusted to ensure all bedding waste produced on the ongoing study was marked and treated prior to disposal by Stericycle. The other study officially ended April 4, 2021.

The Ohio EPA was notified of the disposal issue on March 17, 2021 and the new procedures were put in place to ensure decontamination prior to disposal. On March 18, 2021 the Madison County Health Department, who were in contact with Ohio EPA, conducted a site inspection after the new procedures were implemented and they responded on March 19, 2021 to the notification that the mitigations and response to the incident were appropriate and that no further action was necessary. The response notification was received on March 31, 2021.

A Corrective and Preventive Action (CAPA) investigation was completed to determine the root cause of the environmental release and to identify solutions to mitigate and prevent any future environmental release of recombinant or risk group 2 organisms. The CAPA investigation committee included the IBC chair, biosafety officer, facility management, study directors, QC, QA, and staff knowledgeable on the processes utilized at the facility on animal studies involving recombinant organisms and infectious agents. The investigation reviewed methods, SOPs, guidance on waste practices, staffing issues, training, experience, environment contributors

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(BSL-2, set up, animal care, time of day, room temperature, lighting, etc.), communication (how, when, type) equipment/materials involved, and mapped the process flow to identify potential gaps and hand-offs (touchpoints).

The CAPA investigation determined that the root cause was a communication breakdown. Studies generally begin with a pre-study meeting where the study director and facility safety officer convey methods and procedures that are necessary to be followed during the study to the lead technicians. The lead technicians are then responsible for ensuring all technicians working on the project and facilities staff (cage wash, waste disposal) are aware of any project-specific needs such as biohazard disposal. On these two studies, the lead technicians who had previously been ensuring the cages were marked as biohazard prior to transferring the cages to cage wash had left the company, and replacement staff were not informed of the need for handling the cages and bedding as biohazardous waste. This breakdown in communication led to the bedding being disposed as regular waste instead of going to Stericycle.

The CAPA investigation also determined that special considerations for recombinant organisms or infectious waste were not covered sufficiently in training materials and presentations. Therefore, actions have been taken to include more discussion of procedures to dispose of recombinant organisms and infectious waste. Furthermore, door signs and wall magnets will be installed to indicate all laboratories and vivarium space being used for studies that involve recombinant DNA or infectious material. Studies conducting infectious waste and/or recombinant DNA will have all bedding and waste disposed of as biohazard with Stericycle. This removes the possibility of miscommunications leading to recombinant or infectious waste release into the environment in the future.

**Institutional SOPs and Training Documents for Studies**

- GEN7-005[10] Title: DISPOSAL OF LABORATORY WASTE
- ARF3-014[12] Title: OPERATION OF THE INFECTIOUS WASTE STORAGE AREA
- FACT-049[00] Title: VESICULAR STOMATITIS VIRUS (VSV) FACT SHEET
- Battelle Policy and Procedure- Infectious Waste Management
- MAN-BIO-001[07] Title: CLINICAL AND NON-CLINICAL RESEARCH BIOSAFETY MANUAL FOR JM10 AND BATTELLE COLUMBUS
- Mice - VSV - Health and Safety Review and Door Posting
- BI_SOW10-VSV-GP IV mice - Biodistribution - Door and Health and Safety Summary
- New Hire Hazardous Waste Training

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ☐ NO |
| **Please describe the root cause of this incident:** | |

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):

- **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:** Spurbeck, Rachel (US) <spurbeck@battelle.org>
**Sent:** Thursday, April 15, 2021 5:50 PM
**To:** NIH guidelines
**Subject:** RE: Battelle rDNA Incident 3-15-2021
**Attachments:** NIH recombinant DNA Incident-Report 4-15-2021 final.docx

NIH/OSP,

Attached is the incident report for the accidental environmental release that we initially notified the NIH/OSP about on 3/15/21. Please contact me if you have any questions.

Sincerely,

**Rachel R. Spurbeck, PhD**
*Senior Genomics Research Scientist*
Health Outcomes and Biotechnology Solutions
Office: 614.424.7838
spurbeck@battelle.org

**Battelle**
505 King Ave
Columbus, OH 43201
http://www.battelle.org

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**From:** Spurbeck, Rachel (US)
**Sent:** Monday, March 15, 2021 10:28 PM
**To:** NIHGuidelines@od.nih.gov
**Subject:** Battelle rDNA Incident 3-15-2021

NIH/OSP,

This email serves as an initial notification of a possible accidental environmental release of recombinant VSV that the IBC was notified about today. Bedding from mice that had been inoculated with recombinant VSV-GP (biosafety level 2 recombinant virus) were disposed of without first decontaminating the material. All technicians handling the material wore PPE including a papr with full face mask, tyvex, lab coat, gloves, and booties. The research was previously reviewed and approved by the IBC and had proper SOPs for bedding and waste disposal. A full incident investigation is underway and an incident report will be submitted to NIH/OSP in a timely manner.

Obtained via FOIA by Judicial Watch Inc.

Please contact me with any questions.

Sincerely,

**Rachel R. Spurbeck, PhD**
*Senior Genomics Research Scientist*
Health Outcomes and Biotechnology Solutions
Office: 614.424.7838
spurbeck@battelle.org

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505 King Ave
Columbus, OH 43201
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## Hunter, Renee (NIH/OD) [C]

**From:** Spurbeck, Rachel (US) <spurbeck@battelle.org>
**Sent:** Monday, March 15, 2021 10:28 PM
**To:** NIH guidelines
**Subject:** Battelle rDNA Incident 3-15-2021

NIH/OSP,

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Please contact me with any questions.

Sincerely,

**Rachel R. Spurbeck, PhD**
*Senior Genomics Research Scientist*
Health Outcomes and Biotechnology Solutions
Office: 614.424.7838
spurbeck@battelle.org

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, July 7, 2021 2:11 PM
**To:** Bishop, James E; NIH guidelines
**Cc:** Rayadurg, Vijayasmitha Smitha N; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: possible rDNA exposure notification

Dear James Bishop,

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 while there was retraining regarding safe sharps handling practices and new equipment purchased to minimize the use of needles, there is no specific mention of immediate disposal of contaminated sharps which you may wish to consider when performing activities that may result in percutaneous injuries.

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:** Bishop, James E <JEBishop@uams.edu>
**Sent:** Friday, June 11, 2021 3:04 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>; Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Rayadurg, Vijayasmitha Smitha N <VSRayadurg@uams.edu>
**Subject:** RE: possible rDNA exposure notification

Attached is the completed incident reporting template for the exposure event reported in March. Please let me and Smitha Rayadurg know if there are any issues.

Thank you.

James Bishop, MS, RBP(ABSA)
Director, Occupational Health & Safety
Chair, Safety Coordinator Committee
Biological Safety Officer
FSAP Responsible Official
UAMS Department of Occupational Health & Safety
4301 W. Markham, Slot 617
Little Rock, Arkansas 72205

Obtained via FOIA by Judicial Watch Inc.

Office: (501) 603-1288

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Your **Feedback** is important to us.

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**From:** Bishop, James E
**Sent:** Saturday, March 20, 2021 11:15 AM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
**Cc:** Rayadurg, Vijayasmitha Smitha N <VSRayadurg@uams.edu>
**Subject:** possible rDNA exposure notification

Good morning,

This email is to notify you of a possible exposure to a recombinant strain of *Yersinia pestis*. The event described to me was a needlestick inside a BSC in our BL3. The needle is not believed to have been contaminated with organism, but was present in the BSC during work with the organism. The stick occurred during cleanup. The PI for the laboratory explained that the organism is a gene deletion strain which is actually an attenuated strain. Our campus policy is that personnel in the BL3 must report for medical assessment and medical advice. Generally, prophylaxis antibiotics is prescribed unless refused by personnel.

We will continue to gather information and submit a full notification using the template provided on the NIH OSP webpage. Please let me know if there are any questions in the meantime.

Thank you.

James Bishop, MS, RBP(ABSA)
Director, Occupational Health & Safety
Chair, Safety Coordinator Committee
Biological Safety Officer
FSAP Responsible Official
UAMS Department of Occupational Health & Safety
4301 W. Markham, Slot 617
Little Rock, Arkansas 72205
Office: (501) 603-1288

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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

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | XYES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | UNIVERSITY OF ARKANSAS MEDICAL SCIENCES |
| **Date of Report:** | 3/20/2021 |
| **Reporter name and position:** | JAMES BISHOP |
| **Telephone number:** | 501-603-1288 |
| **Email address:** | JEBishop@uams.edu |
| **Reporter mailing address:** | UAMS Department of Occupational Health & Safety.<br>4301 W. Markham, Slot 617<br>Little Rock, AR 72205 |
| **Date of incident:** | 3/20/2021 |
| **Name of Principal Investigator:** | ROGER PECHOUS |
| **Is this an NIH-funded project?** | XYES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):*<br><br>Yes, this work was funded under award 1R56AI53252-01 (now completed). Institute is NIAID, program officer is Suman Mukhopadhyay, mukhopadhyays@mail.nih.gov. |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>XPersonnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | {YES ☐NO If yes, date<br>f approval: |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>X BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-D-1, Appendix B-III |
| **Has a report of this incident been made to other agencies? If so, please indicate** | X CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Yersinia pestis* CO02, Recombinant, attenuated. Quantity unknown. Possibly contaminated needle. |

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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)

Around 10 am, laboratory personnel had completed animal dissection &was cleaning up the BSC used for that procedure. A needle used to restrain the animal during dissection had been recapped & sprayed with decontamination solution (specifically Vesphene) was sitting in the BSC to be wasted out following cleaning. When personnel picked up the capped needle to place into the sharps container, the needle had punctured the side of the cap and scrapped the employee's finger. No obvious blood was present from the possible exposure, however the glove was broken by the needle. The employee immediately notified their PI (~ 10 am), the PI immediately notified the RO (10:03 am), and the RO notified the FSAP and emailed the CDC DSAT Form 3 to our Primary case manager and the NIH OSP (11:15 am). Due to the Recombinant attenuation of the strain in use. Our facility is also a hospital so our Infection control & Prevention department was notified (10:09 am), the Charge Nurse for the Emergency Department (10:12am) where the potentially exposed personnel reported for medical evaluation, and our APRN on call for the Student and Employee Health Division (10:16 am). All those departments were notified before personnel arrived for assessment to ensure they knew an employee was on their way and what agent to expect may be involved in this potential exposure. Emergency Department personnel prescribed antibiotics and symptom watch.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO |
| **Please describe the root cause of this incident:** | The PI has identified the cause of the incident was recapping a "clean" needle. The PI is purchasing Necropsy Push pins and removing the use of the extra needle tip that were being used for dissection previously.<br><br>Around 10 am, laboratory personnel had completed animal dissection &was cleaning up the BSC used for that procedure. A needle used to restrain the animal during dissection had been recapped & sprayed with decontamination solution (specifically Vesphene) was sitting in the BSC to be wasted out following cleaning. When personnel picked up the capped needle to place into the sharps container, the needle had punctured the side of the cap and scrapped the employee's finger. |

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):

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Medical surveillance & treatment provided to the employee:
Total number of individuals = 1.
Physical evaluation
Fever/Symptom watch
Antibiotics or other prophylaxis

Retraining: The technician was re-trained in handling and discarding needles and sharps. The key points of training included: do not recap needles, and do not decontaminate capped needles and remove from the BSC. Rather, move the sharps container to the opening of the BSC for disposal, or keep sharps container within the BSC.

New Equipment provided:
The PI has purchased the Necropsy push pins from Eisco Scientific. The PI has removed the use of the extra needle tip that were being used for dissection previously.

- **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:** Bishop, James E <JEBishop@uams.edu>
**Sent:** Saturday, March 20, 2021 12:15 PM
**To:** NIH guidelines
**Cc:** Rayadurg, Vijayasmitha Smitha N
**Subject:** possible rDNA exposure notification

Good morning,

This email is to notify you of a possible exposure to a recombinant strain of *Yersinia pestis*. The event described to me was a needlestick inside a BSC in our BL3. The needle is not believed to have been contaminated with organism, but was present in the BSC during work with the organism. The stick occurred during cleanup. The PI for the laboratory explained that the organism is a gene deletion strain which is actually an attenuated strain. Our campus policy is that personnel in the BL3 must report for medical assessment and medical advice. Generally, prophylaxis antibiotics is prescribed unless refused by personnel.

We will continue to gather information and submit a full notification using the template provided on the NIH OSP webpage. Please let me know if there are any questions in the meantime.

Thank you.

James Bishop, MS, RBP(ABSA)
Director, Occupational Health & Safety
Chair, Safety Coordinator Committee
Biological Safety Officer
FSAP Responsible Official
UAMS Department of Occupational Health & Safety
4301 W. Markham, Slot 617
Little Rock, Arkansas 72205
Office: (501) 603-1288

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## Hunter, Renee (NIH/OD) [C]

**From:** Bishop, James E <JEBishop@uams.edu>
**Sent:** Friday, June 11, 2021 3:04 PM
**To:** NIH guidelines; Harris, Kathryn (NIH/OD) [C]
**Cc:** Rayadurg, Vijayasmitha Smitha N
**Subject:** RE: possible rDNA exposure notification
**Attachments:** rDNA Incident-Reporting- Roger Pechous lab - March 2021.pdf

Attached is the completed incident reporting template for the exposure event reported in March. Please let me and Smitha Rayadurg know if there are any issues.

Thank you.

James Bishop, MS, RBP(ABSA)
Director, Occupational Health & Safety
Chair, Safety Coordinator Committee
Biological Safety Officer
FSAP Responsible Official
UAMS Department of Occupational Health & Safety
4301 W. Markham, Slot 617
Little Rock, Arkansas 72205
Office: (501) 603-1288

**Check out our website at** http://uams.edu/campusop/depts/ohs/




Your **Feedback** is important to us.

---

**From:** Bishop, James E
**Sent:** Saturday, March 20, 2021 11:15 AM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
**Cc:** Rayadurg, Vijayasmitha Smitha N <VSRayadurg@uams.edu>
**Subject:** possible rDNA exposure notification

Good morning,

This email is to notify you of a possible exposure to a recombinant strain of *Yersinia pestis*. The event described to me was a needlestick inside a BSC in our BL3. The needle is not believed to have been contaminated with organism, but was present in the BSC during work with the organism. The stick occurred during cleanup. The PI for the laboratory explained that the organism is a gene deletion strain which is actually an attenuated strain. Our campus policy is that personnel in the BL3 must report for medical assessment and medical advice. Generally, prophylaxis antibiotics is prescribed unless refused by personnel.

We will continue to gather information and submit a full notification using the template provided on the NIH OSP webpage. Please let me know if there are any questions in the meantime.

Thank you.

Obtained via FOIA by Judicial Watch Inc.

James Bishop, MS, RBP(ABSA)
Director, Occupational Health & Safety
Chair, Safety Coordinator Committee
Biological Safety Officer
FSAP Responsible Official
UAMS Department of Occupational Health & Safety
4301 W. Markham, Slot 617
Little Rock, Arkansas 72205
Office: (501) 603-1288

**Check out our website at** http://uams.edu/campusop/depts/ohs/




Your **Feedback** is important to us.

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 5:31 PM
**To:** Fischer, Matthew; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: UMB incident report - 3/22/2021

Dear Dr. Matthew Fischer,

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:** Fischer, Matthew <matthew.fischer@umaryland.edu>
**Sent:** Monday, March 22, 2021 3:46 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** UMB incident report - 3/22/2021

Please find an incident report from the University of Maryland Baltimore attached to this email. If any questions arise, please let me know.

Thank you,
Matt

*Matthew A. Fischer, PhD, RBP, CBSP*
*Biosafety Officer and Assistant Director of Environmental Health and Safety*
*University of Maryland, Baltimore*
*matthew.fischer@umaryland.edu*
*(410) 706-7845*

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☑YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Maryland Baltimore |
| **Date of Report:** | March 22, 2021 |
| **Reporter name and position:** | Matthew Fischer<br>Biosafety Officer and Assistant Director of Environmental Health and Safety |
| **Telephone number:** | 410-706-7845 |
| **Email address:** | matthew.fischer@umaryland.edu |
| **Reporter mailing address:** | 714 W. Lombard Street<br>Baltimore, MD 21201 |
| **Date of incident:** | March 19, 2021 |
| **Name of Principal Investigator:** | Richard Eckert, PhD |
| **Is this an NIH-funded project?** | ☑YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>• 5R01CA211909-04, 5R01CA184027-05<br>*NIH funding institute or center:*<br>• NATIONAL CANCER INSTITUTE<br>*NIH program officer (name, email address):*<br>• Young S. Kim - kimyoung@mail.nih.gov |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☑ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ☑ NO<br>If yes, date of approval:<br>anticipated 4/9/2021 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4<br>(Unapproved, but experiment would be 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** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☑ Other (please describe):<br>☐ OSHA UMB IACUC (confirmed they are reporting to NIH OLAW) |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | SCC13-ACTL6A-KOc, SCC13-MET-KOc and Meso-1-MET-KOc (human cancer cell lines with genes knocked out using recombinant technology) |

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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 March 19, 2021, the biosafety officer was contacted by the Office of Animal Welfare Assurance (OAWA; the office that administrates the UMB IACUC). They provided an annual report that the PI submitted that described the use of several recombinant cell lines in mice that were not explicitly described in the IACUC protocol. OAWA asked for confirmation that these cell lines were approved in the PI's IBC protocol. At that time, the biosafety officer confirmed that the PI was not approved for the recombinant cells in question.

The PI was approved for the same parental cell lines with a different gene knocked out using recombinant technology, but not the genes in question. The IBC approved injection of those cells using BL-2 practices, including the use of a biosafety cabinet. Those practices were also appropriately used for these cell lines.

This incident was discussed at the IACUC meeting on March 19th and the committee confirmed that OAWA will file a report with NIH OLAW.

Animal work with the unapproved cell lines has been halted until the PI obtains both IACUC and IBC approval.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ☑ NO<br>The IBC will review this incident at the next convened meeting, which will be on April 9, 2021 |
| **Please describe the root cause of this incident:** | There was a belief that approval of the same parental cell lines for the knockout of a specific gene would cover the same procedures if they knocked out other genes. |

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 IBC office has discussed the need to submit to the IBC for additional genes of interest with the PI. He has already submitted an IBC protocol modification covering the use of the recombinant cell lines in mice. This IBC modification is anticipated to be reviewed at our next convened meeting on 4/9/2021.

- **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 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:** Fischer, Matthew <matthew.fischer@umaryland.edu>
**Sent:** Monday, March 22, 2021 3:46 PM
**To:** NIH guidelines
**Subject:** UMB incident report - 3/22/2021
**Attachments:** Eckert unapproved 031921.pdf

Please find an incident report from the University of Maryland Baltimore attached to this email. If any questions arise, please let me know.

Thank you,
Matt

*Matthew A. Fischer, PhD, RBP, CBSP*
*Biosafety Officer and Assistant Director of Environmental Health and Safety*
*University of Maryland, Baltimore*
*matthew.fischer@umaryland.edu*
*(410) 706-7845*

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 6:03 PM
**To:** Jamie Bishop; NIH guidelines
**Cc:** Alex Moretto; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Exposure incident report

Dear Dr. Jamie Bishop,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). No further information is required at this time.

However, we note that the incident occurred on February 25, 2021, and was not reported to NIH OSP until March 29, 2021. 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Jamie Bishop <bishop@ucsb.edu>
**Sent:** Monday, March 29, 2021 5:14 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Alex Moretto <amoretto@ucsb.edu>
**Subject:** Exposure incident report

To whom it may concern,

This email is to apprise NIH OSP of a recent, potential exposure to recombinant DNA. Enclosed, find the summary of the incident and follow up actions.
Please let me know if NIH OSP requires any additional information.

Regards,
Jamie

**Jamie Bishop, PhD** | Biological Safety Officer | Environmental Health & Safety
Design, Facilities & Safety Services
**o.** 805.893.8894 | **e.** bishop@ucsb.edu | **w.** ehs.ucsb.edu/biosafety

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UC SANTA BARBARA

**Institutional Biosafety Committee**
**Environmental Health & Safety**
Design, Facilities & Safety Services

To: Institutional Biosafety Committee
From: Jamie Bishop, Biosafety Officer
Cc: Alex Moretto, Research Safety Division Manager
Date: March 17, 2021
Re: Incident investigation and follow up

---

## Incident Investigation and Follow up

**Description**
Incident location: UCSB, Biological Sciences II, building 571, room 4185, tissue culture room, laboratory biosafety level 2. Female postdoctoral fellow (postdoc) sustained a cut finger during liquid aspiration of PBS and EDTA off of a genetically modified cell pellet.

**Account of the event as reported by the postdoc:**
This evening (February 25, 2021) around 7:15 - 7:30pm, I was working on the hood passaging the mouse macrophage line (J774A.1) containing the gain of function mutation of {human} Src (SrcE527K). I collected the cells, spun them down, and vacuum the liquid (PBS 1X + EDTA) {from a 50 ml Falcon tube}. When I was trying to remove the glass Pasteur pipette from the tube, the Pasteur pipette broke at the top, and my ring finger on my left hand got cut. I immediately saw blood, removed my glove, and ran to the sink to put my finger in the stream of water for around 10 minutes. I called {the lab manager} at that time to inform her. The bleeding didn't stop, so I had to put ice on my hand for several minutes. Once the bleeding controlled, I applied pressure on the wound with a paper tissue and finally put a bandage on. I went to Goleta Valley Cottage Hospital Emergency at 351 S Patterson. They took a look at the wound and took a picture. They conclude that the cut on my finger does not need any special emergency care and they didn't give me the tetanus vaccine because I got the shot last year. They give me an "Employers workers' compensation information worksheet" that I have to fill with my general information and give to {the lab manager}. This worksheet has to be completed within 3 business days to ensure my visit {is billed correctly} I will bring it to the lab and give it to {the lab manager} tomorrow during my shift.

**Exposure Assessment**
The end of the pipette may be assumed to be wet primarily with PBS and EDTA, and potentially contaminated with cells that were disturbed at the soft interface of the cell pellet. The mouse macrophage line (J774A.1) was stably transduced with lentivirus to express the human

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SrcE527K transgene. The cells had been sorted by FACS, and therefore no residual lentiviral vector was present in the materials involved in the exposure. Mutant protein expression is induced by doxycycline, i.e., the protein will not be expressed in the absence of this antibiotic.

SrcE527K is associated with thrombocytopenia.

**Training**
Bloodborne pathogens annual refresher training has been completed by the postdoc on November 20, 2020, and is tracked within the UCSB Learning Management System. Initial in person training, covering containment practices, the bloodborne pathogens regulations, and Institutional medical waste procedures, was provided by the campus biosafety officer prior.

**PPE**
The postdoc wore disposable gloves and a liquid impervious barrier lab coat. PPE was not a factor in this exposure and no additional PPE is recommended to prevent another similar sharps exposure.

**Root Cause**
Vacuum line tubing became brittle over time and needed replacement.
The glass pipet may have been inserted too far into the tubing, requiring more force to remove it after use.

**Lessons Learned**
The best practice for this procedure has been identified: use light force to seat the pipette in a short distance within the tubing. Placing the glass pipette any farther into the tubing will make it difficult to remove and may cause injury.
The BSO apprised the lab manager of plastic alternatives to glass and the group has purchased plastic pipettes to evaluate.
The lab manager will provide an in-person orientation for all current and future tissue culture room users on the updated safety procedure involving the use of glass pipettes and tubing. Further, the lab manager will do a monthly tubing check to ensure it's not visibly brittle; a usual sign of wear and age is reflected in the color of the tubing, where tubing that looks more worn down tends to have a yellower tint to it.
The lab manager has purchased sterile gauze to supplement the first aid supplies on hand.
Lastly, the lab manager will document this updated procedure for later lab managers.

**IBC Review**
The BSO notified the IBC of this incident at its convened meeting on March 10, 2021, and reviewed the incident report by email prior to submittal to NIH Office of Science Policy.

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## Hunter, Renee (NIH/OD) [C]

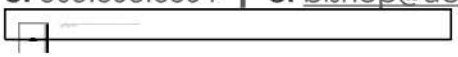
**From:** Jamie Bishop <bishop@ucsb.edu>
**Sent:** Monday, March 29, 2021 5:14 PM
**To:** NIH guidelines
**Cc:** Alex Moretto
**Subject:** Exposure incident report
**Attachments:** Sharps Incident Report 02252021.docx

To whom it may concern,

This email is to apprise NIH OSP of a recent, potential exposure to recombinant DNA. Enclosed, find the summary of the incident and follow up actions.
Please let me know if NIH OSP requires any additional information.

Regards,
Jamie

**Jamie Bishop, PhD** | Biological Safety Officer | Environmental Health & Safety
Design, Facilities & Safety Services
**o.** 805.893.8894 | **e.** bishop@ucsb.edu | **w.** ehs.ucsb.edu/biosafety



Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 4:21 PM
**To:** lydia SOHN
**Cc:** NIH guidelines; Chips Hoai; Brandon Defrancisci; Bso 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** lydia SOHN <sohn@berkeley.edu>
**Sent:** Tuesday, March 30, 2021 7:53 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** NIH guidelines <NIHguidelines@od.nih.gov>; Chips Hoai <chips@berkeley.edu>; Brandon Defrancisci <defran@berkeley.edu>; Bso Departmental <bso@berkeley.edu>; lydia SOHN <sohn@berkeley.edu>
**Subject:** recombinant DNA accident

Dear Dr. Harris,

I would like to send in the report of an incident in the lab of Dr. Randy Schekman at UC Berkeley. On March 23, 2021, where user error in selection of a proper clamp for a shaker resulted in a spill of Recombinant E. coli XL1-Blue strain propagating pLenti-puro Plasmid without any foreign protein being expressed. Research personnel have been retrained on proper restraint selection. A detailed incident report is attached.

If you have any questions, or need additional information, please do not hesitate to contact me.

Best wishes,

Lydia Sohn
CLEB Chair

Obtained via FOIA by Judicial Watch Inc.

**********

Lydia L. Sohn
*Almy C. Maynard and Agnes Offield Maynard Chair in Mechanical Engineering*
Dept. of Mechanical Engineering
Core Member, UCSF-UC Berkeley Graduate Program in Bioengineering
Faculty Assistant to the Vice Chancellor for Research
University of California, Berkeley

Redacted by [redacted] (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.

## 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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, Berkeley |
| **Date of Report:** | March 29, 2021 |
| **Reporter name and position:** | Chips Hoai<br>Biosafety Officer |
| **Telephone number:** | 510-849-7142 |
| **Email address:** | chips@berkeley.edu |
| **Reporter mailing address:** | 317 University Hall #1150<br>Office of Environment, Health & Safety<br>UC Berkeley<br>Berkeley, CA 94720 |
| **Date of incident:** | 03/23/2021 |
| **Name of Principal Investigator:** | Randy Schekman |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known) |

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| | |
|---|---|
| | *NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☒Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: Feb. 2021 |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-2 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or** | pLenti-puro Plasmid (mammalian vector being propagated in E. coli XL1-Blue without any foreign protein being |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **synthetic material involved in incident (strain, attenuation, etc.)** | expressed) |

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 took place in a warm room in the building, outside of the main laboratory. During the night, a flask with 250 mL of E. coli XL1-Blue (containing a pLenti-puro plasmid being prepared for purification) was dislodged from the shaker, and broke on the floor. The owner of the flask (postdoc) was notified by other building occupants that the flask had broken, and he immediately treated the area of the spill with 10% bleach for 20 minutes, then cleaned up the broken glass and liquid. He had taken all of the required general safety and biosafety training required by the university. There was no deviation from standard operating procedures, however, he chose to use a clamp on the shaker which was not ideal for his particular flask. The room was unoccupied at the time of the incident, but he wore a lab coat, safety glasses, and gloves while cleaning up the spill the following morning. No equipment failure, injury, or need for medical surveillance was noted.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br>(scheduled for review 04/06/2021) |
| **Please describe the root cause of this incident:** | User error. Use of a flask clamp on a shaker that did not adequately hold the flask. |

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 user was instructed and retrained as to which flask clamps should be used in the future, and the incident will be discussed at the next lab meeting to ensure all members are aware of the issue.

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, March 30, 2021 7:53 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** NIH guidelines; Chips Hoai; Brandon Defrancisci; Bso Departmental; lydia SOHN
**Subject:** recombinant DNA accident
**Attachments:** Schekman - NIH Spill Report - 2021.03.docx

Dear Dr. Harris,

I would like to send in the report of an incident in the lab of Dr. Randy Schekman at UC Berkeley. On March 23, 2021, where user error in selection of a proper clamp for a shaker resulted in a spill of Recombinant E. coli XL1-Blue strain propagating pLenti-puro Plasmid without any foreign protein being expressed. Research personnel have been retrained on proper restraint selection. A detailed incident report is attached.

If you have any questions, or need additional information, please do not hesitate to contact me.

Best wishes,

Lydia Sohn
CLEB Chair

**********
Lydia L. Sohn
*Almy C. Maynard and Agnes Offield Maynard Chair in Mechanical Engineering*
Dept. of Mechanical Engineering
Core Member, UCSF-UC Berkeley Graduate Program in Bioengineering
Faculty Assistant to the Vice Chancellor for Research
University of California, Berkeley
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:** Wednesday, April 14, 2021 4:55 PM
**To:** Priya Kumar; NIH guidelines
**Cc:** Zara Llewellyn; Katia Harb; Steve Libby; Greg D Horwitz; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report - University of Washington

Dear Dr. Priya Kumar,

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:** Priya Kumar <priyak2@uw.edu>
**Sent:** Thursday, April 8, 2021 4:02 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Zara Llewellyn <zaral@uw.edu>; Katia Harb <kharb@uw.edu>; Steve Libby <slibby@uw.edu>; Greg D Horwitz <ghorwitz@uw.edu>; Priya Kumar <priyak2@uw.edu>
**Subject:** Incident Report - University of Washington

Dear NIH,

Please find attached an incident report involving an employee performing research subjected to Section III-D of the NIH Guidelines.
Please contact me if you have any questions or need additional information.

Thank you,
Priya

PRIYA KUMAR, PhD RBP, SM(NRCM)

Biosafety Officer

Obtained via FOIA by Judicial Watch Inc.

Environmental Health & Safety

Magnuson Health Sciences Building / Box 357165

1705 NE Pacific Street T-287 / Seattle, WA 98195-7165

206.543.7278 / fax 206.221.3068

priyak2@uw.edu / ehs.washington.edu

Hrs: Mon-Fri: 7:00am – 2:00pm

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Washington |
| **Date of Report:** | April 08, 2021<br>Initially reported to NIH via email on March 31, 2021 |
| **Reporter name and position:** | Priya Kumar, PhD, RBP Biosafety Officer |
| **Telephone number:** | 206-543-7278 |
| **Email address:** | Priyak2@uw.edu |
| **Reporter mailing address:** | University of Washington<br>Environmental Health and Safety Department<br>1705 NE Pacific St<br>Room T-287<br>Box 357165<br>Seattle, WA 98195 |
| **Date of incident:** | March 27, 2021 |
| **Name of Principal Investigator:** | Greg Horwitz, PhD Professor, Physiology and Biophysics |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known) |

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| | |
|---|---|
| | *NIH grant of contract number: 1UG3MH120095-01A1*<br>*NIH funding institute or center: National Institute of Mental Health*<br>*NIH program officer (name, email address):*<br>Kim, Douglas S; douglas.kim@nih.gov |

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval:<br><br>Original approval with this vector was on March 20, 2007. This protocol was reviewed and renewed by the IBC on:<br>- April 21, 2010<br>- April 17, 2013<br>- February 17, 2016<br>- March 20, 2019 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-D |
| | |

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| | |
|---|---|
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☒OSHA: This incident will be included in the UW annual OSHA 300A report |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Adeno-associated viral vectors (adenovirus free and replication incompetent). The virus carries the gene for microbial opsins or fluorescent reporters. The virus and the recombinant DNA are biosafety level 1 made by the Allen Institute Viral Vector Core.<br>. |

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

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A veterinary technician (tech) was working in a non-human primate (NHP) ABSL-2 room at the University of Washington. The tech was preparing to sedate a macaque (M. nemestrina male, age 4y 4m) on March 27, 2021 to examine sutures from recent surgery. To do this the tech needed to move the macaque to the front of the cage using a squeeze bar. The macaque pushed against the squeeze causing a seroma on its head to burst. The tech did not visually see the seroma and was not aware of it. The macaque had a habit of seeming to be quiet, and then suddenly pushing in all directions with feet and hands, and in this case, its head, causing the seroma to burst. Blood splashed around the tech's safety glasses into the right eye. The tech flushed the eyes for fifteen minutes and contacted the veterinarian on call. The tech went to the Emergency Department as required by protocol for follow-up for potential exposure to macaque body fluids which could carry Macacine alphaherpevirus 1(B virus).

As the tech was squeezing the macaque to bring it afront, the glasses slipped down on the nose. The safety glasses had been used for a while so the flexible fingers on the nosepiece may have been worn or less stiff. The tech was wearing a style of glasses with wrap-around lens for extra cheek and side coverage but did not have temples that could be shortened to fit the face.

The tech was wearing the appropriate personal protective equipment (PPE). This includes two layers of nitrile gloves, disposable lab gown, shoe covers, scrubs, surgical mask, safety glasses and hair bonnet.

The tech has now disposed of the safety glasses used in the incident and replaced them with a pair of new safety glasses with adjustable temples where the length of the temples can be lengthened or shortened for a tighter fit. The SOP for wearing PPE/protective eyewear was reviewed by the tech, including reminder to ensure a proper fit of protective eyewear each time before working with primates. This reminder was also sent to the Primate Center research support staff in a staff meeting and/or newsletter.

The NHP had been inoculated with adeno-associated viral vector by direct injection into the brain of monkey on March 23, 2021. The adeno-associated viral vector is adenovirus free and replication incompetent. The virus carries the gene for microbial opsins or fluorescent reporters. The virus and the recombinant DNA are biosafety level 1 made by the Allen Institute Viral

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Vector Core.

The tech is enrolled in the Occupational Health program for animal care staff and has recently received annual tuberculosis (TB) screening as well as an annual “Health Assessment" review. The Employee Health Clinic staff will continue to see the tech for follow-up to the potential B virus exposure. The tech was initially provided prophylactic antiviral regimen and B virus testing on the day of the incident while at the Emergency Department.

The tech has extensive experience in working with NHPs for over 5 years. The tech’s training is up to date and listed below.

| **Training** | **Completion Date** | **Expiration Date** |
|---|---|---|
| Biosafety Online | 08/04/2020 | 08/04/2023 |
| Bloodborne Pathogens | 08/04/2020 | 08/04/2021 |

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br>This will be reviewed at the next IBC meeting on April 21st, 2021. |
| **Please describe the root cause of this incident:** | The safety glasses did not provide adequate protection and have been replaced with new safety glasses with adjustable temples. The tech can also wear safety goggles and face shields. |

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 tech has disposed of the glasses after the incident and been provided with a pair of new safety glasses with adjustable temples. Another option is wearing safety goggles and face shields to prevent splashes into the eyes. The tech has now been trained to ‘ensure’ a proper fit of the safety glasses each time before use as part of the SOP on PPE. The tech will wear appropriate eye wear to prevent any splashes into the eyes.

- **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:** Wednesday, March 31, 2021 3:40 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 March 27, 2021.

We are investigating the incident and will be 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

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.

## Hunter, Renee (NIH/OD) [C]

**From:** Priya Kumar <priyak2@uw.edu>
**Sent:** Thursday, April 8, 2021 4:02 PM
**To:** NIH guidelines
**Cc:** Zara Llewellyn; Katia Harb; Steve Libby; Greg D Horwitz; Priya Kumar
**Subject:** Incident Report - University of Washington
**Attachments:** NIH Incident-Report_Horwitz_2021.pdf

Dear NIH,

Please find attached an incident report involving an employee performing research subjected to Section III-D of the NIH Guidelines.
Please contact me if you have any questions or need additional information.

Thank you,
Priya

PRIYA KUMAR, PhD RBP, SM(NRCM)

Biosafety Officer

Environmental Health & Safety

Magnuson Health Sciences Building / Box 357165

1705 NE Pacific Street T-287 / Seattle, WA 98195-7165

206.543.7278 / fax 206.221.3068

priyak2@uw.edu / ehs.washington.edu

Hrs: Mon-Fri: 7:00am – 2:00pm

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, May 6, 2021 3:14 PM
**To:** ANDREA N LADD; NIH guidelines
**Cc:** Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang; Tucker, Jessica (NIH/OD) [E]; Young, Cari (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:** Monday, April 19, 2021 2:35 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 needlestick initially reported on 04/01/21 (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., RBP*
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:** Thursday, April 1, 2021 1:57 PM
**To:** harriskath@mail.nih.gov; NIHGuidelines@od.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

Kathryn or Whom It May Concern,

We were notified today of a potential exposure to a recombinant microbe from a needlestick in one of our ABSL2 laboratories. The employee was directed to Occupational Medicine 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
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

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Wisconsin-Madison |
| **Date of Report:** | 04/01/21 (initial email to OSP)<br>04/19/21 (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<br>30 East Campus Mall<br>Madison, WI 53715 |
| **Date of incident:** | 04/01/21 |
| **Name of Principal Investigator:** | Eva Rakasz |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 11/26/18 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☐BL2 ☐BL2+ ☒ABSL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-1-a, III-D-1-b |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA<br><br>Not applicable |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Recombinant SHIV (SIV engineered to have envelope of HIV), strain SHIV-AD8 |

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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.**

**Location:** barrier primate facility

**Persons involved:** UW-Madison employee

**Training received by individual:** Lab-specific training according to approved biosafety protocol was done and documented. Employee also received Herpes B virus (HBV) training for primate work.

**PPE in use at time of event:** bonnet, surgical mask, face shield, 2 pairs of nitrile gloves, shoe covers, and Tyvek jumpsuit

**Event description:** Two employees were attempting to sedate a macaque that had previously been infected with SHIV one month prior (on March 2, 2021) by immobilizing the animal in its home cage using a restraint device and injecting a sedative. The animal was uncooperative during the application of restraint and the employee giving the injection accidently poked their hand with the needle. The employee was unsure whether the needle had broken the skin of the animal first, but it is the SOP of this facility to treat all incidents in which the skin is breached as exposures that could transmit infection.

**Immediate follow-up and medical follow-up:** The employee immediately stopped work, removed their gloves, and performed a 15 minute flush and scrub of the site with chlorhexidine. The employee notified the Primate Center's Safety Officer and went to University Health Services/Occupational Medicine for medical follow up. A report was submitted to the Office of Biological Safety, and the Biological Safety Officer reported the incident to NIH-OSP.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br>The IBC Chair was aware of the event upon initial report to OSP. The IBC was apprised of the incident at the next IBC meeting on April 7, 2021. |
| **Please describe the root cause of this incident:** | A root cause is the natural instinct of the animal to be uncooperative with a procedure it dislikes. It was previously determined that the chance of incidental exposure (e.g., from bites or scratches) is greater when each animal is transferred from its cage to a separate restraint device for injection and back again than |

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| | |
|---|---|
| | performing injections in the home cage. Therefore, animals are immobilized in place. However, it should be noted that sufficient immobilization can be difficult if an animal is not amenable to the restraint method. |

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 Safety Officer for the primate facility to discuss the incident and review the emergency follow-up.

The employee and supervisor followed the established emergency procedures as outlined in the IBC-approved biosafety protocol and facility SOPs. The Safety Officer reviewed the incident with the employee. It was determined that the individual followed established SOPs and does not need retraining.

The Primate Center maintains a list of animals that, due to their behavior, are removed from their cages and placed in a table-top restraint device for injection rather than being immobilized in their home cage. The animal involved in this incident is being evaluated for whether it should be included on this list moving 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:** ANDREA N LADD <andrea.ladd@wisc.edu>
**Sent:** Monday, April 19, 2021 2:35 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
**Subject:** Incident report attached
**Attachments:** Rakasz_040121_OSP Reportable.docx

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the needlestick initially reported on 04/01/21 (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., RBP*
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:** Thursday, April 1, 2021 1:57 PM
**To:** harriskath@mail.nih.gov; NIHGuidelines@od.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

Kathryn or Whom It May Concern,

We were notified today of a potential exposure to a recombinant microbe from a needlestick in one of our ABSL2 laboratories. The employee was directed to Occupational Medicine 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.

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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
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

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## Hunter, Renee (NIH/OD) [C]

**From:** ANDREA N LADD <andrea.ladd@wisc.edu>
**Sent:** Thursday, April 1, 2021 2:57 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**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.*
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

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 5:55 PM
**To:** Karen McCulloch; NIH guidelines
**Cc:** Chris Doyle (cdoyle@wirb.com); Sarah Roberge; Johnson Megan - Nashville; Marx Scott; Britton Kathryn; Berdeja Jesus - Concur - INTERNET; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: IBC Incident Report - TriStar Centennial Medical Center

Dear Karen McCulloch,

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.

However, we note that the incident occurred on February 15, 2021, and was not reported to NIH OSP until April 5, 2021. Please note that under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), any significant problems or violations of the *NIH Guidelines* must be reported to NIH within 30 days. 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:** Karen McCulloch <KMcCulloch@wcgclinical.com>
**Sent:** Monday, April 5, 2021 4:33 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Chris Doyle (cdoyle@wirb.com) <cdoyle@wirb.com>; Sarah Roberge <sroberge@wirb.com>; Johnson Megan - Nashville <Megan.Roberts4@SarahCannon.com>; Marx Scott <Scott.Marx@SarahCannon.com>; Britton Kathryn <Kathryn.Britton@SarahCannon.com>; Berdeja Jesus - Concur - INTERNET <jberdeja@tnonc.com>
**Subject:** IBC Incident Report - TriStar Centennial Medical Center

To Whom it May Concern,

Please see the attached incident report related to IBC oversight. Please feel free to reach out with any questions or if I can provide additional details.

Best,
Karen

**Karen A. McCulloch | IBC Chair**

Obtained via FOIA by Judicial Watch Inc.

**WCG IBC Services**
1019 39th Avenue SE
Suite 120
Puyallup, WA 98374
o/ +1 651.429.1058
m/ Redacted by agreement
**kmcculloch@wcgclinical.com** | **www.wcgirb.com**




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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | TriStar Centennial Medical Center |
| **Date of Report:** | April 5, 2021 |
| **Reporter name and position:** | Karen McCulloch, BS<br>IBC Chair, TriStar Centennial Medical Center |
| **Telephone number:** | 651-429-1058 |
| **Email address:** | kmcculloch@wcgclinical.com |
| **Reporter mailing address:** | 1019 39th Ave SE, Suite 120<br>Puyallup, WA 98374 |
| **Date of incident:** | 02-15-2021 |
| **Name of Principal Investigator:** | Jesus G Berdeja, MD |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other: Premature closure of IBC oversight; a subject was retreated without re-establishment of IBC oversight. |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐YES ☐NO<br><br>Initial: 02-11-2016<br>Reapproved: 02-07-2017<br>Reapproved: 03-09-2018<br>Modification Approved: 10-23-2018<br>Reapproved: 03-05-2019<br>Reapproved: 03-18-2020<br>Reapproved: 03-24-2021 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation,** | Autologous T cells transduced with a 3rd generation lentiviral vector encoding a BCMA-specific chimeric antigen receptor (CAR). |

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| | |
|---|---|
| **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)
  - TriStar Centennial Medical Center 3rd Floor Clinic.

- Who was involved in the incident/violation, including others present at the incident location?
  - Regulatory and Study Staff members.

  **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 Institution informed IBC Services of study activities that occurred during the process of re-treating a subject.
  - 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
  - Staff members had trained on the Biosafety SOP on 02-15-2021, the day the subject was re-treated.

- 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.

- 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
  - Gloves, gown/lab coat, eye protection and mask.

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- The occupational health requirements for laboratory personnel involved in the research
  - Not applicable.
- Any medical surveillance provided or recommended after the incident
  - Not applicable.
- Any injury or illness associated with the incident
  - No.
- Equipment failures
  - No.

DESCRIPTION OF INCIDENT:

Based on information provided to the IBC by the Institution, IBC oversight for this study ended on March 25, 2020. However, re-treatment of subjects enrolled in this study remained a possibility. One subject was retreated with the study agent in this trial on February 15, 2021 prior to re-establishment of IBC oversight.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | The site notified WIRB to close IBC oversight due to study enrollment closure. Following IBC closure, the site did not appropriately reestablish IBC oversight with retreatment of subject 401-131-0001. Per protocol, eligible subjects may retreat if the protocol specified criteria is met and if cryopreserved bb2121 drug is available. Subject 401-131-0001 met this protocol specified criteria resulting in the site retreating the patient while the study was still closed at IBC. |

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 reached out to the IBC and the IBC held a convened meeting on March 24, 2021 in which this research was re-approved and IBC oversight was re-established. The Institution is creating a formal process for IBC operations which will be outlined in a formal WI or SOP to ensure that studies are not prematurely closed. The timeline for implementation is to have the process drafted by April 16, 2021 and all applicable staff members trained by May 31, 2021.

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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:** Karen McCulloch <KMcCulloch@wcgclinical.com>
**Sent:** Monday, April 5, 2021 4:33 PM
**To:** NIH guidelines
**Cc:** Chris Doyle (cdoyle@wirb.com); Sarah Roberge; Johnson Megan - Nashville; Marx Scott; Britton Kathryn; Berdeja Jesus - Concur - INTERNET
**Subject:** IBC Incident Report - TriStar Centennial Medical Center
**Attachments:** OSP Incident Report, Dr. Berdeja, dated 04-05-2021.pdf

To Whom it May Concern,

Please see the attached incident report related to IBC oversight. Please feel free to reach out with any questions or if I can provide additional details.

Best,
Karen

**Karen A. McCulloch | IBC Chair**
**WCG IBC Services**
1019 39th Avenue SE
Suite 120
Puyallup, WA 98374
o/ +1 651.429.1058
m/ Redacted by agreement
**kmcculloch@wcgclinical.com** | **www.wcgirb.com**

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 4:45 PM
**To:** Kapsalis, Ellen; NIH guidelines
**Cc:** ekobetz; Stamates, Johanna; Tsoulfas, Pantelis; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Needlestick incident exposure

Dear Dr. Ellen Kapsalis,

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. However, we note that as discussed with NIH OSP staff over the phone. this work was not exempt.

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:** Kapsalis, Ellen <EKapsali@med.miami.edu>
**Sent:** Tuesday, April 6, 2021 6:21 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** ekobetz <ekobetz@med.miami.edu>; Stamates, Johanna <JStamates@med.miami.edu>; Tsoulfas, Pantelis <PTsoulfa@med.miami.edu>
**Subject:** Needlestick incident exposure

To whom it may concern,

Please see attached a report concerning a recent needlestick exposure incident.

Please note that the University of Miami's policy has now expanded to require NIH Guidelines training for all investigators working with rDNA and/or transgenic animals whose work falls under Section IIIF of the NIH guidelines.

With kind regards,

Eleni

Obtained via FOIA by Judicial Watch Inc.

*Ellen Kapsalis, PhD, CPIA, CHRC*
Director for Compliance, IACUC/IBC/ESCRO/DEA
Office of the Vice Provost for Research + Scholarship
University of Miami
*Ph: (305) 243 2311 Cell:* Redacted by agreement

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☒YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Miami |
| **Date of Report:** | 04-06 -21 |
| Reporter name and position: | Ellen Kapsalis, Ph.D, CPIA, CHRC<br>Director for Compliance, IACUC/IBC/ESCRO/DEA<br>Office of the Vice Provost for Research + Scholarships<br>University of Miami |
| **Telephone number:** | Office: (305) 243-2311<br>Cell: (305) 305-301-3315 |
| **Email address:** | ekapsali@med.miami.edu |
| **Reporter mailing address:** | University of Miami<br>1400 NW 10th Ave<br>Miami, FL, 33136 |
| **Date of incident:** | 3-16-2021 |
| **Name of Principal Investigator:** | Elenore Beurel, Ph.D. |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>*NIH grant of contract number: MH104656*<br>*NIH funding institute or center: NIMH*<br>*NIH program officer (name, email address):*<br>• **Administration:** Program Official(PO)<br>• **Name:** *Leonardo Tonelli, Ph.D.* |

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| | |
|---|---|
| | Neuroendocrinology and Neuroimmunology Program<br>Division of Neuroscience and Basic Behavioral Science<br>6001 Executive Blvd<br>Bethesda, MD 20892 |

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 8-19-20 |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | IIIF |
| **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.)** | Cells were extracted from a WT Il-17A-IRES-GFP-KI transgenic mouse and processed to obtain Th17 cells. The TH17 cells were slated to be injected into recipient a Rag2-/-).transgenic mouse at the time of the exposure. |

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On the morning of 3/16/2019, a female faculty member was injecting th17 cells (taken from Thy.1 GFP mice) into Rag2-/- mice. At the time of the incident, the faculty member was alone in an BL1 animal holding room. While the investigator prepared to inject the cells into a mouse, the animal moved and the needle penetrated the skin of one of her fingertips. She was wearing appropriate PPE (gloves and laboratory coat). There were no deviations from biosafety SOPs or from the IBC approved containment level at the time of the incident/violation. There were no equipment failures.

Following Occupational Health and Safety protocols, the Investigator immediately cleaned the skin with soap and water and reported to the University's Employee Health Clinic approximately a half hour later. The nurse practitioner treated the wound, drew blood for analysis, prescribed antibiotics and provided medical advice. The investigator had a follow-up appointment two days later and no further issues were reported.

The exposed person's most recent biosafety training included:

- Bloodborne Pathogen training on 8-7-2020. This is renewed on an annual basis.
- Biosafety training on 3-6-2020. Training is renewed every three years.
- Laboratory Safety training on 11-13-17. Training is renewed every five years.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The incident was reviewed at a convened IBC meeting on March 18, 2021. |
| **Please describe the root cause of this incident:** | The animal moved unexpectedly. All requisite personal protective equipment was in place. |

**The following measures have been taken by the institution:**

The University of Miami does not require NIH Guidelines training for individuals working on IBC exempt studies however the annual Bloodborne Pathogen training covers in-depth the topic of incident exposures. This policy has been reconsidered in light of this exposure. Going forward, the University of Miami will require NIH Guidelines training for all investigators using recombinant DNA and/or transgenic animals regardless of whether protocol is exempt or not.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Kapsalis, Ellen <EKapsali@med.miami.edu>
**Sent:** Tuesday, April 6, 2021 6:21 PM
**To:** NIH guidelines
**Cc:** ekobetz; Stamates, Johanna; Tsoulfas, Pantelis
**Subject:** Needlestick incident exposure
**Attachments:** Incident Exposure Report Beurel 4-6-21.docx

To whom it may concern,

Please see attached a report concerning a recent needlestick exposure incident.

Please note that the University of Miami's policy has now expanded to require NIH Guidelines training for all investigators working with rDNA and/or transgenic animals whose work falls under Section IIIF of the NIH guidelines.

With kind regards,

Eleni

*Ellen Kapsalis, PhD, CPIA, CHRC*
Director for Compliance, IACUC/IBC/ESCRO/DEA
Office of the Vice Provost for Research + Scholarship
University of Miami
*Ph: (305) 243 2311 Cell:* Redacted by agreement

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 1:01 PM
**To:** Kumar, Asmita/Research and Technology Mgmt; NIH guidelines
**Cc:** Glickman, Michael/Sloan Kettering Institute; Cottington, Eric M./Research and Technology Mgmt; Schaller-Demers, Debra S./Research and Technology Mgmt; Gibson, James H./Facilities Management; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Potential exposure report

Dear Dr. Asmita Kumar,

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:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Sent:** Monday, May 10, 2021 2:58 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Glickman, Michael/Sloan Kettering Institute <glickmam@MSKCC.ORG>; Cottington, Eric M./Research and Technology Mgmt <cottinge@mskcc.org>; Schaller-Demers, Debra S./Research and Technology Mgmt <schalled@mskcc.org>; Gibson, James H./Facilities Management <GibsonJ2@mskcc.org>
**Subject:** Potential exposure report

Good Afternoon,

Please find attached report on behalf of the IBC Chairman, Dr. Michael Glickman. This potential exposure was originally reported to the OSP on 4/7/21 as a pre-report.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

Obtained via FOIA by Judicial Watch Inc.

**Memorial Sloan Kettering Cancer Center**
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10017
C Redacted by agreement
kumara1@mskcc.org

==========

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Memorial Sloan Kettering Cancer Center

May 10, 2021

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: rDNA exposure at Memorial Sloan Kettering Cancer Center

In accordance with the NIH guidelines, this report is a follow up of an initial incident report submitted to the NIH Office of Science Policy via email on 4/7/2021.

A research technician sustained a potential eye-splash involving BSL-1 recombinant nucleic acids while working as approved personnel under an approved IBC Registration. The research technician was performing a tail vein injection of a pool of transduced mouse bone marrow cells in a certified biosafety cabinet within the vivarium. She was wearing the required PPE: gown and gloves, but did not have her safety glasses on. She was concentrating on the proper placement of the syringe into the mouse tail vein and had placed her face very close to the mouse. The needle missed the vein and the cells were released. She felt a few small droplets on her face and possibly in her eyes. It was difficult to determine if the eyes were exposed due to the use of contact lenses. She washed her eyes with water, removed her contacts, and called Employee Health and Wellness to report the incident. The mouse bone marrow were transduced with non-replicating ecotropic retrovirus. The rDNA vehicle was a pMIGRII backbone with human cDNAs of known and unknown function cloned into the backbone.

Our Biosafety Officer and EHS Director counseled her about the hazards of wearing contact lens when performing procedures or experiments and reinforced the use of eye protection and the proper use of a biosafety cabinet. The IBC agreed that the reeducation was appropriate and adequate. We believe that retraining will help reduce the recurrence of such issues. 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 email at: glickmam@mskcc.org.

Sincerely,

Redacted by agreement

Michael Glickman, MD
IBC Chairperson

Cc: Eric Cottington, PhD, Senior Vice President, Research and Technology Management

Obtained via FOIA by Judicial Watch Inc.

Memorial Sloan Kettering
Cancer Center

April 7, 2021

**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 potential eye splash of murine bone marrow cells transduced with a non-replicating ecotropic retrovirus that occurred at our institution on 3/26/2021. We are gathering the necessary information for a full report, which will follow.

Our Evironmental Health and Safety department and the IBC are reviewing the incident and the laboratory worker has received appropriate medical attention.

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 646.888.1077 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:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Sent:** Monday, May 10, 2021 2:58 PM
**To:** NIH guidelines
**Cc:** Glickman, Michael/Sloan Kettering Institute; Cottington, Eric M./Research and Technology Mgmt; Schaller-Demers, Debra S./Research and Technology Mgmt; Gibson, James H./Facilities Management
**Subject:** Potential exposure report
**Attachments:** rDNA Exposure report 3-26-2021.pdf

Good Afternoon,

Please find attached report on behalf of the IBC Chairman, Dr. Michael Glickman. This potential exposure was originally reported to the OSP on 4/7/21 as a pre-report.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

**Memorial Sloan Kettering Cancer Center**
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10017
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kumara1@mskcc.org

==========

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## Hunter, Renee (NIH/OD) [C]

**From:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Sent:** Thursday, April 1, 2021 8:17 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Subject:** Potential eye splash

Good Evening Kathryn,
Hope you are doing well. I wanted to ask you for your opinion about whether a potential exposure should be reported to OSP. A technician reported a potential eye splash of murine bone marrow cells transduced with a non-replicating ecotropic retrovirus that only infects mouse cells (BSL-1). The cells were a pool of cells that were transduced with many different human cDNAs ranging from luciferase, mCherry, tumor suppressors , proto-oncogenes, unknown function etc. cloned into the ecotropic retroviral vector mentioned previously. Should we report this potential exposure to OSP?

Your help is greatly appreciated.

Have a wonderful evening.
Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

**Memorial Sloan Kettering Cancer Center**
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10017
C Redacted by agreement
kumara1@mskcc.org

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## Hunter, Renee (NIH/OD) [C]

**From:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Sent:** Wednesday, April 7, 2021 8:48 AM
**To:** NIH guidelines
**Cc:** Glickman, Michael/Sloan Kettering Institute; Cottington, Eric M./Research and Technology Mgmt; Schaller-Demers, Debra S./Research and Technology Mgmt; Gibson, James H./Facilities Management
**Subject:** Preliminary Report- potential exposure
**Attachments:** MSKCC Exposure 3-26-2021.pdf

Good Morning,

Please see attached preliminary report on behalf of the IBC Chairman, Dr. Michael Glickman.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

**Memorial Sloan Kettering Cancer Center**
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10017
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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, May 6, 2021 3:12 PM
**To:** Priya Kumar; NIH guidelines
**Cc:** Zara Llewellyn; Katia Harb; Steve Libby; Deborah L Fuller; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report - University of Washington

Dear Dr. Priya Kumar,

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

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**From:** Priya Kumar <priyak2@uw.edu>
**Sent:** Tuesday, April 27, 2021 3:58 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Zara Llewellyn <zaral@uw.edu>; Katia Harb <kharb@uw.edu>; Steve Libby <slibby@uw.edu>; Deborah L Fuller <fullerdh@uw.edu>; Priya Kumar <priyak2@uw.edu>
**Subject:** Incident Report - University of Washington

Dear NIH,
Please find attached an incident report involving an employee performing research subjected to Section III-D of the NIH Guidelines.

Thank you,
Priya

PRIYA KUMAR, PhD RBP, SM(NRCM)

Biosafety Officer

Environmental Health & Safety

Obtained via FOIA by Judicial Watch Inc.

Magnuson Health Sciences Building / Box 357165

1705 NE Pacific Street T-287 / Seattle, WA 98195-7165

206.543.7278 / fax 206.221.3068

priyak2@uw.edu / ehs.washington.edu

Hrs: Mon-Fri: 7:00am – 2:00pm

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Washington |
| **Date of Report:** | 4/27/2021<br>First reported via email to NIH on 4/7/2021 |
| **Reporter name and position:** | Priya Kumar, PhD, RBP Biosafety Officer |
| **Telephone number:** | 206-543-7278 |
| **Email address:** | Priyak2@uw.edu |
| **Reporter mailing address:** | University of Washington<br>Environmental Health and Safety Department<br>1705 NE Pacific St<br>Room T-287<br>Box 357165<br>Seattle, WA 98195 |
| **Date of incident:** | April 02, 2021 |
| **Name of Principal Investigator:** | Deborah Fuller, PhD |
| **Is this an NIH-funded project?** | xYES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* 1K01MH123258-01<br>*NIH funding institute or center: National Institute of Mental Health (NIMH)*<br>*NIH program officer (name, email address):Vasudev R Rao Vasudev.rao@NIH.gov* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>xPersonnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ xYES ☐NO<br><br>If yes, date of approval: July 16, 2018 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ xBL2 ☐xBL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ xOSHA<br>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;<br>Zika virus wild type |

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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)

A student at the University of Washington was working in a non-human primate (NHP) ABSL-2 necropsy suite handling and cutting duodenum tissue from a wild type Zika virus and recombinant SIV-infected macaque. As the student moved the scalpel blade to cut the tissue, it slipped across the forceps and made a cut <1mm in the left index finger, which was double gloved. The student had picked short forceps (3-4 inches long) for the tissue processing, which left the student vulnerable to this accident as the fingers were closer to the cutting surface. The student immediately noticed that the outer and inner gloves were punctured and removed them. The student 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 veterinary technicians in the same room at the time of the incident, and three other people (including the veterinary pathologist performing the necropsy) in the adjacent room who immediately assisted. The student immediately went to the Emergency Department as required by the protocol for follow up, was prescribed post exposure prophylaxis and is being monitored by the University Employee Health Center.

The student was wearing the appropriate personal protective equipment (PPE): double nitrile gloves, hairnet, facility scrubs, Tyvek suit, face shield, mask, and facility shoes.

The necropsy room keeps numerous quantities of long forceps (6-7 inches long) and an even larger number of short forceps (3-4 inches long) for the technicians to select. The long forceps are suitable for handling tissue larger than 5 inches in length. The student selected the shorter forceps for working with this small piece of tissue (duodenum, a 1.5 x 1.5-inch intestinal tissue). The student was used to selecting the long forceps for this work, but perchance, this time the student selected a short one bringing the fingers closer to the cutting edge. In this case, the longer forceps would have been a better option or using a shorter pair properly by handling the forceps higher up to prevent fingers from being overly close to the scalpel blade.

The NHP was inoculated with wild type Zika virus on 3/8/2021 and SIVmac239M on 01/05/2021. SIVmac239M is a recombinant barcoded strain of SIVmac239, a wild virus https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1006359 SIVmac239M virus was provided by the Frederick National Laboratory for Cancer Research. SIVmac239M viral load is not known at this time, but since the NHP was not on cART it was actively shedding. Zika virus viral load is not known at this time. Zika virus in the blood is usually cleared by 14 days after infection but can persist in tissues for more than 21 days. This NHP was 25 days post Zika virus infection, therefore it is possible it was shedding virus in some tissues.

The NHP was consistently negative for herpes B virus, most recently tested on 9/14/2020.

All procedures with macaques are performed at a minimum of BSL-2 in the primate center. Zika virus is approved at BSL-2 and SIV at BSL-2+ in macaques by the IBC. All agents in the primate center are administered at BSL-2+ and housed at BSL-2 containment. The student has 41/2 years of experience in performing necropsies of NHPs and is current on all trainings, including biosafety and bloodborne pathogens. The student's training is up to date and listed below.

| Training | Completion Date | Expiration Date |
|---|---|---|
| Biosafety Online | 10/14/2019 | 10/14/2022 |

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Bloodborne Pathogens 06/12/2020 06/12/2021

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐XYES ☐NO<br>This was reviewed at the IBC meeting on April 21st, 2021. |
| **Please describe the root cause of this incident:** | The student picked short forceps (3-4" long), which left the student vulnerable to this accident as the fingers were closer to the cutting surface. The student was used to selecting the long forceps (6-7" long) for this work, but per chance, this time the student selected a short one bringing the fingers closer to the cutting edge. The student should have sought out longer forceps for tissue dissections or should have had the fingers higher up on the short forceps to keep them away from the scalpel blade. The student has been retrained for proper scalpel technique when used with small forceps as well as proper forceps 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):

The student has been retrained to always use longer forceps for duodenal or other tissue dissections. The student has been retrained for proper scalpel technique when using smaller forceps and proper forceps technique. The laboratory had previously revised the standard operating procedures (SOP) for dissection, which includes the use of scalpels or alternatives to include the use of scissors for tissues that can be cut easily. The SOP also includes the use of forceps for use in the non-cutting hand. All lab staff was trained on the updated SOP. In addition, the primate center has purchased cut resistant gloves that can 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 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:** Priya Kumar <priyak2@uw.edu>
**Sent:** Tuesday, April 27, 2021 3:58 PM
**To:** NIH guidelines
**Cc:** Zara Llewellyn; Katia Harb; Steve Libby; Deborah L Fuller; Priya Kumar
**Subject:** Incident Report - University of Washington
**Attachments:** NIH Incident-Report_Fuller_2021.pdf

Dear NIH,
Please find attached an incident report involving an employee performing research subjected to Section III-D of the NIH Guidelines.

Thank you,
Priya

PRIYA KUMAR, PhD RBP, SM(NRCM)

Biosafety Officer

Environmental Health & Safety

Magnuson Health Sciences Building / Box 357165

1705 NE Pacific Street T-287 / Seattle, WA 98195-7165

206.543.7278 / fax 206.221.3068

priyak2@uw.edu / ehs.washington.edu

Hrs: Mon-Fri: 7:00am – 2:00pm

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## Hunter, Renee (NIH/OD) [C]

**From:** Zara Llewellyn <zaral@uw.edu>
**Sent:** Wednesday, April 7, 2021 7:02 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 April 2, 2021.

We are investigating the incident and will be 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:** Friday, April 9, 2021 1:30 PM
**To:** Joseph, Elaine
**Cc:** NIH guidelines
**Subject:** RE: NIH Incident
**Attachments:** Incident Reporting – May 2019.pdf

Dear Dr. Elaine Joseph,

Thank you for your email to the NIH Office of Science Policy (OSP) regarding incident reporting requirements under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*). In your email you ask about reporting requirements for an animal bite from a transgenic mouse infected with an adeno-associated virus.

As indicated in the attached FAQs (https://osp.od.nih.gov/biotechnology/faqs-on-incident-reporting/), the *NIH Guidelines* state 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 accidents must be reported on a more expedited basis as described in the FAQs. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, including percutaneous injury from animal bites.

We understand that immediately after an incident not all of the information may be available to complete a full report. In such instances an initial notification to OSP that an incident has occurred is sufficient. A full report may then be submitted later when all of the information regarding the incident and the institution's response has been gathered. Initial notifications and follow on reports may be emailed to NIHGuidelines@od.nih.gov.

If you have any additional questions about whether a particular incident would be reportable, please feel free to contact us and we will be happy to provide guidance.

Regards, Michelle

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

---

**From:** Joseph, Elaine <Elaine.Joseph@UToledo.Edu>
**Sent:** Thursday, April 8, 2021 4:40 PM
**To:** McKinney, Michelle (NIH/OD) [E] <michelle.mckinney@nih.gov>
**Subject:** NIH Incident

Dr. McKinney:

I have a potential Incident to report, but wanted your opinion before we write up the report for NIH Office of Science Policy. One of our technicians was bit by a transgenic mouse that had been infected two days prior by adeno-associate virus. The only question we have is whether this is an incident – in other words whether the AAV could have

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transmitted to the tech. I am assuming this is an incident and we will write it up as a BSL-1 incident. However, I wanted your opinion.

Thank you,
Elaine

Elaine Joseph, Ph.D.
Project Administrator, IACUC/IBC/IRE
Research and Sponsored Programs
R1 Building/Suite 1020E, Mail Stop 218

University of Toledo
2801 W. Bancroft St.
Toledo, Ohio 43606-3390
Office: 419-383-4251

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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Toledo |
| **Date of Report:** | April 12, 2021 |
| **Reporter name and position:** | Frank Calzonetti, Ph.D.<br>Vice President of Research |
| **Telephone number:** | 419-530-4749 |
| **Email address:** | frank.calzonetti@utoledo.edu |
| **Reporter mailing address:** | University of Toledo<br>2801 Bancroft St, MS 218<br>Toledo, OH 43606 |
| **Date of incident:** | April 8, 2021 |
| **Name of Principal Investigator:** | James Burkett, Ph.D. |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: October 5, 2016 |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Appendix B-I.<br>III-D-4a<br>III-E-3 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Adeno-associated Virus (AAV2) |

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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 April 8, 2021, a female graduate student was restraining a transgenic mouse that had been previous infected with Adeno-associated virus (AAV2). This restraint was used in order to give a dosage of analgesic. During the restraint, the mouse reached back and was able to accidentally bite the student in the index finger, breaking through the glove into the skin and drawing blood. The transgenic mouse had been injected with replication deficient AAV2 into the brain two days prior to the incident. The student had received, prior to the incident, Laboratory Safety Training, Biological Safety Training, Rodent Handling Training, and Biohazard Safety Working with Animals Training. Following the incident, the student went to the University of Toledo Medical Center emergency room for treatment of her wound. The incident was reported to her supervisory faculty member (the principal investigator of the protocol). and UToledo's Occupational Health and Safety Department, Environmental Health and Radiation Safety Department and the Institutional Biosafety Committee (IBC).

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO<br>It will be reviewed at the next meeting on April 15, 2021 |
| **Please describe the root cause of this incident:** | Improper mouse restraint technique. |

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 graduate student was retaught proper mouse restraint technique by the principal investigator (Supervisor). An email will be sent to all IBC and IACUC principal investigators reminding them of proper rodent restraint techniques during rodent transfers and 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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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 5:23 PM
**To:** Joseph, Elaine; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident subject to the NIH Guidelines

Dear Dr. Elaine Joseph,

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:** Joseph, Elaine <Elaine.Joseph@UToledo.Edu>
**Sent:** Monday, April 12, 2021 3:32 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Incident subject to the NIH Guidelines

To Whom it May Concern:

Please see the attached Incident Report related to the 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.

Sincerely,
Elaine

Elaine Joseph, Ph.D.
Project Administrator, IACUC/IBC/IRE
Research and Sponsored Programs
R1 Building/Suite 1020E, Mail Stop 218

University of Toledo
2801 W. Bancroft St.
Toledo, Ohio 43606-3390
Office: 419-383-4251

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Joseph, Elaine <Elaine.Joseph@UToledo.Edu>
**Sent:** Monday, April 12, 2021 3:32 PM
**To:** NIH guidelines
**Subject:** Incident subject to the NIH Guidelines
**Attachments:** Incident Report - April 2021.docx

To Whom it May Concern:

Please see the attached Incident Report related to the 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.

Sincerely,
Elaine

Elaine Joseph, Ph.D.
Project Administrator, IACUC/IBC/IRE
Research and Sponsored Programs
R1 Building/Suite 1020E, Mail Stop 218

University of Toledo
2801 W. Bancroft St.
Toledo, Ohio 43606-3390
Office: 419-383-4251

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Friday, April 9, 2021 1:43 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Subject:** FW: NIH Incident

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

---

**From:** Joseph, Elaine <Elaine.Joseph@UToledo.Edu>
**Sent:** Thursday, April 8, 2021 4:40 PM
**To:** McKinney, Michelle (NIH/OD) [E] <michelle.mckinney@nih.gov>
**Subject:** NIH Incident

Dr. McKinney:

I have a potential Incident to report, but wanted your opinion before we write up the report for NIH Office of Science Policy. One of our technicians was bit by a transgenic mouse that had been infected two days prior by adeno-associate virus. The only question we have is whether this is an incident – in other words whether the AAV could have transmitted to the tech. I am assuming this is an incident and we will write it up as a BSL-1 incident. However, I wanted your opinion.

Thank you,
Elaine

Elaine Joseph, Ph.D.
Project Administrator, IACUC/IBC/IRE
Research and Sponsored Programs
R1 Building/Suite 1020E, Mail Stop 218

University of Toledo
2801 W. Bancroft St.
Toledo, Ohio 43606-3390
Office: 419-383-4251

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, April 14, 2021 4:50 PM
**To:** Matt Anderson; NIH guidelines
**Cc:** Dustin Loy; Institutional Biosafety Committee; 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). 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

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**From:** Matt Anderson <manderson11@unl.edu>
**Sent:** Tuesday, April 13, 2021 6:04 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Dustin Loy <jdloy@unl.edu>; Institutional Biosafety Committee <ibc@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,

Obtained via FOIA by Judicial Watch Inc.

Matt

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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
Chat with me in Teams

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*"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

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☒YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Nebraska – Lincoln |
| **Date of Report:** | March 15, 2021 |
| **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<br>Lincoln, NE 68583-0824 |
| **Date of incident:** | December 2020 and January 2021 |
| **Name of Principal Investigator:** | Mark Wilkins, Ph.D. |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☒Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 4/12/21 |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | This work falls under Section III-E. |
| **Has a report of this incident been made to other agencies? If so, please indicate**<br><br>**No other agencies were notified.** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Transgenic Camelina sativa seeds were processed to extract oil and protein. The Camelina was engineered to enhance oil production |

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 March 15, 2021, it was discovered that the lab staff had processed and extracted oil from transgenic Camelina seeds, which were engineered to produce a higher oil content. The oil was extracted using a mechanical screw press in a BSL-1 laboratory at the UNL campus. The extraction occurred from December 2020 through January 2021. The extract, usually both the oil and seed cake, was delivered back to the collaborating PI for additional studies. Standard laboratory PPE was worn, which included lab coat, eye protection and gloves. Any unused cake or oil was autoclaved or disposed of through UNL's medical waste vendor.

Upon this discovery, the PI was notified that this work had not been included in their previously approved IBC protocol, was a reportable non-compliance incident with the NIH Guidelines, and UNL Biosafety Guidelines, and to cease the extraction process pending the submission and approval of an IBC protocol amendment.

The cause of the non-compliance was oversight by the PI, he thought transgenic Camelina seeds had been previously added to his protocol and approved by the IBC.

The PI las completed training on the NIH guidelines and research compliance on 6/1/2017.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>Reviewed at IBC meeting on 4/12/21 |
| **Please describe the root cause of this incident:** | PI incorrectly thought they were approved to work with transgenic Camelina seeds. |

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):

PI has submitted an amendment to his IBC protocol describing the transgenic Camelina.

Refresher training related to the NIH Guidelines and IBC protocol updates for PI and lab staff was conducted on 4/7/21.

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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:** Matt Anderson <manderson11@unl.edu>
**Sent:** Tuesday, April 13, 2021 6:04 PM
**To:** NIH guidelines
**Cc:** Dustin Loy; Institutional Biosafety Committee; Dan Hoyt; Brenda Osthus
**Subject:** Report of Non-compliance Incident at UNL
**Attachments:** UNL NIH Incident Report _Wilkins_3-15-21.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
Chat with me in Teams

*"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:** Wednesday, April 14, 2021 5:08 PM
**To:** Harding, Beverly; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: University of Pittsburgh incident reports (2)

Dear Beverly Harding,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

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**From:** Harding, Beverly <beverlyh@pitt.edu>
**Sent:** Tuesday, April 13, 2021 3:22 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Harding, Beverly <beverlyh@pitt.edu>
**Subject:** University of Pittsburgh incident reports (2)

Dear Dr. Harris et al,

Please find the attached summary of two separate incidents that were reviewed at the recent IBC meeting.

Thanks,

Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
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**

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☒YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Pittsburgh |
| **Date of Report:** | 04/08/2021 |
| **Reporter name and position:** | Beverly Harding |
| **Telephone number:** | 412-383-1766 |
| **Email address:** | beverlyh@pitt.edu or ibo@pitt.edu |
| **Reporter mailing address:** | |
| **Date of incident:** | March 2021 |
| **Name of Principal Investigator:** | Stephen Y. Chan, MD, PhD |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other (please describe):<br><br>Investigator clerical errors in the approved IBC protocol amendment:<br><br>1. Using the term "commercial" and not specifically referring to "Addgene" for the listed AAV6 and AAV8 viruses.<br>2. Not pursuing the appropriate BSL downgrade request and erroneously assuming the downgrade would be "automatic."<br>3. Not listing explicitly the post-doctoral fellow handling the viruses in the IBC amendment.<br><br>In that context, known BSL1-level replication incompetent AAV8-DREADD viruses from Addgene (these viruses have been used in the past and currently with BSL- containment by our Pitt collaborator) were utilized for stereotactic injections in mouse experiments in the collaborator's BSL-1 facility, based on our approved IACUC protocol and approved IBC amendment (with errors listed above).<br><br>After the fact, we were alerted to the fact that our IBC protocol in fact did not include the above information and request for appropriate BSL downgrade. We immediately submitted an amendment to more specifically ask for a downgrade for these AAV vectors and inclusive of the source of those viruses. In this amendment, we also were more specific to list these AAV vectors separately from the other AAV vectors that we use in our laboratory under BSL-2 conditions. We are planning a separate amendment to list all lab members in our group performing both BSL-1 and BSL-2 protocols. |

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| | |
|---|---|
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: April 27, 2020 (NOD202000452). This was an approved amendment for IBC201700077<br><br>As noted above, these AAV8-DREADD viruses were in fact listed in our prior IBC approved protocol. In retrospect, a mistake was not asking for a downgraded BSL and not listing separately from other AAVs that we use in BSL-2 containment.<br><br>The IBC reviewed the incident at the 4/12/21 meeting. |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☒Other (please describe): None<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | From Addgene:<br><br>1. Ready-to-use AAV8 particles (#114472-AAV8) produced from pAAV-hSyn-mCherry (#114472) without helper virus. Considered BSL-1 per Addgene and approved for such BSL-1 use in our collaborator's lab at Pitt now and in the past.<br>2. Ready-to-use AAV8 particles (#50474-AAV8) produced from pAAV-hSyn-hM3D(Gq)-mCherry (#50474) without helper virus. Considered BSL-1 |

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| | |
|---|---|
| | per Addgene and approved for such BSL-1 use in our collaborator's lab at Pitt now and in the past. hSyn-driven hM3D(Gq) receptor with an mCherry reporter for CNO-induced neuronal activation. |

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

DESCRIPTION OF INCIDENT: (use additional space as necessary)

*My laboratory has established a new collaboration with another laboratory at Pitt. The Collaborating lab has had substantial experience with using known BSL1-level replication incompetent AAV-DREADD viruses for stereotactic administration to mouse brain tissue in vivo, with active protocols and personnel with experience in this regard. Our plan was to perform this procedure in mice in the Collaborator's space with personnel from that lab, followed by transfer of such mice to SBST, exposure to hypoxia, and determination of manifestations of pulmonary hypertension. Notably, the plan was always to perform these experiments in BSL-1 conditions: these viruses from Addgene are recommended at BSL-1 and have been used in the past and currently with approved BSL-1 containment approval by the collaborating lab.*

*There was substantial planning of the experimentation, with our groups agreeing that the Chan lab will obtain approval for use of the viruses (by IBC protocol) and for use of the viruses in animals (by IACUC protocol). An approved IACUC protocol was obtained by the Chan laboratory, appropriately listing the animal experiments with these viruses and including the post-doctoral fellow performing these injections in the collaborating lab. Additionally, an IBC protocol amendment was approved where the experiments with AAV-DREAAD viruses are described (MOD2020000227) in an amendment to IBC 201700077.*

*However, in retrospect, the IBC amendment that had been submitted and approved, carried inadvertent but important clerical errors that resulted in confusion. The intent was always to purchase these DREADD viruses from Addgene and handle via BSL-1 use. In the approved version of the protocol, both AAV6 and AAV8 DREADD viruses are used in the description of the experiments, and both AAV6 and AAV8 DREADD viruses are separately specified. Yet, in the description of AAV6 viruses, the source states "Commercial" when it should have specified Addgene (as this is what we intended throughout). Furthermore, in the AAV8 description, the source only refers to "Vector Biolabs" which refers to the source for the PCSK9 virus (not used in this incident). The "Commercial Addgene" source for the DREADD viruses was inadvertently omitted.*

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*In both AAV6 or AAV8 contexts, we also did not request the appropriate BSL downgrade on the protocol from "Commercial" sources such as Addgene and Vector Biolabs. To explain more fully, we misinterpreted the IBC virus and vector standard instructions on the IBC Guidance, (https://www.ibc.pitt.edu/sites/default/files/ibc_guidance_-_aav_usage_revised_09_nov_20.pdf) which state on p. 4-5 that there is an "Automatic BSL1 downgrade." Thus, we mistakenly assumed the downgrade would occur without our explicit request. In the future, we will be sure to request the downgrade, as the investigator had been informed.*

*Finally, while our parent Chan lab IBC protocol lists all of our lab members appropriately, our group erroneously believed that, because this amendment was assumed to have an automatic BSL downgrade and was being performed at a site away from where the rest of our lab operates, we didn't have to explicitly name this post-doctoral fellow from the collaboratory lab in this amendment (only in the IACUC protocol). In retrospect, we now realize that all relevant persons should be listed on any IBC amendment, regardless of whether persons only engage in BSL-1 work away from the rest of our lab.*

*In that context (and with our assumption that we had "automatic" BSL-1 approval), these viruses were utilized for stereotactic injections in mouse experiments in our collaborator's Pitt BSL-1 facility, based on our approved IACUC protocol. The person who performed these experiments was a post-doctoral fellow in the collaborating lab but listed on our IACUC protocol and who has substantial experience in handling these viruses under BSL-1 conditions.*

*There was otherwise no deviation from laboratory SOP; no medical surveillance was needed; no illness or injury was observed. These experimental procedures occurred in late March 2021.*

*After the fact, and in the context of attempting to transfer these mice to SBST, we were alerted (April 5, 2021) to the fact that our IBC protocol in fact did not include the information above and did not receive an automatic BSL downgrade. We immediately submitted an amendment to more specifically ask for a downgrade for these AAV vectors and inclusive of the source of those viruses. In this amendment, we also were more specific to list these AAV vectors separately from the other AAV vectors that we use in our lab under BSL2 conditions. We are planning a separate amendment to list this post-doctoral fellow performing this BSL1 work.*

In summary, despite substantial planning and what we thought was the appropriate information being transmitted through the IBC protocols, we acknowledge errors in the approved IBC protocol including:

1. Using the term "commercial" and not specifically referring to "Addgene" for the listed AAV6 and AAV8 viruses.
2. Not pursuing the appropriate BSL downgrade request and erroneously assuming the downgrade would be "automatic."
3. Not listing explicitly the post-doctoral fellow handling the viruses in the IBC amendment.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br>At the April 12, 2021 meeting |
| **Please describe the root cause of this incident:** | Error in IBC protocol request |

**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 investigator has submitted an amendment to request a BSL downgrade to BSL-1. The amendment, was more specific to list the AAV vectors and source separately from the other AAV vectors that will be used in the lab under BSL-2 conditions.*

2. *The investigator will submit an amendment to include all lab personnel inclusive of all BSL-1 or BSL-2 work in the current IBC protocol. This is a requirement for the overall biosafety of the laboratory.*

3. *The PI and lab manager will re-review the NIH guidelines (NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)) for appropriate approval for use of replication incompetent viruses (immediately). And also re-review the IBC guidelines for protocol generation, to ensure new protocols and amendments carry all of the necessary information with sufficient detail.*

4. *The PI and lab manager will meet monthly to review all lab IBC and IACUC protocols (current and pending applications) to ensure inclusion of appropriate information of experiments, involved personnel, and BSL requests (within 1 month)*

5. *Because the investigator's lab uses a number of different replication viruses, the lab manager and investigator will re-review all of the IACUC and IBC protocols with lab members twice yearly (immediately and every 6 months thereafter).*

6. *Confusion likely occurred by attempting to propose new work via amendments to previously approved IBC protocols. When possible, entirely new protocols will be submitted for new work, rather than via amendments.*

7. *Before embarking on collaborative projects, the investigator and lab manager will schedule a dedicated meeting to review our relevant IBC and IACUC protocols with the collaborative team (as new collaborations are formed).*

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8. *The investigator will consult IBC and EH&S for further instruction as needed, particularly to clarify language in SOP (i.e., use of the term "automatic", etc.)*

- ***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 <u>NOT</u> 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.



April 13, 2021

Dear Dr. Harris/NIH OSP Incident Reporting,

The attached two incident reports are to inform the NIH OSP of the IBC deliberation of incidents under the *NIH Guidelines* Sections *IV-B-2-a-(5)*, *IV-B-2-b-(4)* and reporting under Section *IV-B-2-b-(7)*.

The incidents were reviewed at the April 12, 2021 IBC meeting. The initial reporting forms were reviewed by the committee.

To summarize the first incident (IR-21-03), the incident report was sent to the IBC the day following the March meeting, so it was unable to be reviewed in March. The IBC reviewed the incident details at the April meeting, and determined that the incident required reporting to the NIH OSP per the *NIH Guidelines*. The incident involved a needlestick injury resulting from refilling a syringe from a small tube. The was treated in the emergency clinic and there were no expected adverse events from the injury. The supervisor conducted re-training for handling of sharps in the laboratory. The committee determined that the incident did not require any additional actions.

To summarize the non-compliance incident (IR-21-04), the University of Pittsburgh's IBC became aware that the investigator failed to apply for IBC review for a downgrade of a strain of AAV. An incident inquiry was sent to the investigator upon IBC Staff notification. The investigator has since submitted the incident form and an IBC application (modification of existing protocol) to cover the work described. The committee determined that the incident did not require any additional actions.

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:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Wednesday, April 14, 2021 8:23 AM
**To:** Harding, Beverly
**Subject:** RE: University of Pittsburgh incident reports (2)

Hi Beverly:

The incident report from the Lohmueller lab indicates the incident was reported 1/13/21 and the incident occurred on 3/5/21. I assume this is a typo and the report should be dated 4/13?

Regards,

Kathryn

---

**From:** Harding, Beverly <beverlyh@pitt.edu>
**Sent:** Tuesday, April 13, 2021 3:22 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Harding, Beverly <beverlyh@pitt.edu>
**Subject:** University of Pittsburgh incident reports (2)

Dear Dr. Harris et al,

Please find the attached summary of two separate incidents that were reviewed at the recent IBC meeting.

Thanks,

Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
beverlyh@pitt.edu or ibo@pitt.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Harding, Beverly <beverlyh@pitt.edu>
**Sent:** Tuesday, April 13, 2021 3:22 PM
**To:** NIH guidelines
**Cc:** Harding, Beverly
**Subject:** University of Pittsburgh incident reports (2)
**Attachments:** OSP Summary for IR-21-03 and IR-21-04 Reports 4-13-21.doc; IR-21-03 J. Lohmueller 04-09-21 final.pdf; IR-21-04 S. Chan 04-08-21 final.pdf

Dear Dr. Harris et al,

Please find the attached summary of two separate incidents that were reviewed at the recent IBC meeting.

Thanks,

Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
beverlyh@pitt.edu or ibo@pitt.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Wednesday, April 14, 2021 8:23 AM
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Regards,

Kathryn

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**Sent:** Tuesday, April 13, 2021 3:22 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Harding, Beverly <beverlyh@pitt.edu>
**Subject:** University of Pittsburgh incident reports (2)

Dear Dr. Harris et al,

Please find the attached summary of two separate incidents that were reviewed at the recent IBC meeting.

Thanks,

Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
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:** Wednesday, April 14, 2021 5:08 PM
**To:** Harding, Beverly; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: University of Pittsburgh incident reports (2)

Dear Beverly Harding,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

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**From:** Harding, Beverly <beverlyh@pitt.edu>
**Sent:** Tuesday, April 13, 2021 3:22 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Harding, Beverly <beverlyh@pitt.edu>
**Subject:** University of Pittsburgh incident reports (2)

Dear Dr. Harris et al,

Please find the attached summary of two separate incidents that were reviewed at the recent IBC meeting.

Thanks,

Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Pittsburgh |
| **Date of Report:** | 01/13/21 |
| **Reporter name and position:** | Beverly Harding |
| **Telephone number:** | 412-383-1766 |
| **Email address:** | beverlyh@pitt.edu or ibo@pitt.edu |
| **Reporter mailing address:** | University of Pittsburgh<br>Institutional Biosafety Division<br>Suite 202 Hieber Building<br>3500 Fifth Avenue<br>Pittsburgh, PA 15213 |
| **Date of incident:** | 3/5/21 |
| **Name of Principal Investigator:** | Jason Lohmueller |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 10/14/2020; date of incident review 04/12/21 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | NSG Mice |

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 Post-Doc was at the IVIS imager and with an insulin syringe with luciferin. The personnel was injecting NSG mice which already had Raji CD20+ human leukemia cell line, with the luciferin syringe intra peritoneal. The luciferin-syringe was injected in these tumor positive mice then, in order to refill it, the personnel accidently pricked their middle left finger instead of inserting the syringe in the Eppendorf containing luciferin.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | Accident |

**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 investigator reviewed the incident with the individual to ensure that all procedures and PPE and other devices are appropriate so that the injury has less of a chance of happening again. This review included planning steps to decrease the number of injections per needle, with the major step including only a single syringe loading step per needle. The investigator is also obtaining safety engineered sharps to be used for BSL-2 injections when possible.

Obtained via FOIA by Judicial Watch Inc.

- ***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.



April 13, 2021

Dear Dr. Harris/NIH OSP Incident Reporting,

The attached two incident reports are to inform the NIH OSP of the IBC deliberation of incidents under the *NIH Guidelines* Sections *IV-B-2-a-(5)*, *IV-B-2-b-(4)* and reporting under Section *IV-B-2-b-(7)*.

The incidents were reviewed at the April 12, 2021 IBC meeting. The initial reporting forms were reviewed by the committee.

To summarize the first incident (IR-21-03), the incident report was sent to the IBC the day following the March meeting, so it was unable to be reviewed in March. The IBC reviewed the incident details at the April meeting, and determined that the incident required reporting to the NIH OSP per the *NIH Guidelines*. The incident involved a needlestick injury resulting from refilling a syringe from a small tube. The was treated in the emergency clinic and there were no expected adverse events from the injury. The supervisor conducted re-training for handling of sharps in the laboratory. The committee determined that the incident did not require any additional actions.

To summarize the non-compliance incident (IR-21-04), the University of Pittsburgh's IBC became aware that the investigator failed to apply for IBC review for a downgrade of a strain of AAV. An incident inquiry was sent to the investigator upon IBC Staff notification. The investigator has since submitted the incident form and an IBC application (modification of existing protocol) to cover the work described. The committee determined that the incident did not require any additional actions.

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:** Tuesday, April 13, 2021 3:22 PM
**To:** NIH guidelines
**Cc:** Harding, Beverly
**Subject:** University of Pittsburgh incident reports (2)
**Attachments:** OSP Summary for IR-21-03 and IR-21-04 Reports 4-13-21.doc; IR-21-03 J. Lohmueller 04-09-21 final.pdf; IR-21-04 S. Chan 04-08-21 final.pdf

Dear Dr. Harris et al,

Please find the attached summary of two separate incidents that were reviewed at the recent IBC meeting.

Thanks,

Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
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, May 6, 2021 2:21 PM
**To:** Major, Sheryl; NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; tideker@health.ucsd.edu; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: UCSD Injury 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). 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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Friday, April 23, 2021 12:31 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** McMahill, Angela <amcmahill@ucsd.edu>; Scott, Lance <lscott@ucsd.edu>; tideker@health.ucsd.edu
**Subject:** UCSD Injury 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 a cut to a researcher's hand due to a broken glass Pasteur pipet that was contaminated with human-derived cells and lentivirus, tissue culture media and puromycin. The lentivirus was genetically modified to package sgRNA for CRISPR. This incident will be discussed with the Institutional Biosafety Committee on May 14, 2021.

This injury was first reported to the NIH on 04/14/2021 after a cursory review of the incident. The attached report includes the results of the injury investigation and correction actions.

Please let me know if you have any questions regarding this report.

Best,

Obtained via FOIA by Judicial Watch Inc.

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

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | X YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, San Diego |
| **Date of Report:** | 04/14/2021 |
| **Reporter name and position:** | Sheryl Major, Biosafety Officer |
| **Telephone number:** | (858) 822-2493 |
| **Email address:** | smajor@ucsd.edu |
| **Reporter mailing address:** | 9500 Gilman Drive #0090, La Jolla, CA 92093 |
| **Date of incident:** | 04/09/2021 |
| **Name of Principal Investigator:** | Trey Ideker |
| **Is this an NIH-funded project?** | YES NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES NO<br><br>If yes, date of approval: 3/9/2018 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 X BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-3 Experiments involving the use of infectious or defective Risk Group 2 viruses Expression using viral vectors in vitro, tissue culture |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | The lab is working on packaging and amplifying sgRNA libraries. The sgRNA were cloned into commercially purchased lentiviral vector, LentiGuide-Puro (LGP vector). |

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 April 9, 2021, an undergrad lab assistant, was removing a used glass Pasteur pipet from a previous users biohazard waste liquid vacuum hose in the biosafety cabinet. The pipet broke cutting her hand. The researcher was given first aid, including washing with soap and water for 15 minutes, and reported the incident to her supervisor. She was sent to Occupational Health clinic for medical treatment immediately (April 9, 2021).

The broken glass pipet was potentially contaminated with human-derived cells, lentiviral vector, tissue culture media waste and puromycin. The lentivirus was used for CRISPR work, packaging and amplifying sgRNA libraries. The laboratory package sgRNA into lentiviral vector. The sgRNA were cloned into commercially purchased lentiviral vector, LentiGuide-Puro (LGP vector).

The researcher was wearing disposable nitrile gloves, laboratory coat, and safety glasses during the incident. The researcher completed required IBC training class “Biosafety: Recombinant and Synthetic Nucleic Acids and Biosafety: Bloodborne Pathogens Training and Annual Refresher” on September 9, 2020.

This incident will be reported at a convened IBC meeting on May 14, 2021.

The IBC approved this lab to work at BSL-2+ based on the use of oncogenes in viral vectors.
***BL2+ (describe specific enhancement in report):***

In 2018, IBC approved this laboratory for BSL-2+ work with oncogenes used in viral vector. The following are the work practices for BSL-2+:

In addition to BSL-2 practices and containment, when working with oncogenes with viral vectors the following BSL-2+ practices are required: (as per 2018 BUA approval)

1. All work must be done in a biological safety cabinet.
2. Safety cups or sealed rotors must be used when centrifuging outside of the biosafety cabinet.
3. Double gloves must be worn; the exception being that if this prevents needed dexterity, then a single layer of nitrile gloves can be used. This exception must be approved by the IBC.
4. When using double gloves, the interior glove must be taped (use lab tape, masking tape, painter’s tape) to the laboratory coat to prevent bare skin exposure.
5. All sharps must have engineered protection devices or provide a written response as to why this cannot be accomplished.
6. No clean areas are allowed in laboratory areas where this agent is handled.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | YES X NO<br><br>This case will be reported at the May 2021 IBC meeting |
| **Please describe the root cause of this incident:** | Glass Pasteur pipettes are thin and when connected to a vacuum line via a tube, the pipette can become difficult to remove from the tube causing the user to twist and possibly pinch the pipette to the point of crushing. |

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 lab and Biosafety staff reviewed the laboratory's method in removing pipets from the vacuum hose. This is a common procedure that occurs in the lab. It is recommended that lab members check that the vacuum is turned off when removing to improve ease of replacement. The lab discussed substituting glass with plastics where feasible and providing refresher training/reminders for disinfecting and removing waste items after work is completed in the BSC.

The lab implemented the following changes:

- Lab switched to using plastic pipet for cell culture and work with viral vectors
- Liquid waste vacuum flask system updated to plastic containers.
- Implemented BSC Checklist including cleaning and disinfection between users and after work is complete

The IBC updated the BSL-2+ IBC approval conditions to include substitution of glass products with plastics when feasible. Here are the updated BSL-2+ requirements:

<u>ONCOGENES USED IN VIRAL VECTORS</u>

In addition to BSL-2 practices and containment, when working with oncogenes with viral vectors the following BSL-2+ practices are required:

1. All work must be done in a biological safety cabinet.
2. Safety cups or sealed rotors must be used when centrifuging outside of the biosafety cabinet.
3. Double gloves must be worn; the exception being that if this prevents needed dexterity, then a single layer of nitrile gloves can be used. This exception must be approved by the IBC.

Obtained via FOIA by Judicial Watch Inc.

4. When using double gloves, the interior glove must be taped (use lab tape, masking tape, painters tape) to the laboratory coat to prevent bare skin exposure.
5. All sharps must have engineered protection devices or provide a written response as to why this cannot be accomplished. The IBC will review exceptions on a case by case basis.
6. No glass is to be used without an exception granted by the IBC.
7. No eating or drinking is allowed in laboratory areas where this agent is handled.

- **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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Friday, April 23, 2021 12:31 PM
**To:** NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; tideker@health.ucsd.edu
**Subject:** UCSD Injury Report to the NIH
**Attachments:** 04.14.2021_NIH Incident Report_Ideker.pdf; UCSD Injury Notification 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 a cut to a researcher's hand due to a broken glass Pasteur pipet that was contaminated with human-derived cells and lentivirus, tissue culture media and puromycin. The lentivirus was genetically modified to package sgRNA for CRISPR. This incident will be discussed with the Institutional Biosafety Committee on May 14, 2021.

This injury was first reported to the NIH on 04/14/2021 after a cursory review of the incident. The attached report includes the results of the injury investigation and correction actions.

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.

**Hunter, Renee (NIH/OD) [C]**

**From:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Wednesday, April 14, 2021 11:17 AM
**To:** NIH guidelines
**Cc:** tideker@health.ucsd.edu; Licon, Katherine; Scott, Lance; McMahill, Angela
**Subject:** UCSD Injury Notification to the NIH

Dear NIH Office of Science Policy,

This is an initial notification of an incident case that is subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids. The injury involves a cut of a researcher's hand due to a broken glass Pasteur pipet that was contaminated with human-derived cells and lentivirus, tissue culture media and puromycin. The lentivirus was genetically modified to package sgRNA for CRISPR.

The researcher sought medical attention immediately on the day of the incident, 4/9/2021. This incident was reported to the Biosafety Program on 04/9/202. After the report was received and an initial interview was conducted with the injured party, it was then known the Pasteur pipet was used with human-derived cells and lentivirus, tissue culture media and puromycin prior to the injury occurring.

We are currently in the process of gathering more information and discussing corrective actions. We will provide NIH a detailed report on the incident as soon as the follow up investigation is complete.

Please let me know if you have any questions regarding this report.

Best,

Sheryl Major

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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, May 6, 2021 2:11 PM
**To:** Sylvie Blondelle; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: incident report

Dear Dr. Sylvie Blondelle,

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:** Sylvie Blondelle <sylvieb@sbpdiscovery.org>
**Sent:** Wednesday, April 14, 2021 12:28 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** incident report

Good morning,

Attached is a incident report for a needlestick while handling adenoviral vectors in vitro. Please feel free to contact me if you need further information.

Sincerely,
Sylvie Blondelle

**Sylvie Blondelle, Ph.D., RBP**
Director of EH&S
Sanford Burnham Prebys Medical Discovery Institute
10901 N. Torrey Pines Road, La Jolla, CA 92037
T 858.646.3100 M Redacted by agreement sylvieb@SBPdiscovery.org

Sanford Burnham Prebys

*Science Benefiting Patients™*

Obtained via FOIA by Judicial Watch Inc.

Note: This email is for use of the internet recipient only & may contain privileged or confidential information. If you received this e-mail in error, please notify the sender immediately. Thank you.

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Sanford Burnham Prebys medical Discovery Institute |
| **Date of Report:** | 4/14/21 |
| **Reporter name and position:** | Sylvie Blondelle, EH&S Director, IBC Chairperson |
| **Telephone number:** | 858-646-3100, ext 3613 |
| **Email address:** | sylvieb@sbpdiscovery.org |
| **Reporter mailing address:** | 10901 North Torrey Pines Rd, La jolla CA 92037 |
| **Date of incident:** | 3/31/21 |
| **Name of Principal Investigator:** | Chun-Teng Huang |
| **Is this an NIH-funded project?** | XYES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:AG059418*<br>*NIH funding institute or center: National Institute of Aging*<br>*NIH program officer (name, email address):Dr. John Williams, williamsj6@mail.nih.gov* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | XYES ☐NO If yes, date<br><br>of approval:8/14/2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>XBL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-E1 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Recombinant adeno-associated viruses (replicase type 2, capsid serotype 2). The rAAV genome does not have replicase and capsid. This rAAV2/2-CAG-FOXO1 contains chicken actin (CAG) promoter expressing human FOXO1 gene. |

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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)

The employee, Core Director, accidentally stabs the left-hand thumb. Before the incident, he was using the syringe with 18G needle to transfer recombinant adeno-associated virus supernatant into ultracentrifuge tube for virus purification. This was done inside a biosafety cabinet. Eventhough the employee was careful and slow, the syringe slipped and reach the thumb holding the tube. The gloves were not sufficient to prevent a slight needlestick. After the incident, he immediately squeezed blood out of the thumb and rinsed the thumb with tap water and contacted EH&S.
The employee was asked to follow up with the Occupational Medicine Office.

The employee was wearing the required PPE: lab coat, double pair of nitrile gloves to protect the wrist area and was following the SOP for handling viral vectors.

This employee has received the Biosafety level 2 and bloodborne pathogen training at the start of employment on November 18, 2008, and a viral vector handling training also covering rDNA guidelines on November 18, 2008, and annual Biosafety refresher training since then.

This experiment was part of a service by the SBP core facility requested by a Principal Investigator from the Scripps Research Institute. The Core Facility has its own approved protocol from SBP IBC to generate viral vectors for other investigators.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES X☐NO |
| **Please describe the root cause of this incident:** | The syringe/needle slipped while holding a tube by hand. |

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 employee was asked in the past to use blunt needles instead of hypodermic needles for similar procedures. However, when asked why he was not using them anymore, he mentioned that blunt needles were not practical and switched back to hypodermic needles but forgot to mention it to EH&S and IBC.

The employee was provided cut resistance gloves to wear underneath the nitrile gloves, and based on trials using a sterile needle, it was recommended to wear 3 pairs of cut resistance gloves to prevent a needle to cross the barrier while keeping the dexterity. The employee was also reminded to contact the EH&S Department and/or IBC for approval in any change of recommended PPE and practice.

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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:** Sylvie Blondelle <sylvieb@sbpdiscovery.org>
**Sent:** Wednesday, April 14, 2021 12:28 PM
**To:** NIH guidelines
**Subject:** incident report
**Attachments:** Incident-Reporting-Needlestick 3-31-21.docx

Good morning,

Attached is a incident report for a needlestick while handling adenoviral vectors in vitro. Please feel free to contact me if you need further information.

Sincerely,
Sylvie Blondelle

**Sylvie Blondelle, Ph.D., RBP**
Director of EH&S
Sanford Burnham Prebys Medical Discovery Institute
10901 N. Torrey Pines Road, La Jolla, CA 92037
**T** 858.646.3100 **M** Redacted by agreement sylvieb@SBPdiscovery.org

Sanford™ Burnham Prebys

*Science Benefiting Patients™*

Note: This email is for use of the internet recipient only & may contain privileged or confidential information. If you received this e-mail in error, please notify the sender immediately. Thank you.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, July 8, 2021 8:08 AM
**To:** Kara Drolet; Sarah Byers; NIH guidelines
**Cc:** Dana Director; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: OHSU initial incident report 3/2/2021

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 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:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Wednesday, June 23, 2021 3:41 PM
**To:** Sarah Byers <byerssa@ohsu.edu>; Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>
**Cc:** Dana Director <director@ohsu.edu>
**Subject:** RE: OHSU initial incident report 3/2/2021

Hello Dr. Harris,
Please find the final report for this incident attached. Let us know if you have any questions.
Thank you,
Kara

Kara Manning Drolet, Ph.D.
Pronouns: she/her/hers
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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

Obtained via FOIA by Judicial Watch Inc.

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Tuesday, June 1, 2021 1:11 PM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** RE: OHSU initial incident report 3/2/2021

Hello Kathryn,

The final report for this incident is pending. The OHSU IBC is still coordinating with others on the resolution of this incident.

Sarah

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Tuesday, June 1, 2021 5:57 AM
**To:** Sarah Byers <byerssa@ohsu.edu>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** [EXTERNAL] RE: OHSU initial incident report 3/2/2021

Hi Sarah and Kara:

Just following up on this incident. I believe this is still waiting a final report but please let me know if I missed it.

Thanks!

Kathryn

---

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Wednesday, April 14, 2021 3:41 PM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** OHSU initial incident report 3/2/2021

Dear Dr. Harris,

This email serves as the initial notification on an exposure that occurred at Oregon Health & Science University on 3/2/2021. The incident report describing a sharps injury involving a SHIV infected non-human primate was submitted to the IBC on 4/12/2021.

A complete report of the incident, cause of delayed IBC/NIH reporting, and follow up actions 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

Obtained via FOIA by Judicial Watch Inc.

byerssa@ohsu.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Kara Drolet <manningk@ohsu.edu>
**Sent:** Wednesday, June 23, 2021 3:41 PM
**To:** Sarah Byers; Harris, Kathryn (NIH/OD) [C]
**Cc:** Dana Director
**Subject:** RE: OHSU initial incident report 3/2/2021
**Attachments:** OHSU SHIV incident Final report 06232021.pdf

Hello Dr. Harris,
Please find the final report for this incident attached. Let us know if you have any questions.
Thank you,
Kara

Kara Manning Drolet, Ph.D.
Pronouns: she/her/hers
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
Executive Asst: Ann Trione | : trione@ohsu.edu
www.ohsu.edu/researchintegrity

---

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**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** RE: OHSU initial incident report 3/2/2021

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Sarah

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**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** [EXTERNAL] RE: OHSU initial incident report 3/2/2021

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Obtained via FOIA by Judicial Watch Inc.

Thanks!

Kathryn

---

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Wednesday, April 14, 2021 3:41 PM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Cc:** Kara Drolet <manningk@ohsu.edu>
**Subject:** OHSU initial incident report 3/2/2021

Dear Dr. Harris,

This email serves as the initial notification on an exposure that occurred at Oregon Health & Science University on 3/2/2021. The incident report describing a sharps injury involving a SHIV infected non-human primate was submitted to the IBC on 4/12/2021.

A complete report of the incident, cause of delayed IBC/NIH reporting, and follow up actions 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.

OREGON HEALTH & SCIENCE UNIVERSITY

**Institutional Biosafety Committee**

Mail code L106RI
3181 SW Sam Jackson Park Rd
Portland, OR 97239
tel 503 494-7887
fax 503 346-6808
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

June 23, 2021

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

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 4/14/2021.

| | |
|---|---|
| OHSU IBC registration number | IBC-08-05 |
| OHSU project title | Cloning and expression of HIV and SIV genomes and subgenomic fragments |
| Nature of the material | Recombinantly derived SHIV SF169P3 with wild type pathogenicity |
| Risk Group | III |
| Containment level | ABSL-2+, enhancement is through PPE and work practices |
| Nature of the incident | Personnel Exposure, delayed initial reporting of the incident |
| PPE in use | Dedicated footwear or boot covers, scrubs, disposable gown, hair bonnet, double gloves, face shield, and fiber mask |

**Description of incident:**

On March 2, 2021 a research assistant #1(RA#1) was performing a blood draw on a SHIV-infected non-human primate when the safety device on the needle broke. Another research assistant (RA#2) was asked to dispose of the broken safety sharp while RA#1 applied pressure on the animal's vein. While transporting the needle with the broken safety device, RA#2 accidentally poked their finger with the needle.

RA#2 followed normal post exposure procedures and reported to campus Occupational Health. The SHIV viral load in the non-human primate at the time of the incident was 8,400 copies of vRNA per ml of plasma and anti-retroviral therapy was prescribed for RA#2. RA#2 had severe side effects due to the anti-retroviral therapy and was away from work as a result. No other medical issues related to this incident have been reported.

When RA#2 returned to work in the first week of April 2021, their supervisor requested additional sharps training for RA#2. This is when it was determined that the incident had not been reported to the IBC. A safety officer met with RA#2 to review the incident and to provide safe sharps handling refresher training. The researchers submitted the incident report to the IBC on April 12, 2021.

**Actions taken:**

The IBC Administrative group and campus incident review board reviewed this incident and determined that insufficient training was the primary cause of the incident. The safety sharps retraining that was provided to the individual was deemed sufficient for this specific incident. Additionally, as a biosafety program process improvement, safety staff is collaborating with the Division of Comparative Medicine (DCM) Training and Quality Assurance Program to advise on incorporating additional safety concepts into standard operating procedures. The DCM Training and Quality Assurance Program is also establishing a new process for training proficiency verification.

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The IBC also reviewed the issue of delayed reporting. The post exposure communication process to have Occupational Health notify the biosafety officer and the individual's supervisor did not occur. There has been turn over in staffing in the campus Occupational Health office combined with an increased work load due to ongoing COVID testing requirements. The IBC Manager and the Biosafety Officer met with the new Occupational Health Nurse Practitioner to review and update the post exposure communication process.

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,

Kara Drolet

Digitally signed by Kara Drolet
Date: 2021.06.23 12:36:17 -07'00'

Kara Manning Drolet, PhD
Associate Vice President of Research Integrity
Oregon Health & Science University

cc: Dana Director, PhD, OHSU Institutional Official

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Sarah Byers <byerssa@ohsu.edu>
**Sent:** Wednesday, April 14, 2021 3:41 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Kara Drolet
**Subject:** OHSU initial incident report 3/2/2021

Dear Dr. Harris,

This email serves as the initial notification on an exposure that occurred at Oregon Health & Science University on 3/2/2021. The incident report describing a sharps injury involving a SHIV infected non-human primate was submitted to the IBC on 4/12/2021.

A complete report of the incident, cause of delayed IBC/NIH reporting, and follow up actions 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:** Wednesday, July 7, 2021 1:54 PM
**To:** Frothingham, Richard; NIH guidelines
**Cc:** Wayne Thomann; Antony Schwartz, PhD; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Final report: Eye exposure to plasmid DNA

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 no further information about this incident is required at this time. However, we note that while there was a discussion with the safety office regarding safer approaches to opening microfuges tubes, there is no specific mention eye protection which you may wish to consider using when performing activities that may result in splashes.

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:** Richard Frothingham, M.D. <richard.frothingham@duke.edu>
**Sent:** Monday, June 7, 2021 8:24 AM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Wayne Thomann <wayne.thomann@duke.edu>; Antony Schwartz, PhD <antony.schwartz@duke.edu>
**Subject:** Final report: Eye exposure to plasmid DNA

Dear Dr. Harris,

I am writing to provide a final report for an eye exposure to plasmid DNA that occurred on April 12, 2020 in a BSL2 environment. I sent you a preliminary report on April 15, 2020 (attached below).

**Event:** Researcher A opened an flip-top microcentrifuge tube containing HBV DNA plasmid. A drop of the material splashed the researcher in the left eye. The researcher flushed the eye, then reported the event to employee health.

**Material description and risk assessment:** Plasmid DNA containing hepatitis B virus (HBV) infectious molecular clone. Transduction of similar plasmids into permissive cell lines (hepatocytes) has led to production of HBV virion particles. In animal models, similar plasmids have generated productive infection only when injected directly into the liver, but have not led to HBV infection when injected by other routes. This is in contrast to human samples containing HBV virion particles which commonly lead to infection in unvaccinated individuals after percutaneous exposure, and rarely lead to infection after eye exposure. Successful HBV vaccination is protective against such exposures.

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**Employee health response:** Researcher A contacted employee health. The researcher had completed HBV vaccination series and had a recent positive hepatitis B surface antibody titer. Employee health advised no further follow-up in the absence of symptoms.

**Corrective action:** Researcher A discussed the event with the Duke safety office, and reviewed safer approaches to opening flip-top microcentrifuge tubes.

**IBC review:** The IBC reviewed this event at the next regularly scheduled meeting. The IBC agreed with the risk assessment and corrective action outlined above.

Thank you for your support for safe, compliant, and productive nucleic acid research.
Rich Frothingham

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:** Richard Frothingham, M.D.
**Sent:** Thursday, April 15, 2021 10:49 AM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIHGuidelines@od.nih.gov
**Cc:** Wayne Thomann <wayne.thomann@duke.edu>; Antony Schwartz, PhD (antony.schwartz@duke.edu) <antony.schwartz@duke.edu>
**Subject:** Preliminary report: Eye exposure to plasmid DNA

Dear Dr. Harris,

We received a report yesterday about an eye exposure to plasmid DNA that occurred on April 12. The researcher was working in a BSL2 environment, so we are providing this immediate report.

We are gathering additional information about the event, and will review it at our next monthly IBC meeting. We will provide a final report after that review.

Thank you for your support for safe, compliant, and productive nucleic acid research.
Rich Frothingham

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:** Frothingham, Richard
**Sent:** Monday, June 7, 2021 8:24 AM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Wayne Thomann; Antony Schwartz, PhD
**Subject:** Final report: Eye exposure to plasmid DNA

Dear Dr. Harris,

I am writing to provide a final report for an eye exposure to plasmid DNA that occurred on April 12, 2020 in a BSL2 environment. I sent you a preliminary report on April 15, 2020 (attached below).

**Event:** Researcher A opened an flip-top microcentrifuge tube containing HBV DNA plasmid. A drop of the material splashed the researcher in the left eye. The researcher flushed the eye, then reported the event to employee health.

**Material description and risk assessment:** Plasmid DNA containing hepatitis B virus (HBV) infectious molecular clone. Transduction of similar plasmids into permissive cell lines (hepatocytes) has led to production of HBV virion particles. In animal models, similar plasmids have generated productive infection only when injected directly into the liver, but have not led to HBV infection when injected by other routes. This is in contrast to human samples containing HBV virion particles which commonly lead to infection in unvaccinated individuals after percutaneous exposure, and rarely lead to infection after eye exposure. Successful HBV vaccination is protective against such exposures.

**Employee health response:** Researcher A contacted employee health. The researcher had completed HBV vaccination series and had a recent positive hepatitis B surface antibody titer. Employee health advised no further follow-up in the absence of symptoms.

**Corrective action:** Researcher A discussed the event with the Duke safety office, and reviewed safer approaches to opening flip-top microcentrifuge tubes.

**IBC review:** The IBC reviewed this event at the next regularly scheduled meeting. The IBC agreed with the risk assessment and corrective action outlined above.

Thank you for your support for safe, compliant, and productive nucleic acid research.
Rich Frothingham

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:** Richard Frothingham, M.D.
**Sent:** Thursday, April 15, 2021 10:49 AM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIHGuidelines@od.nih.gov
**Cc:** Wayne Thomann <wayne.thomann@duke.edu>; Antony Schwartz, PhD (antony.schwartz@duke.edu) <antony.schwartz@duke.edu>
**Subject:** Preliminary report: Eye exposure to plasmid DNA

Dear Dr. Harris,

We received a report yesterday about an eye exposure to plasmid DNA that occurred on April 12. The researcher was working in a BSL2 environment, so we are providing this immediate report.

Obtained via FOIA by Judicial Watch Inc.

We are gathering additional information about the event, and will review it at our next monthly IBC meeting. We will provide a final report after that review.

Thank you for your support for safe, compliant, and productive nucleic acid research.

Rich Frothingham

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:** Antony Schwartz, PhD <antony.schwartz@duke.edu>
**Sent:** Thursday, June 3, 2021 5:24 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Preliminary report: Eye exposure to plasmid DNA

Hi Kathryn,
Thank you for following up. Our IBC co-chair is finalizing this report and will send it to you shortly. We apologize for the delay.

Best,
Antony

---

**From:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>
**Sent:** Tuesday, June 1, 2021 8:51 AM
**To:** Antony Schwartz, PhD <antony.schwartz@duke.edu>
**Subject:** RE: Preliminary report: Eye exposure to plasmid DNA

Hi Anthony:

Just following up on this incident. I believe this is still waiting a final report but please let me know if I missed it.

Thanks!

Kathryn

---

**From:** Richard Frothingham, M.D. <richard.frothingham@duke.edu>
**Sent:** Thursday, April 15, 2021 10:49 AM
**To:** Harris, Kathryn (NIH/OD) [C] <harriskath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Wayne Thomann <wayne.thomann@duke.edu>; Antony Schwartz, PhD <antony.schwartz@duke.edu>
**Subject:** Preliminary report: Eye exposure to plasmid DNA

Dear Dr. Harris,

We received a report yesterday about an eye exposure to plasmid DNA that occurred on April 12. The researcher was working in a BSL2 environment, so we are providing this immediate report.

We are gathering additional information about the event, and will review it at our next monthly IBC meeting. We will provide a final report after that review.

Thank you for your support for safe, compliant, and productive nucleic acid research.

Rich Frothingham

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.

## Hunter, Renee (NIH/OD) [C]

**From:** Frothingham, Richard
**Sent:** Thursday, April 15, 2021 10:49 AM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Wayne Thomann; Antony Schwartz, PhD
**Subject:** Preliminary report: Eye exposure to plasmid DNA

Dear Dr. Harris,

We received a report yesterday about an eye exposure to plasmid DNA that occurred on April 12. The researcher was working in a BSL2 environment, so we are providing this immediate report.

We are gathering additional information about the event, and will review it at our next monthly IBC meeting. We will provide a final report after that review.

Thank you for your support for safe, compliant, and productive nucleic acid research.

Rich Frothingham

_____

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:** Thursday, June 3, 2021 1:12 PM
**To:** IBC; NIH guidelines
**Cc:** 'Krystal Toups'; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Final Report of Exposure Incident on 4-15-2021 at Rice University

Dear Dr. Daniel Kirienko,

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:** IBC <ibc@rice.edu>
**Sent:** Wednesday, May 12, 2021 10:53 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** 'Krystal Toups' <kt23@rice.edu>
**Subject:** Final Report of Exposure Incident on 4-15-2021 at Rice University

Dear OSP Staff,

Please find attached our final report of the exposure incident that occurred at William Marsh Rice University on April 15th. The report details the incident, outcomes, and the changes in procedure to prevent its reoccurrence.

Please do not hesitate to reach out if you require additional information.

Thank you,

**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:** IBC <ibc@rice.edu>
**Sent:** Friday, April 16, 2021 10:58 AM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
**Cc:** 'Krystal Toups' <kt23@rice.edu>
**Subject:** Preliminary Report of Exposure Incident on 4-15-2021 at Rice University

Dear OSP Staff,

Attached is a very preliminary report intended to serve as a notification of an incident that occurred after business hours on April 15, 2021. A member of a lab on campus at William Marsh Rice University was exposed to an adeno-associated virus. We are collecting information about what the virus may have been engineered to contain and how this incident occurred. This preliminary report is intended to fulfill the requirement of immediate reporting. Attempts were made to call two different OSP offices. Voicemails were also left with brief messages and contact information.

We are in the process of gathering additional information, and will file a more complete report as soon as possible.

Thank you,

**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.

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | William Marsh Rice University<br>6100 Main St<br>Houston TX 77005 |
| **Date of Report:** | 5/12/2021 |
| **Reporter name and position:** | Daniel Kirienko<br>IBC and SCRO Administrator |
| **Telephone number:** | 713-348-7349 |
| **Email address:** | ibc@rice.edu |
| **Reporter mailing address:** | Rice University Office of Research Compliance<br>Allen Center 350<br>MS 16<br>6100 Main St<br>Houston, TX 77005 |
| **Date of incident:** | 4/15/2020 |
| **Name of Principal Investigator:** | Dr. Gang Bao |
| **Is this an NIH-funded project?** | X YES ☐NO<br><br>If yes, please provide the following information (if known)<br>5-R01-HL152314-02<br>5-R01-HL138126-04<br>5-UG3-HL151545-02<br>1-OT2-HL154977-01<br>5-R01-CA207497-05 |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>X Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br><br>Research was approved September 14, 2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 x BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | The research is governed by sections III-D-1, III-D-2, III-D-4, III-E-1, III-F-1, III-F-2, III-F-3, and III-F-8 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | No other report has been made<br><br>☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Laboratory member was accidentally exposed to a recombinant adeno-associated virus carrying GFP during a virus harvesting procedure. |

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 April 15th, 2021, an exposure incident occurred in the laboratory of Dr. Gang Bao at William Marsh Rice University. This event occurred in Room 440E, in the Biosciences Research Collaborative building. Present and involved in the incident were MALE GRADUATE STUDENT 1 (MGS1), MALE GRADUATE STUDENT 2 (MGS2), and FEMALE POSTDOCTORAL FELLOW 1 (FPF1). Additionally present were a female graduate student and a female research technician, but they were not involved in the incident. During this incident, MGS 2 was exposed to an adeno-associated virus viral delivery vector containing a gene encoding a derivative of green fluorescent protein (GFP).

At the time in question, FPF1 was training MGS1, MGS2, and the other personnel how to purify adeno-associated virus (AAV) from an iodixanol gradient in a biosafety cabinet. This process is routinely performed in the Bao lab, and involves collecting material via side-puncture of a plastic ultracentrifugation tube with a syringe. FPF1 has performed this procedure many times since joining the lab in 2014. All personnel were wearing gloves, safety glasses, and lab coats and were up to date on their annual General Laboratory Safety Training courses and their Biosafety and Bloodborne Pathogen Safety Training courses.

The Bao lab has an approved IBC protocol from Rice University's IBC. As a general practice, each lab at Rice has a single IBC protocol to cover their research. In the case of the Bao lab, the highest containment level for the protocol is BSL2+, but that designation is for work involving the use of viral delivery vectors to deliver nucleases like TALENs or Cas9 into human cells. The enhanced precautions associated with this containment level include a dedicated biosafety cabinet for work with viral vectors, increased sanitation of the biosafety cabinet with bleach prior to and after use, use of respirators or face shields while using these materials, and sequestration of materials involving these viral delivery agents away from other materials in the cell culture incubator. Additionally, when this work takes place, extra signage is placed on the door and access to the room is restricted to personnel who have received extra training for these materials.

The incident in question involved AAV without these materials. Instead, the AAV only included a GFP derivative. This work would have been assigned a containment level of BSL1 by the Rice IBC.

AAV purification is typically performed using an iodixanol gradient in a plastic ultracentrifuge tube. The material has to be collected via side-puncture with a sterile syringe. FPF1 was training MGS1 and MGS2 in this procedure. After placing the tube into a tube clamp, MGS1 had difficulty piercing the side and was concerned about missing the appropriate location in the gradient to harvest the virus from the tube. MGS2 removed the tube from the clamp to improve MGS1's ability to see the gradient. MGS1 performed the side puncture while MGS2 was holding the tube. The syringe passed through the tube and entered the finger of MSG2.

At this point, MGS1 transferred the tube and the syringe to FPF1, removed his hands from the biosafety cabinet, removed his gloves, and immediately washed his hands with soap and water. Afterward, he used an iodine pad from the lab's first aid kit to disinfect it. FPF1 completed the aspiration of the material and safely disposed of the materials (the syringe was placed into a sharps container, the tube was placed into a bleach bath. MGS2.

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FPF1 informed the lab manager and Rice University's Office of Environmental Health and Safety (EHS). MGS2 was directed to a local emergency room, where he was seen by a physician. MGS2 reported no pain, and was told to self-monitor for signs of infection. MGS2 was also directed to a local clinic for occupational therapy. Given the nature of the virus in question (AAV), it is expected that no illness will result.

On April 16th, 2021, a Biosafety Officer for Rice University went to the lab to investigate what happened. No equipment failures were noted at that time. The Biosafety Officer made the recommendation that a ring stand and tube clamp should be used exclusively for procedures requiring a side puncture.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES x NO<br>As of this notice, the IBC Chair has been notified. The IBC will be notified at the next meeting. |
| **Please describe the root cause of this incident:** | The root cause of the incident was an unsafe practice. The IBC has requested that this practice be discontinued in favor of a more appropriate technique, where the tube in question will be held with a ring stand and tube clamp. |

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 Bao lab has modified their procedures to require that side puncture take place only with the use of a ring stand and a tube clamp. This has already been obtained and placed in the cell culture room. One member of the lab will train all other members about the proper procedure for harvest, and no members of the lab will be allowed to purify AAV until they have been retrained on the use of the equipment. During inspections, the Biosafety Office will check whether the ring stand and tube clamp are present in the room.

- **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.

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

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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

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | X YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | William Marsh Rice University<br>6100 Main St<br>Houston TX 77005 |
| **Date of Report:** | 4/16/2021 |
| **Reporter name and position:** | Daniel Kirienko<br>IBC and SCRO Administrator |
| **Telephone number:** | 713-348-7349 |
| **Email address:** | ibc@rice.edu |
| **Reporter mailing address:** | Rice University Office of Research Compliance<br>Allen Center 350<br>MS 16<br>6100 Main St<br>Houston, TX 77005 |
| **Date of incident:** | 4/15/2020 |
| **Name of Principal Investigator:** | Dr. Gang Bao |
| **Is this an NIH-funded project?** | X YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>X Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br><br>Research was approved September 14, 2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 x BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | The research is governed by sections III-D-1, III-D-2, III-D-4, III-E-1, III-F-1, III-F-2, III-F-3, and III-F-8 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Laboratory member was accidentally exposed to a recombinant adeno-associated virus strain. Additional details will be provided as soon as possible. We are still collecting information. |

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)

THIS IS A PRELIMINARY REPORT, BEING FILED AS A NOTICE. Due to the ongoing SARS-CoV-2 pandemic, we were unable to reach the NIH OSP via telephone (messages were left at two different numbers).

This incident occurred after business hours on 4/15/2021. We currently are gathering information about the incident, who was involved, how it happened, etc. A more detailed report will be filed as soon as possible.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES x NO<br>As of this notice, the IBC Chair has been notified, but the rest of the IBC has not yet been informed. |
| **Please describe the root cause of this incident:** | To be determined. |

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):

This is a preliminary report. We will decide on these measures once additional details are available.

- **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:** Wednesday, May 12, 2021 10:53 AM
**To:** NIH guidelines
**Cc:** 'Krystal Toups'
**Subject:** Final Report of Exposure Incident on 4-15-2021 at Rice University
**Attachments:** April 15 2021 Incident Report FINAL.pdf

Dear OSP Staff,

Please find attached our final report of the exposure incident that occurred at William Marsh Rice University on April 15th. The report details the incident, outcomes, and the changes in procedure to prevent its reoccurrence.

Please do not hesitate to reach out if you require additional information.

Thank you,

**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

---

**From:** IBC <ibc@rice.edu>
**Sent:** Friday, April 16, 2021 10:58 AM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
**Cc:** 'Krystal Toups' <kt23@rice.edu>
**Subject:** Preliminary Report of Exposure Incident on 4-15-2021 at Rice University

Dear OSP Staff,

Attached is a very preliminary report intended to serve as a notification of an incident that occurred after business hours on April 15, 2021. A member of a lab on campus at William Marsh Rice University was exposed to an adeno-associated virus. We are collecting information about what the virus may have been engineered to contain and how this incident occurred. This preliminary report is intended to fulfill the requirement of immediate reporting. Attempts were made to call two different OSP offices. Voicemails were also left with brief messages and contact information.

We are in the process of gathering additional information, and will file a more complete report as soon as possible.

Thank you,

**Daniel R. Kirienko, Ph.D.**
Preferred pronouns: he, him, his
Compliance Administrator I (IBC and SCRO)

Obtained via FOIA by Judicial Watch Inc.

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.

## Hunter, Renee (NIH/OD) [C]

**From:** IBC <ibc@rice.edu>
**Sent:** Friday, April 16, 2021 11:58 AM
**To:** NIH guidelines
**Cc:** 'Krystal Toups'
**Subject:** Preliminary Report of Exposure Incident on 4-15-2021 at Rice University
**Attachments:** Preliminary April 15 2021 Incident Report.pdf

Dear OSP Staff,

Attached is a very preliminary report intended to serve as a notification of an incident that occurred after business hours on April 15, 2021. A member of a lab on campus at William Marsh Rice University was exposed to an adeno-associated virus. We are collecting information about what the virus may have been engineered to contain and how this incident occurred. This preliminary report is intended to fulfill the requirement of immediate reporting. Attempts were made to call two different OSP offices. Voicemails were also left with brief messages and contact information.

We are in the process of gathering additional information, and will file a more complete report as soon as possible.

Thank you,

**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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 12:57 PM
**To:** Johnson,Christine; NIH guidelines
**Cc:** Rudolph,Alan; Rupprecht,Jo; Dobos,Karen; Moritz,Rebecca; Chen,Chaoping; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Final Incident Report-CSU 033021

Dear Christine Johnson,

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:** Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Sent:** Tuesday, May 25, 2021 11:56 AM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Rudolph,Alan <Alan.Rudolph@colostate.edu>; Rupprecht,Jo <Jo.Rupprecht@colostate.edu>; Dobos,Karen <Karen.Dobos@colostate.edu>; Moritz,Rebecca <Rebecca.Moritz@colostate.edu>; Chen,Chaoping <Chaoping.Chen@colostate.edu>; Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Subject:** Final Incident Report-CSU 033021

Dear Dr. Harris,

In follow up to the initial incident report emailed on 4/22/21 regarding recombinant lentivirus work being conducted without IBC approval, please see attached the final incident report. Let me know if you have any questions.

Thank you,
Christy

**Christine M. Johnson, MS, RBP**
Senior IBC Coordinator
Research Integrity & Compliance Review Office
2011 Campus Delivery | Fort Collins, CO 80523-2011
200D University Services Center | Colorado State University
Office: (970) 491-1553 | Direct: (970) 491-8690 | https://www.research.colostate.edu/ricro/ibc/

*"We must find time to stop and thank the people who make a difference in our lives."*

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**–John F. Kennedy**

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*?** | X YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Colorado State University |
| **Date of Report:** | Initial report emailed on 4/22/21; final report date: 5/25/21 |
| **Reporter name and position:** | Christine Johnson<br>Senior IBC Coordinator |
| **Telephone number:** | 970-491-8690 |
| **Email address:** | Christine.johnson@colostate.edu |
| **Reporter mailing address:** | Christine Johnson<br>Colorado State University<br>Campus Delivery 2011<br>Fort Collins, CO 80523-2011 |
| **Date of incident:** | 3/30/21 |
| **Name of Principal Investigator:** | Tingting Yao, PhD<br>Associate Professor<br>Department of Biochemistry and Molecular Biology<br>Colorado State University |
| **Is this an NIH-funded project?** | X YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:* R21ES029150<br>*NIH funding institute or center:* NIEHS<br>*NIH program officer (name, email address):* Frederick Tyson, (919) 541-0176, tyson2@niehs.nih.gov |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>X Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ X YES ☐NO<br><br>If yes, date of approval: 4/26/21 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-1 and III-D-3 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Recombinant lentivirus used for gene delivery into somatic cells or embryonic stem cells of either human or mouse origin. cDNAs encoding various ubiquitin or histone-binding domains cloned into the pTRIPZ vector, and packaged into lentivirus with 2nd generation packaging system to be delivered into various immortalized human cell lines. |

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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 3/16/2021 our office was notified of a potential project involving recombinant lentivirus being conducted without IBC approval. The IBC Chair reached out to the PI and on 3/30/2021 received confirmation that work with recombinant lentiviral vectors was indeed being conducted. The PI was instructed to submit an Agent Approval Request Form (AARF) and Project Approval Request Form (PARF) to the IBC for review, and a Biosafety Lab Visit was scheduled.

The PI submitted the forms on 4/11/2021, which further confirmed that recombinant lentivirus vectors were being used for gene delivery into somatic cells or embryonic stem cells of either human or mouse origin. The genes cloned into pTRIPZ vector encode various ubiquitin or histone-binding domains, which are packaged into lentivirus with 2nd generation packaging system to be delivered into various immortalized human cell lines. The cells are then subject to live or fixed imaging analysis to visualize the sensors. The PARF also confirmed that the work is performed under BSL2 conditions and falls under sections III-D-1 and III-D-3 of the NIH Guidelines.

On 4/14/2021, the IBC reviewed the AARF and PARF, and was informed that the work was being done without IBC approval and the forthcoming NIH Incident Report. The IBC found all containment practices to be in order and had no concerns regarding the project. The project was approved pending the completion of the Biosafety Lab Visit. The Biosafety Lab Visit was conducted on 4/21/2021 and also found the lab to be in good order. There were a few training items that needed to be updated. With the completion of the lab visit and the training, final IBC approval was granted on 4/26/2021. The PI is now in compliance with the IBC.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO<br>The incident has been reviewed by a subcommittee of the IBC and will be reviewed by the full committee during the June meeting. |
| **Please describe the root cause of this incident:** | The PI believed that since they had BSL2 status and appropriate training, that they did not need to be approved for lentivirus usage. However, upon request she was very responsive in submitting the appropriate forms. |

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):

- On 3/30/2021, the PI was instructed to submit the appropriate Agent Approval Request Forms (AARF) and PARFs to the IBC for review.
- On 4/14/2021, the IBC reviewed the AARF and PARF, and was notified of the forthcoming NIH Incident Report. The IBC had no concerns regarding the project and the AARF and PARF were approved pending the completion of the Biosafety Lab Visit. The lab visit was conducted on 4/21/21 and final IBC approval granted on 4/26/21.
- An incident review meeting was conducted on 5/21/21 to answer any questions the PI had.
- The PI was given additional training and reference materials regarding the use of rDNA and lentiviral vectors.
- A formal IBC education/outreach program is currently being developed to help bring greater awareness to IBC approval requirements.

- **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:** Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Sent:** Tuesday, May 25, 2021 11:56 AM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Rudolph,Alan; Rupprecht,Jo; Dobos,Karen; Moritz,Rebecca; Chen,Chaoping; Johnson,Christine
**Subject:** Final Incident Report-CSU 033021
**Attachments:** Final_OSP Incident Report_CSU033021.pdf

Dear Dr. Harris,

In follow up to the initial incident report emailed on 4/22/21 regarding recombinant lentivirus work being conducted without IBC approval, please see attached the final incident report. Let me know if you have any questions.

Thank you,
Christy

**Christine M. Johnson, MS, RBP**
Senior IBC Coordinator
Research Integrity & Compliance Review Office
2011 Campus Delivery | Fort Collins, CO 80523-2011
200D University Services Center | Colorado State University
Office: (970) 491-1553 | Direct: (970) 491-8690 | https://www.research.colostate.edu/ricro/ibc/

*"We must find time to stop and thank the people who make a difference in our lives."*
**–John F. Kennedy**

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## Hunter, Renee (NIH/OD) [C]

**From:** Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Sent:** Thursday, April 22, 2021 12:51 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Johnson,Christine; Chen,Chaoping; Dobos,Karen; Moritz,Rebecca
**Subject:** initial incident report - CSU 033021

Dear Dr. Harris,

On March 30, 2021 our office became aware of a project involving recombinant lentivirus being conducted without IBC approval. I am submitting this email as an initial report as we are still gathering the information needed to fill out the Template for Reporting Incidents Subject to the NIH Guidelines. I will submit the full report as soon as possible.

Best regards,
Christy

**Christine M. Johnson, MS, RBP**
Senior IBC Coordinator
Research Integrity & Compliance Review Office
2011 Campus Delivery | Fort Collins, CO 80523-2011
200D University Services Center | Colorado State University
Office: (970) 491-1553 | Direct: (970) 491-8690 | https://www.research.colostate.edu/ricro/ibc/

*"We must find time to stop and thank the people who make a difference in our lives."*
**–John F. Kennedy**

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 12:54 PM
**To:** Rausch, Tamara (Tammy); NIH guidelines
**Cc:** Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Corsmo, Jeremy; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: CCHMC Spill 4/22/2021

Dear Tamara Rausch,

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:** Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
**Sent:** Wednesday, May 12, 2021 4:22 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Waggoner, Stephen <Stephen.Waggoner@cchmc.org>; Gulick, James <James.Gulick@cchmc.org>; Dowdy, Tabitha <Tabitha.Dowdy@cchmc.org>; Corsmo, Jeremy <Jeremy.Corsmo@cchmc.org>
**Subject:** CCHMC Spill 4/22/2021

Good afternoon,

Attached is the formal report for a spill that was reported to you by e-mail on 4/22/2021.

Please feel free to contact me with any questions.

Sincerely,

Tammy

**Tamara B. Rausch, MLT(ASCP)SLS$^{CM}$**
*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



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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

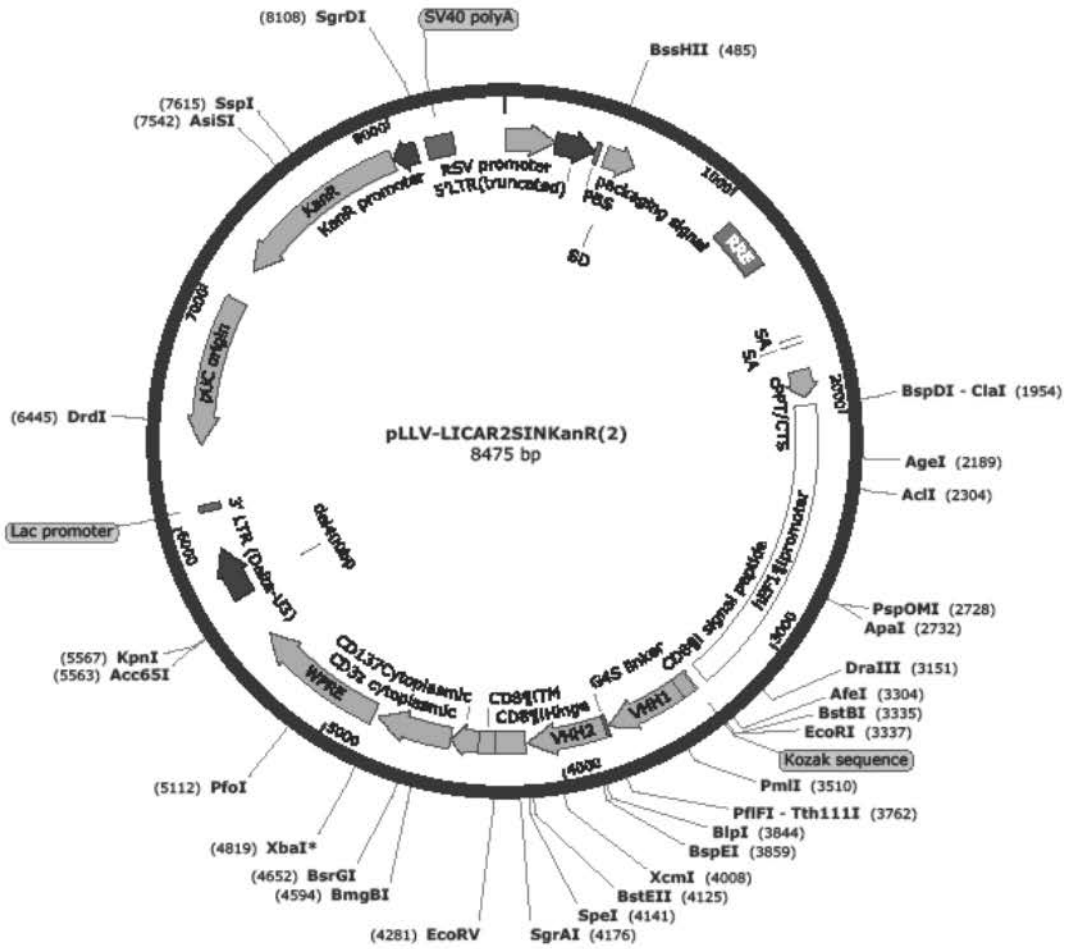
| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ✓YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Cincinnati Children's Hospital |
| **Date of Report:** | 5/12/2021 |
| **Reporter name and position:** | Tamara B. Rausch, Biosafety Officer |
| **Telephone number:** | 513-636-4843 |
| **Email address:** | Tamara.rausch@cchmc.org |
| **Reporter mailing address:** | 240 Albert Sabin Way<br>MLC7040<br>Cincinnati, OH 45229 |
| **Date of incident:** | 4/22/2021 |
| **Name of Principal Investigator:** | Robert Holdcraft, PhD |
| **Is this an NIH-funded project?** | ☐YES ✓NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>✓ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ✓ NO<br>Date of approval: Renewal – 7/14/2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>✓ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-D-2<br>III-D-3<br>III-D-6<br>III-E |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ✓ Other (please describe): Sponsor<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Unconcentrated lentiviral vector supernatant leaked from a line from a 20L Flexboy bioprocess bag during transfer from a 5L Labtainer bag through a Leukocyte Reducing Filter (LRF). The product spilled onto the floor. Map is included. |

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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 Redacted by agreement an ISO 7 cleanroom, in the Vector Production Facility (VPF).

- Who was involved in the incident/violation, including others present at the incident location? There were four GxP technicians in the room.

  **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: Staff immediately cleaned the spill with alcohol wipes. The compromised bioprocess bag was double-bagged in biohazard bags, labeled as waste, and removed from the room to be decontaminated with bleach and discarded.

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

| Name | Biosafety Training | Cleanroom Operations Training | Cleanroom Cleaning Training | Biohazardous Waste Training |
|---|---|---|---|---|
| GxP Technician 1 | 1/4/2021 | 12/30/2019 | 4/23/2020 | 12/17/19 |
| GxP Technician 2 | 2/14/2020 | 3/11/2020 | 2/28/2020 | 2/5/2020 |
| GxP Technician 3 | 10/23/2019 | 2/28/19 | 10/28/19 | 2/20/2019 |
| GxP Technician 4 | 2/1/2021 | 4/1/21 | Employee currently in training for this SOP (new employee) | 1/20/21 |

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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: The approved IBC protocol for the production of viral vectors was followed. In addition, the technicians complied with the SOPs for cleanroom cleaning and handling of biohazard waste. 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 in containment level or the IBC approved protocol, or divisional protocols.

- The personal protective equipment in use at the time of the incident/violation: Cleanroom suits, including full zip-up coverall, high top boots, hood, mask, and splash eye protection (goggles and face shield), two pair of gloves, and Tyvek arm sleeves are worn during the post transient transfection media change procedure.

- The occupational health requirements for laboratory personnel involved in the research: Employees working with human derived materials are required to have the Hepatitis B vaccine series. Vaccination records must be kept on file in the employees' medical record.

- Any medical surveillance provided or recommended after the incident: Medical surveillance was not required as there were no injuries or exposures.

- 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.

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

Incident date: 4/22/21

Incident Location: Cincinnati Children's Hospital Vector Production Facility, Redacted by agreement (ISO 7 cleanroom area)

Staff Present: 4 GxP Technicians

Vector Production Facility staff were harvesting an unconcentrated lentiviral vector supernatant from 10-layer CellStacks. Supernatant was drained from the CellStacks into 5L Labtainer bioprocess bags. Then, the contents of the 5L Labtainer bags was passed through a Leukocyte Reducing Filter (LRF) and collected in a 20L Flexboy bioprocess bag. After approximately 10L of supernatant had passed the filter, staff noticed leakage of media from the terminal 20L Flexboy bag. Staff stopped the pump and clamped all lines to inspect for the source of the leak. The leak was determined to be from one of the lines on the 20L Flexboy. This line has a tri-clamp fitting at the end, which is not supplied with a rigid cap. The bag is supplied with a plastic bag covering the tri-clamp fitting, secured by a zip tie. Although the clamp on the line was closed, a small amount of liquid (approximately 20 mL) leaked past the closed clamp, out the end of the open tri-clamp fitting, and past the zip tie.



Source of leak. Line from 20L Flexboy bioprocess bag with tri-clamp fitting at end.

Staff immediately cleaned the spill with alcohol wipes. Staff double-bagged the compromised bioprocess bag in biohazard bags, labeled as waste, and removed from the facility to be decontaminated with bleach and discarded. All staff were wearing full cleanroom PPE including coveralls, boots, hoods, double gloves, and goggles or face shields. No staff were physically exposed to the supernatant. At the conclusion of work in the suite, all work surfaces and the floor were cleaned with disinfectant (routine post-production cleaning) according to cleaning SOP. All waste was disposed according to the VPF Biohazard Waste SOP. The product in the 20L Flexboy was treated with bleach per the CCHMC protocol for treatment of biohazardous liquid waste.

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The VPF staff notified the institutional safety hotline, 803-SAFE, to report the incident. The VPF Director, Biosafety Officer and QA Officer were also notified.

The 20L Flexboy bags were supplied by the sponsor of the project in response to a shortage of Labtainer bags due to the COVID-19 pandemic. Although the 20L Flexboy bags are appropriate in terms of their plastic composition and other connecting lines, the fact that the tri-clamp fitting line is not capped is suboptimal.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ✓YES (5/11/2021 IBC Meeting)<br>☐NO |
| **Please describe the root cause of this incident:** | The root cause is use of a 20L Flexboy bioprocess bag with tri-clamp fitting line as a substitute for the preferred container (20L 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):

In the future, whenever the Flexboy bags need to be used, a hemostat will be added to the tri-clamp line, in addition to using the supplied clamp on the tri-clamp line.

- **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:** Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
**Sent:** Wednesday, May 12, 2021 4:22 PM
**To:** NIH guidelines
**Cc:** Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Corsmo, Jeremy
**Subject:** CCHMC Spill 4/22/2021
**Attachments:** VPF Incident April 22, 2021 Final Report.pdf

Good afternoon,

Attached is the formal report for a spill that was reported to you by e-mail on 4/22/2021.

Please feel free to contact me with any questions.

Sincerely,

Tammy

**Tamara B. Rausch, MLT(ASCP)SLS$^{CM}$**
*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



Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Rausch, Tamara (Tammy) <Tamara.Rausch@cchmc.org>
**Sent:** Thursday, April 22, 2021 11:52 AM
**To:** NIH guidelines
**Cc:** Waggoner, Stephen; Gulick, James; Dowdy, Tabitha; Corsmo, Jeremy
**Subject:** CCHMC Spill Incident - 4/22/2021

Good morning,

I am notifying you as required by the NIH Guidelines of a spill that occurred this morning in the Viral Vector Production Facility at Cincinnati Children's. Approximately 50 mL of a lentiviral vector in a labtainer BPC bag spilled onto the floor. The technicians in the room cleaned the spill per their SOP. I am in the process of investigating the incident and upon completion, a formal report will be submitted.

Please feel free to contact me with any questions.

Sincerely,

Tammy

**Tamara B. Rausch, MLT(ASCP)SLS$^{CM}$**
*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



Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, May 6, 2021 2:43 PM
**To:** Matt Anderson; NIH guidelines
**Cc:** Dan Hoyt; Dustin Loy; Institutional Biosafety Committee; Donald Becker; Brenda Osthus; Tucker, Jessica (NIH/OD) [E]; Young, Cari (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). 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:** Matt Anderson <manderson11@unl.edu>
**Sent:** Friday, April 23, 2021 3:14 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Dan Hoyt <dhoyt2@unl.edu>; Dustin Loy <jdloy@unl.edu>; Institutional Biosafety Committee <ibc@unl.edu>; Donald Becker <dbecker3@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
Chat with me in Teams

*"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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Nebraska Lincoln |
| **Date of Report:** | 4/23/21 |
| **Reporter name and position:** | Matt Anderson, Biosafety Officer |
| **Telephone number:** | 402-472-9554 |
| **Email address:** | Manderson11@unl.edu |
| **Reporter mailing address:** | 3630 E. Campus Loop<br>Lincoln, NE 68583-0824 |
| **Date of incident:** | Discovered on 3/24/21 |
| **Name of Principal Investigator:** | Edgar Cahoon |
| **Is this an NIH-funded project?** | ☐YES ☑NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☑ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ☑ NO<br>If yes, date of approval:<br>An amendment covering this work has been submitted and will be reviewed at the May 10th IBC Meeting. |
| **What was the approved biosafety level of the research?** | ☑ BL1<br>☐ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | III-E-2a, III-E |
| **Has a report of this incident been made to other agencies? If so, please indicate**<br>No other agencies were notified of this incident. | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Lipid metabolism and lipid biosynthesis pathway genes from non-pathogenic bacteria and various plant species were expressed in food crops (Soybean, camelina and sorghum) to enhance lipid production for biofuel and other applications. Creation of these transgenic plants involved cloning of genes in E. coli (DH5a, DH10B, BL21) followed by incorporation into plasmids for expression via exposure of the plant to Agrobacterium tumefaciens. |

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)

During an investigation into unapproved work for a different PI (Dr. Wilkins), it was discovered that the recombinant Camelina seeds processed by Dr. Wilkins were obtained from Dr. Cahoon. In reviewing the IBC protocol of Dr. Cahoon, it was determined that the genes expressed in the recombinant Camelina seeds were not explicitly listed in Dr. Cahoon's IBC protocol. This discovery occurred on 3/24/21. Dr. Cahoon's lab focuses on enhancing oil, vitamin E and fatty acid production in plants for biofuel and other applications and all work is conducted at BSL-1.

Discussion with the PI on 3/30/21 revealed that the scope of the incident was larger than just the Camelina seed project. The PI's lab has been conducting experiments involving the cloning of genes and expression via agrobacterium in various plant systems with a multitude of genes related to lipid metabolism and oil production in plants that were not explicitly described in the IBC protocol. While the approved research description in the IBC protocol provides an accurate overview of the work conducted, the details of the genes and plasmids utilized to conduct the work and generate the transgenic plant variants is not present in the most recent amendment.

As this incident of non-compliance involves a variety of genes and creation of a multitude of transgenic organisms, it is not feasible to effectively determine when the unapproved work was first initiated, but according to the PI, it has been ongoing for the past few years at least.

The PI last completed Biosafety training related to research compliance and NIH guidelines requirements on 2/14/2019. All other lab staff have taken initial or refresher training related to research compliance within the last two years.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ☑ NO<br>The IBC will review this incident at the 5/10/21 meeting. |
| **Please describe the root cause of this incident:** | PI thought the description of work in the protocol and the genes and plasmids listed in the protocol were sufficient to allow work with related genes from other species not explicitly described in the protocol. |

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):

- PI was contacted on March 30th and notified of the discovery of this suspected non-compliance. Refresher training was scheduled at the time of notification for the PI, lab manager, post-docs and lab technicians for April 6th.
- PI was notified on April 8th to suspend all new work not currently described in the IBC protocol until an amendment was submitted.
- BSO worked with lab manager and PI to revise the IBC protocol through an amendment that would cover all current and planned work in the lab, explaining that new genes and constructs must be added to the IBC protocol prior to use.
- An amendment to the IBC protocol describing all genes and plasmids currently used in the lab was submitted on 4/21/21.
- The amendment will be reviewed by the IBC at the May 10, 2021 regular committee meeting.

- **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, April 23, 2021 3:14 PM
**To:** NIH guidelines
**Cc:** Dan Hoyt; Dustin Loy; Institutional Biosafety Committee; Donald Becker; Brenda Osthus
**Subject:** Report of Non-compliance Incident at UNL
**Attachments:** UNL NIH Incident Report_Cahoon_3-24-21.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
Chat with me in Teams

*"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:** Thursday, June 3, 2021 1:37 PM
**To:** Arriaga, Berenice; NIH guidelines
**Cc:** Rodriguez, Emilio Jr. (EH&S); Spencer, Charles T; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report

Dear Berenice Arriaga,

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:** Arriaga, Berenice <barriaga@utep.edu>
**Sent:** Wednesday, May 19, 2021 1:13 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Rodriguez, Emilio Jr. (EH&S) <erodriguez22@utep.edu>; Spencer, Charles T <ctspencer@utep.edu>
**Subject:** Incident Report
**Importance:** High

Good Morning,

Please see the detailed NIH OSP UTEP Incident Report attached as well as the Novicida Plate SOP and the SDS's for the bacterial mutant plates # 3,10 and 15. If you have any questions, I can be contacted directly via email or at the number listed below.

Sincerely,

**Berenice Arriaga**
Biocontainment Safety Manager
BS, MBA, SM(NRCM), CBSP

Environmental Health and Safety
The University of Texas at El Paso
500 W. University Ave.
El Paso, TX 79968

Obtained via FOIA by Judicial Watch Inc.

Office: 915-747-8124
Fax: 915-747-8126
Cell: Redacted by agreement
ehs.utep.edu

**From:** Arriaga, Berenice
**Sent:** Friday, April 23, 2021 7:22 PM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
**Cc:** Rodriguez, Emilio Jr. (EH&S) <erodriguez22@utep.edu>; Spencer, Charles T <ctspencer@utep.edu>
**Subject:** Initial Contact for Reported Incident
**Importance:** High

Good Afternoon,

I would like to inform you that we have received notice of a laboratory incident involving a commercially available mutant bacterial library for risk group 2 agent *Francisella novicida*. We are investigating the potential exposure and will provide a detailed report of the incident when we conclude our investigation. If you have any questions, I can be contacted directly via email or at the number listed below.

Sincerely,

**Berenice Arriaga**
Biocontainment Safety Manager
BS, MBA, SM(NRCM), CBSP

Environmental Health and Safety
The University of Texas at El Paso
500 W. University Ave.
El Paso, TX 79968
Office: 915-747-8124
Fax: 915-747-8126
Cell: Redacted by agreement
ehs.utep.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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | The University of Texas at El Paso |
| **Date of Report:** | May 6, 2021 |
| **Reporter name and position:** | Emilio Rodriguez, Director and Biosafety Officer |
| **Telephone number:** | (915) 747-7124 |
| **Email address:** | erodriguez22@utep.edu |
| **Reporter mailing address:** | Environmental Health and Safety<br>The University of Texas at El Paso<br>500 W. University Ave.<br>Carl Hertzog Bldg., Rm. 170<br>El Paso, TX 79968 |
| **Date of incident:** | April 20, 2021 |
| **Name of Principal Investigator:** | Charles Spencer, Ph.D. |
| **Is this an NIH-funded project?** | ☐ YES X NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>X Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ X YES ☐NO<br><br>If yes, date of approval: 11/12/2018 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-D-1-RG2 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Francisella tularensis subsp. novicida,* "Two Allele" Transposon Mutant Library plates, (see attached SDS). |

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)

TIMELINE OF EVENTS:

On Thursday April 15, 2021 a female teaching assistant (TA), left three (3) 96-well plates of *Francisella tularensis subsp. novicida,* "Two Allele" Transposon Mutant Library plates in an ice bucket inside a refrigerator. The plates were covered with foil and placed inside an open plastic sleeve. The TA in an advanced teaching laboratory had just worked in a BSC to scrape a thawed mutant colony from the library; prepared aliquots, performed serial dilutions, and grew macrophages in cell culture in preparation for students in the teaching laboratory. The students in the lab then perform ELISA assays as they look for lipids associated with *Francisella* novicida pathogenicity. After the prep work was completed, the TA did not take the mutant plates back to the -80 freezer.

The TA returned to the teaching laboratory five (5) days later (Tuesday April 20, 2021) and found the three plates in the open plastic sleeve inside the refrigerator partially submerged in the ice bucket water. The TA lifted the sleeve with plates from the bucket causing some drops of potentially contaminated water from inside the plastic sleeve to splash into her left eye. The student immediately flushed her eyes for approximately 5 minutes and reported the incident to Environmental Health and Safety (EH&S) and her PI.

EH&S contacted the student the same day and advised the student to seek medical attention. EH&S also contacted the PI and he provided information on the library mutant plates which are commercially available and purchased thru BEI. The PI also provided the Safety Data Sheets (SDS) for the transposon Mutant Library Plates number 3, 10, and 25 involved in the incident.

On Wednesday April 21, 2021, the TA met with an infectious disease doctor at the university's Student Health and Wellness Center (SHWC) and was prescribed a prophylactic antibiotic and medication for eye irritation. She was scheduled for a follow up visit at the SHWC for April 28, 2021. The follow up exam on April 28, 2021 was normal however, the student indicated feeling something in her eye when she moves it from side to side and was referred to an ophthalmologist for another examination.

TRAINING, IBC, and PPE:

The student has taken the institution's safety classes. She took the General Laboratory Safety class on 01/25/2019 and the Biosafety/Blood Borne Pathogens class on 02/04/2020. The student is enrolled in the University's Occupational Health Program (OHP) and is listed in her PI's approved IBC protocol. The student was wearing a laboratory coat and single use disposable gloves at the time of the incident and no safety goggles or glasses. She works in the Biosafety Cabinet (BSC) to conduct her work with the mutant colony plates. EH&S staff presented the incident to the IBC on Friday April 30, 2021. The IBC reviewed the incident and findings and agreed with the proposed corrective actions.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO |
| **Please describe the root cause of this incident:** | Allowing the plates to thaw. Not handling the plates inside the biological safety cabinet. |

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):

ROOT CAUSE AND CORRECTIVE ACTIONS:

EH&S met with the PI and the student to discuss the events leading to the incident. It was determined that the root causes were allowing the plates to thaw instead of picking the colony frozen from the plates as well as the lack of handling the plates in a biological safety cabinet (BSC).

Scrapping a frozen colony from the plates inside the BSC was an unwritten procedure. An SOP that indicates that the mutant library plates must not be thawed and picked from the plates frozen while working in a BSC has now been written and communicated to laboratory personnel. The SOP also states that the TA must place the plates in the freezer prior to leaving for the day and not the refrigerator. The SOP states that the plates must not be allowed to thaw as it reduces the viability of the cells if they go through repeated freeze and thaw cycles. Should the plates accidently be thawed, they should be immediately returned to the freezer to refreeze.

- **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:** Arriaga, Berenice <barriaga@utep.edu>
**Sent:** Wednesday, May 19, 2021 1:13 PM
**To:** NIH guidelines
**Cc:** Rodriguez, Emilio Jr. (EH&S); Spencer, Charles T
**Subject:** Incident Report
**Attachments:** NIH OSP-UTEP Incident-Report 202021-05-18.pdf; Novicida plate SOP 202021-05-18.pdf; Plate03-Bacterial Mutants.pdf; Plate10- Bacterial Mutants.pdf; Plate25- Bacterial Mutants.pdf

**Importance:** High

Good Morning,

Please see the detailed NIH OSP UTEP Incident Report attached as well as the Novicida Plate SOP and the SDS's for the bacterial mutant plates # 3,10 and 15. If you have any questions, I can be contacted directly via email or at the number listed below.

Sincerely,

**Berenice Arriaga**
Biocontainment Safety Manager
BS, MBA, SM(NRCM), CBSP

Environmental Health and Safety
The University of Texas at El Paso
500 W. University Ave.
El Paso, TX 79968
Office: 915-747-8124
Fax: 915-747-8126
Cell: Redacted by agreement
ehs.utep.edu

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**From:** Arriaga, Berenice
**Sent:** Friday, April 23, 2021 7:22 PM
**To:** 'NIHGuidelines@od.nih.gov' <NIHGuidelines@od.nih.gov>
**Cc:** Rodriguez, Emilio Jr. (EH&S) <erodriguez22@utep.edu>; Spencer, Charles T <ctspencer@utep.edu>
**Subject:** Initial Contact for Reported Incident
**Importance:** High

Good Afternoon,

I would like to inform you that we have received notice of a laboratory incident involving a commercially available mutant bacterial library for risk group 2 agent *Francisella novicida*. We are investigating the potential exposure and will provide a detailed report of the incident when we conclude our investigation. If you have any questions, I can be contacted directly via email or at the number listed below.

Obtained via FOIA by Judicial Watch Inc.

Sincerely,

**Berenice Arriaga**
Biocontainment Safety Manager
BS, MBA, SM(NRCM), CBSP

Environmental Health and Safety
The University of Texas at El Paso
500 W. University Ave.
El Paso, TX 79968
Office: 915-747-8124
Fax: 915-747-8126
Cell: Redacted by agreement
ehs.utep.edu

Obtained via FOIA by Judicial Watch Inc.

# Standard Operating Procedure (SOP)
# Handling of Francisella tularensis subspecies novicida

**Purpose:**

The purpose of the SOP is to list and communicate the necessary steps to ensure safe handling of Francisella tularensis subspecies novicida mutant plates. Safe handling of the risk group 2 agents is important to protect students, faculty, and staff from an injury.

**Scope:**

This SOP applies to all individuals handling Francisella tularensis subspecies novicida mutant plates.

**Resources:**

- Francisella tularensis subspecies novicida SDS
- BMBL 6th Edition.

**Procedures:**

1. Prior to handling the Francisella tularensis subspecies novicida. Individuals must read through the safety data sheets (SDS)
2. Minimum personal protective equipment for working with the mutant plates is lab coat and single-use disposable gloves. Eye protection must be worn when conducting procedures that have the potential to create splashes and sprays.
3. All work with the Francisella tularensis subspecies novicida must be done inside of a biological safety cabinet (BSC). When using the BSC properly, the BSC protects the user, the environment, and allows for the sterile manipulation of the mutant colony plates.
4. The plates must not be allowed to thaw and colonies must be scrapped from the plates while frozen inside of a BSC. Allowing the plates to thaw creates potential splash hazard to the user.
5. After the colony has been picked from the frozen plates the plates must be returned to the freezer and not allowed to thaw. Repeated freeze and thaw cycles reduces the viability of the mutant colonies.
6. Should the plates thaw, eye protection must be donned in order to handle the plates. The plates must be refrozen prior to additional handling.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Arriaga, Berenice <barriaga@utep.edu>
**Sent:** Friday, April 23, 2021 9:22 PM
**To:** NIH guidelines
**Cc:** Rodriguez, Emilio Jr. (EH&S); Spencer, Charles T
**Subject:** Initial Contact for Reported Incident

**Importance:** High

Good Afternoon,

I would like to inform you that we have received notice of a laboratory incident involving a commercially available mutant bacterial library for risk group 2 agent *Francisella novicida*. We are investigating the potential exposure and will provide a detailed report of the incident when we conclude our investigation. If you have any questions, I can be contacted directly via email or at the number listed below.

Sincerely,

**Berenice Arriaga**
Biocontainment Safety Manager
BS, MBA, SM(NRCM), CBSP

Environmental Health and Safety
The University of Texas at El Paso
500 W. University Ave.
El Paso, TX 79968
Office: 915-747-8124
Fax: 915-747-8126
Cell: Redacted by agreement
ehs.utep.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, May 6, 2021 2:37 PM
**To:** David Pawlowski; NIH guidelines
**Cc:** David Vasbinder; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: reportable exposure

Dear Dr. David Pawlowski,

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
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

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**From:** David Pawlowski <drp@buffalo.edu>
**Sent:** Wednesday, April 28, 2021 12:06 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** David Vasbinder <dvasbind@buffalo.edu>
**Subject:** reportable exposure

Please find attached to this message an incident report detailing a potential exposure to AAV9 expressing a short hairpin RNA to knock out a targeted gene. the AAV was intracranially injected into a mouse and is unlikely to pass through the saliva from the bite.

Thank you

David R. Pawlowski, PhD, RBP (ABSA, Int'l)
University at Buffalo (SUNY)
Biosafety Officer
FSAP Alternate Responsible Official

716-829-5816 (o)/Redacted by agreement (c)

Obtained via FOIA by Judicial Watch Inc.

drp@buffalo.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*?** | ☐YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | UB JSMBS |
| **Date of Report:** | 4/27/21 |
| **Reporter name and position:** | Jamal Williams/ Research Assistant |
| **Telephone number:** | 716-289-9978 |
| **Email address:** | jbwillia@buffalo.edu |
| **Reporter mailing address:** | 540 Shirley Ave Buffalo, NY |
| **Date of incident:** | 4/21/21 |
| **Name of Principal Investigator:** | Zhen Yan |
| **Is this an NIH-funded project?** | ☐YES ☐NO<br>If yes, please provide the following information (if known)<br>***NIH grant of contract number:*** *AG056060*<br>***NIH funding institute or center:*** *NIA*<br>***NIH program officer (name, email address):*** *YAO, ALISON Q yaoal@nia.nih.gov* |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): Mouse (infected with AAV9 in brain) bite |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ☐NO<br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☐ BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | rAAV9 plasmid containing shRNA for the gene Fbxo2. Stereotaxically injected in the prefrontal cortex of C57 mouse. |

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)

BL1 Laboratory space

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

Male 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

Mouse was put back into home cage. The graduate student then immediately washed affected area with soap and water, then bandaged the puncture and took an antihistamine.

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

The graduate student received all necessary animal handling training including an in-perosn animal handling class offered by LAF in 2018. The student also completed all necessary CITI training including Biomedical Responsible Conduct of Research (2017), Conflicts of Interest (2020), and Working with Rats in Research Settings (2019). Working with the IACUC, Investigators, Staff and Students (2020), Aseptic Surgery (2020), Working with Mice in Research Settings, Reducing Pain and Distress in Laboratory Mice and Rats (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

http://www.buffalo.edu/research/research-services/animal-research/cm-laf/reporting-injuries-when-working-with-animals.html

Immediate first-aid was applied, but immediate outside medical attention was not saught.

- 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

Gloves, lab coat, and surgical mask were worn by the student at the time if incident.

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

Enrollment in Enroll into the Occupational Health Monitoring Program at Erie County Medical Center.

- Any medical surveillance provided or recommended after the incident

None

- Any injury or illness associated with the incident

None

Obtained via FOIA by Judicial Watch Inc.

- Equipment failures

None

Obtained via FOIA by Judicial Watch Inc.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

A C57 mouse that was previously given stereotaxic injection of the AAV9 shRNA for the gene Fbxo2 was being scruffed for an IP injection. During this time, the freed its head before scruff and bit graduate student in the left hand. The graduate student then safely put the mouse back into its home cage and then immediately performed first-aid, washed hands and cleaned wound with soap and warm water. For precaution the student took antihistamine. The student then monitored the affected area for the next few days but did not seek immediate medical attention.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☐NO |
| **Please describe the root cause of this incident:** | A mouse that had been previously injected with a AAV9 virus in the prefrontal cortex (2.5 weeks prior) was being scruffed for IP injection. The mouse which was very aggressive turned and bit me on my left hand. The led to bleeding and swelling. |

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):

Annual OSHA BBP & Biosafety training describes who to contact and what to do in the event of an exposure. All personnel in the lab will be re-trained.

- **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:** David Pawlowski <drp@buffalo.edu>
**Sent:** Wednesday, April 28, 2021 12:06 PM
**To:** NIH guidelines
**Cc:** David Vasbinder
**Subject:** reportable exposure
**Attachments:** Incident-Reporting-Template_UB 4-21-2021.pdf

Please find attached to this message an incident report detailing a potential exposure to AAV9 expressing a short hairpin RNA to knock out a targeted gene. the AAV was intracranially injected into a mouse and is unlikely to pass through the saliva from the bite.

Thank you

David R. Pawlowski, PhD, RBP (ABSA, Int'l)
University at Buffalo (SUNY)
Biosafety Officer
FSAP Alternate Responsible Official

716-829-5816 (o)/Redacted by agreement (c)
drp@buffalo.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 1:50 PM
**To:** Andrea Badger; NIH guidelines
**Cc:** Zara Llewellyn; Katia Harb; Steve Libby; berndtuw; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report - University of Washington

Dear Andrea Badger,

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:** Andrea Badger <abadger@uw.edu>
**Sent:** Tuesday, May 18, 2021 6:13 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Zara Llewellyn <zaral@uw.edu>; Katia Harb <kharb@uw.edu>; Steve Libby <slibby@uw.edu>; berndtuw <berndtuw@uw.edu>
**Subject:** Incident Report - University of Washington

Dear NIH,

Please find attached an incident report involving an employee performing research subject to the NIH guidelines.

Please let me know if you have any questions or need additional information.

Sincerely,
Andrea Badger

ANDREA BADGER

Biosafety Officer

Obtained via FOIA by Judicial Watch Inc.

Environmental Health & Safety / Research & Occupational Safety

Health Sciences Building Box 357165

1959 NE Pacific St T-287 Seattle, WA 98195

206.685.0667 / fax 206.221.3068

abadger@uw.edu / ehs.washington.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*?** | xYES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Washington |
| **Date of Report:** | 5/18/21<br>First reported via email to NIH on 4/28/21 |
| **Reporter name and position:** | Andrea Badger<br>Biosafety Officer |
| **Telephone number:** | 206-685-0667 |
| **Email address:** | abadger@uw.edu |
| **Reporter mailing address:** | Andrea Badger<br>Environmental Health & Safety Department<br>1705 NE Pacific St<br>Room T287<br>Box 357165<br>Seattle, WA 98195 |
| **Date of incident:** | 4/23/21 |
| **Name of Principal Investigator:** | Andre Berndt, Ph.D. |
| **Is this an NIH-funded project?** | xYES NO<br><br>If yes, please provide the following information (if known)<br><br>NIH grant of contract number*: 1R01GM139850-01*<br>NIH funding institute or center*: NIGMS*<br>NIH program officer (name, email address*): Ansong, Charles Kwaku, PhD, charles.ansong@nih.gov* |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>x Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | x YES ☐NO<br>If yes, date of approval: Originally approved on March 15, 2017, renewed by the IBC on February 19, 2020 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>X OSHA This incident will be included in the UW annual OSHA 300A report. |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Human induced pluripotent stem cells (cardiomyocytes) originally reprogrammed via lentiviral transduction, and transfected via lipofectamine transfection with a plasmid encoding GFP (green 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:

- 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 April 23, 2021, in a BSL-2 laboratory, a research assistant poked their right thumb with a pair of sharp forceps. The forceps were precision tweezers, stainless steel with fine sharp tips. The forceps had been used to transfer a coverslip that contained human induced pluripotent cardiomyocytes that were transfected with recombinant DNA via lipofectamine transfection. The injury occurred after the coverslip was transferred, as the research assistant prepared to disinfect the forceps. There was a small wound (about 1 millimeter) that was bleeding.

The individual was working inside a biosafety cabinet and was wearing a lab coat, a surgical face mask, and nitrile gloves. The individual immediately washed the affected area with soap and water for more than fifteen minutes, and performed first aid, applying a latex bandage to the area. No one else was in the room at the time of the injury. The incident was reported to the individual's supervisor as well as the university via the Online Accident Reporting System on the same day as the injury occurred, on April 23, 2021.

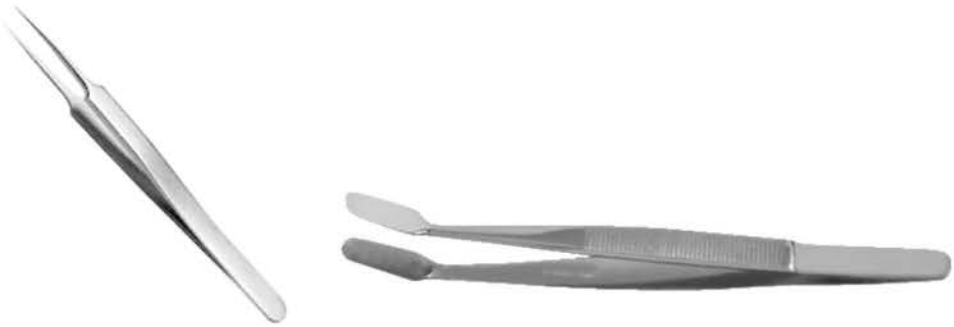
The research assistant was seen at the UW Employee Health Clinic on April 27, 2021. The clinician examined the wound and sent the research assistant for baseline bloodborne pathogen laboratory diagnostic testing (ALT, hepatitis B surface Ab and Ag, hepatitis C Ab, and HIV serology). The individual received a Hepatitis B booster vaccine (the individual had the original Hepatitis B vaccine series in 1991/1992) and a Tdap (tetanus, diphtheria, pertussis) vaccine. Additional labs will be drawn at four weeks and four months post-exposure.

The research assistant is current on the required EH&S trainings. The most recent completion dates are February 9, 2021 for the Bloodborne Pathogens for Researchers, and October 30, 2020 for the Biosafety Training. The research assistant received laboratory-specific training from the principal investigator most recently on October 29, 2020. The laboratory-specific training included training for the tissue culture room and covered the handling of all cell cultures, including the transfer of the coverslips and the cleaning of the equipment. The individual had seven years of experience performing the procedure and had done it several hundred times.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES x NO<br>The incident will be reviewed by the IBC at their next meeting on May 19, 2021. |
| **Please describe the root cause of this incident:** | The incident involved the use of a sharp pair of forceps with straight sharp tips to transfer a coverslip. The root cause of the incident was the unnecessary use of a particularly sharp style of forceps, which led to the individual accidentally puncturing the skin while getting ready to clean the instrument. Also, the researcher accidentally applied too much pressure with the holding hand (the left hand), which then caused the forceps to slip and penetrate the nitrile glove and the right thumb. |

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 lab has switched from using a particularly sharp, watchmaker-style of forceps (like those on the left) to a less sharp style of tweezers (like those seen on the right) when transferring coverslips.

The lab has modified their SOP for disinfecting reusable sharps to include instructions about holding and manipulating sharps carefully, being careful to avoid contact with any sharp tips. The lab has also incorporated the use of a labeled storage tray to contain reusable sharps to help avoid accidental needlesticks or punctures that may occur if sharps are left unattended on a benchtop or inside the biosafety cabinet. The research assistant and other lab members will be trained on these revised SOPs.

- **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:** Andrea Badger <abadger@uw.edu>
**Sent:** Tuesday, May 18, 2021 6:13 PM
**To:** NIH guidelines
**Cc:** Zara Llewellyn; Katia Harb; Steve Libby; berndtuw
**Subject:** Incident Report - University of Washington
**Attachments:** NIH_Incident_Report_Berndt_2021-04.pdf

Dear NIH,

Please find attached an incident report involving an employee performing research subject to the NIH guidelines.

Please let me know if you have any questions or need additional information.

Sincerely,
Andrea Badger

**ANDREA BADGER**
Biosafety Officer
Environmental Health & Safety / Research & Occupational Safety
Health Sciences Building Box 357165
1959 NE Pacific St T-287 Seattle, WA 98195
206.685.0667 / fax 206.221.3068
abadger@uw.edu / ehs.washington.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Zara Llewellyn <zaral@uw.edu>
**Sent:** Wednesday, April 28, 2021 2:19 PM
**To:** NIH guidelines
**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 April 23, 2021.

We are investigating the incident and will be 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
Interim 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

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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 1:02 PM
**To:** Kumar, Asmita/Research and Technology Mgmt; NIH guidelines
**Cc:** Glickman, Michael/Sloan Kettering Institute; Cottington, Eric M./Research and Technology Mgmt; Schaller-Demers, Debra S./Research and Technology Mgmt; Gibson, James H./Facilities Management; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: rDNA exposure report

Dear Dr. Asmita Kumar,

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:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Sent:** Wednesday, June 2, 2021 8:26 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Glickman, Michael/Sloan Kettering Institute <glickmam@MSKCC.ORG>; Cottington, Eric M./Research and Technology Mgmt <cottinge@mskcc.org>; Schaller-Demers, Debra S./Research and Technology Mgmt <schalled@mskcc.org>; Gibson, James H./Facilities Management <GibsonJ2@mskcc.org>
**Subject:** rDNA exposure report

Good Morning,

Please find attached report on behalf of the IBC Chairman, Dr. Michael Glickman. This exposure was originally reported to the OSP on 4/30/21 as a pre-report.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

Obtained via FOIA by Judicial Watch Inc.

**Memorial Sloan Kettering Cancer Center**
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10017
C Redacted by agreement
kumara1@mskcc.org

==========

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 30, 2021

**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 BSL-1 exposure (glass cut) to mouse pancreatic duct epithelial cells stably transduced with two lentiviral vectors that express:

- a catalytically dead Cas9-cytidine deaminase protein and
- a guide RNA

that occurred at our institution on 4/28/2021. We are gathering the necessary information for a full report, which will follow.

Our Evironmental Health and Safety department and the IBC are reviewing the incident and the laboratory worker has received appropriate medical attention.

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 646.888.1077 F 646.888.1120
www.mskcc.org

NCI-designated Comprehensive Cancer Center

Obtained via FOIA by Judicial Watch Inc.

Memorial Sloan Kettering Cancer Center

June 2, 2021

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: rDNA exposure at Memorial Sloan Kettering Cancer Center

In accordance with the NIH guidelines, this report is a follow up of an initial incident report submitted to the NIH Office of Science Policy via email on 4/30/2021.

A graduate student sustained a glass cut involving BSL-1 recombinant nucleic acids while working as approved personnel under an approved IBC Registration. The graduate student was manipulating primary mouse pancreatic duct epithelial cells (PDEC) stably transduced with two lentiviral vectors in a certified biosafety cabinet. She was wearing the required PPE: lab coat and gloves while manipulating a glass Pasteur pipette for aspiration and possibly exterted too much force during handling which resulted in the glass breaking and cutting her left thumb. She applied pressure to the cut to stop the bleeding and her colleague helped wrap her thumb in gauze and medical tape. She subsequently visited Employee Health and Wellness for medical attention and to report the incident. The PDEC cell lines had two plasmids stably integrated into the cellular DNA via lentivirus (no viral particles present in the cell line): one plasmid expressed a catalytically dead Cas9-cytidine deaminase protein and the other plasmid expressed a guide RNA.

Our Biosafety Officer counseled her about washing the wound for 10-15 minutes prior to bandaging. Substitution of glass pipettes with plastic was highly recommended and Polystyrene pipette information was forwarded to the lab manager. The IBC agreed that the reeducation was appropriate and adequate. We believe that retraining will help reduce the recurrence of such issues. 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 email at: glickmam@mskcc.org.

Sincerely,

Redacted by agreement

Michael Glickman, MD
IBC Chairperson

Cc: Eric Cottington, PhD, Senior Vice President, Research and Technology Management

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Sent:** Wednesday, June 2, 2021 8:26 AM
**To:** NIH guidelines
**Cc:** Glickman, Michael/Sloan Kettering Institute; Cottington, Eric M./Research and Technology Mgmt; Schaller-Demers, Debra S./Research and Technology Mgmt; Gibson, James H./Facilities Management
**Subject:** rDNA exposure report
**Attachments:** rDNA Exposure report 4-28-2021.pdf

Good Morning,

Please find attached report on behalf of the IBC Chairman, Dr. Michael Glickman. This exposure was originally reported to the OSP on 4/30/21 as a pre-report.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

**Memorial Sloan Kettering Cancer Center**
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10017
C Redacted by agreement
kumara1@mskcc.org

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## Hunter, Renee (NIH/OD) [C]

**From:** Kumar, Asmita/Research and Technology Mgmt <kumara1@mskcc.org>
**Sent:** Friday, April 30, 2021 12:20 PM
**To:** NIH guidelines
**Cc:** Glickman, Michael/Sloan Kettering Institute; Cottington, Eric M./Research and Technology Mgmt; Schaller-Demers, Debra S./Research and Technology Mgmt; Gibson, James H./Facilities Management
**Subject:** Preliminary Report- rDNA exposure
**Attachments:** MSKCC Exposure 4-28-2021.pdf

Good Afternoon,

Please see attached preliminary report on behalf of the IBC Chairman, Dr. Michael Glickman.

Regards,
Asmita

**Asmita Kumar, Ph.D.** *(she/her/hers)*
Associate Director, Research Compliance (IBC and IACUC)
Co-lead RTM ED&I Council
Research and Technology Management / Office of Research Outreach and Compliance

**Memorial Sloan Kettering Cancer Center**
633 Third Avenue, 15 Floor, 3a-1584C , New York, NY10017
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kumara1@mskcc.org

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## Hunter, Renee (NIH/OD) [C]

**From:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Wednesday, May 5, 2021 4:24 PM
**To:** sweaver; Brocard, Anne-Sophie
**Subject:** RE: Containment lowering incident

Dear Drs. Brocard and Weaver:

Thank you for your report to the NIH Office of Science Policy (OSP) regarding research that was approved by the UTMB Institutional Biosafety Committee (IBC) and conducted at a containment level below the minimum specified in Section III of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*).

From your report, we understand that research involved *Burkholderia mallei* (strain CLH001 (ΔtonB Δbcp1)). The investigator received approval from the UMTB IBC to work with this agent at biosafety level (BL2) on Dec 4, 2015. *Burkholderia mallei* is listed as a Risk Group (RG) 3 agent in Appendix B-III-A of the *NIH Guidelines*. Under Section III-D-1-b, experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 3 agents will usually be conducted at BL3 containment.

As described in Section II-A-3 (Comprehensive Risk Assessment) of the *NIH Guidelines,* the Institutional Biosafety Committee (IBC) must approve the biosafety level for recombinant or synthetic nucleic acid molecules experiments described in Section III of the *NIH Guidelines*. Under Section IV-C-1-b-(2)-(a) of the *NIH Guidelines*, requests to lower the containment level below the minimum specified in Section III require review and approval from the NIH OSP in addition to approval from the IBC.

Your report indicates that, in response to this incident, the investigator was informed to stop all current work with this agent at BL2 on April 28, 2021. The investigator indicated that no research is currently being conducted with the agent. In your report, you state that no additional incidents occurred during the handling of this agent at BL2. In addition, the UTMB IBC submission form has been modified to better identify agents that would require NIH OSP approval. A memo is being prepared to notify all research faculty of this requirement and the annual training presentation will also be updated with this information.

We understand that UTMB is conducting a complete review of its IBC registrations and will notify NIH OSP once completed if any additional research conducted without appropriate approval is identified. If UTMB identifies any additional research being conducted at a lower containment level than the minimum specified in Section III of the *NIH Guidelines*, such work should not proceed at that lower containment until and unless NIH OSP approval has been obtained. Work may be conducted at the containment level specified in Section III until such approval to lower containment is granted.

Please contact us if you have any additional questions.

Regards,

Dr. Kathryn Harris

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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

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☒YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | The University of Texas Medical Branch, Galveston |
| **Date of Report:** | 4/30/2021 |
| **Reporter name and position:** | Anne-Sophie Brocard, Institutional Biosafety Officer, Biosafety Program Director |
| **Telephone number:** | 409-772-8472 |
| **Email address:** | anbrocar@utmb.edu |
| **Reporter mailing address:** | UTMB<br>301 University Blvd,<br>Galveston, Tx 77555-1111 |
| **Date of incident:** | 2015 |
| **Name of Principal Investigator:** | Alfredo Torres |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number: not known*<br>*NIH funding institute or center: not known*<br>*NIH program officer (name, email address): not known* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☒ Other (please describe): Did not obtain approval from NIH-OSP to lower the biosafety level of the recombinant agent prior to starting experiment at a lower containment level |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒ YES ☐ NO If yes, date of approval:12/4/2015 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☒ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section IIID1b |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☒ Other (please describe): None<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Burkholderia mallei strain CLH001 (ΔtonB Δbcp1) |

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DESCRIPTION OF INCIDENT: (use additional space as necessary)

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

  Burkholderia mallei strain CLH001 (ΔtonB Δbcp1) was approved by FSAP to be excluded from the requirements of the select agent regulations, August 20, 2015.

  FSAP determination was based on the following criteria: Burkholderia mallei strain CHL00l (ΔtonB Δbcp1) was determined to be attenuated compared to wild-type B. mallei, such that it does not pose a severe threat to public and animal health and safety. Therefore, B. mallei strain CHL00l (ΔtonB Δbcp1) is excluded from the requirements of the select agent regulations effective August 20, 2015.

  The faculty received approval from The UMTB IBC to work with this agent at BSL2 on Dec 4, 2015. Since then, the lab has been using this agent for vaccine development.

  At the time of IBC approval, the committee didn't realize, that the FSAP exclusion approval was separate from the NHI-OSP approval for down-grading and agent. This information was recently made know to us.

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

  The lab over this time period has employed several post-doctoral fellows, graduate students and research staff that have handled this agent at different time.

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

  The faculty was informed to stop all current work with this agent at BSL2 on April 28, 2021. If work needed to be conducted it would have to take place at BSL3 until NHI-OSP approval was obtained. The faculty indicated that no research was being conducted with the agent. The next set of experiments are scheduled until early summer to fulfill a contract requirement.

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

  Individuals working in this laboratory have received BSL2 and BSL3 training both be EHS

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in the senior laboratory 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**

  The laboratory is in good standing with EHS annual laboratory audits, and IBC submission and annual review.

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

  No deviation form IBC approval or institutional policy.

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

  Laboratory staff where lab coats, eye protection, close toe shoes and gloves when working with the agent at BSL2.

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

  Staff and students working in research laboratory and working in an animal facility must complete an annual health evaluation which is managed by the UTMB Employee Health Center and the information provided is reviewed by medical personnel.

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

  No incident occurred during the handling of this agent at BSL2 since approval by the IBC for use at BSL2. As staff are instructed to immediately report any signs and symptoms associate with any agent they handled to their supervisor and the Biosafety office. No such report occurred. Therefore, no medical surveillance is recommended at this time.

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

  No incident occurred during the handling of this agent at BSL2 since approval by the IBC for use at BSL2. Staff are instructed to immediately report any signs and symptoms associate with any agent they handled to their supervisor and Biosafety. No such report occurred.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☒NO<br><br>The IBC chair was notified of the situation and this will be discussed at the next IBC meeting on 5/7/2021 |
| **Please describe the root cause of this incident:** | The IBC did not fully understand the requirement set forth in the NIH-guidelines regarding down-grading agents that fall in section III D1-b that have been excluded from FSAP requirement. |

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 IBC submission form has been modified to better identify agents that would require NHI-OSP approval. A memo is being prepared to notify all research faculty of this requirement and the annual training presentation will also be updated with this information.
We are also conducting a complete review of our IBC submissions to identify any other required submission and will notify NIH-OSP once completed if any have been identified.

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## Hunter, Renee (NIH/OD) [C]

**From:** Brocard, Anne-Sophie <anbrocar@utmb.edu>
**Sent:** Friday, April 30, 2021 5:06 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** sweaver; Bouyer, Donald
**Subject:** Incident report
**Attachments:** Incident-Reporting-Torres-30Apr21.docx

Dr. Harris

Please find attached an incident report for UTMB.

Feel free to contact me should you need additional information

Regards,

**Anne-Sophie Brocard, Ph.D., RBP, SM(NRCM), CBSP, CHMM, ASP, CSP**

Biosafety Program Director
Institutional Biosafety Officer
Alternate Responsible Official
Redacted by agreement
ironmental Health and Safety
stant Professor of Pathology

utmb Health
Working together to work wonders.

301 University Blvd, TX 77555-1111
**P** 409.772.8472 **M**
anbrocar@utmb.edu
https://www.utmb.edu/ehs/biosafety/

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, May 6, 2021 2:49 PM
**To:** Arseneau, Linda Marie; NIH guidelines
**Cc:** DRS-IBC; Maddox, Carol W; Kraft, Mary L; Rhodes, Justin S; Miller, Monica A; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Report of Failure to Obtain IBC Approval -Rhodes

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:** Wednesday, May 5, 2021 4:07 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** DRS-IBC <ibc@illinois.edu>; Maddox, Carol W <maddox@illinois.edu>; Kraft, Mary L <mlkraft@illinois.edu>; Rhodes, Justin S <jrhodes@illinois.edu>; Miller, Monica A <mamiller@illinois.edu>
**Subject:** Report of Failure to Obtain IBC Approval -Rhodes

Dear OSP,
On behalf of the IBC co-chairs, please find the attached incident report regarding a Principal Investigator, Dr. Justin Rhodes, who did not receive IBC approval prior to initiating experiments that fell under sections III D-2a and III D-4a of the NIH Guidelines. The PI has since submitted a registration and is currently going through the IBC approval process.

Please feel free to contact me or the Chairs 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

Obtained via FOIA by Judicial Watch Inc.

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

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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

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☒YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Illinois Urbana Champaign |
| **Date of Report:** | May 5, 2021 |
| **Reporter name and position:** | Dr. Carol Maddox<br>Professor of Pathobiology, Veterinary Diagnostic Laboratory<br>IBC Co-chair |
| **Telephone number:** | 217-265-0399 |
| **Email address:** | maddox@illinois.edu |
| **Reporter mailing address:** | Pathobiology<br>College of Veterinary Medicine<br>2001 S Lincoln Ave.<br>1219 Vet. Med. Basic Sciences Bldg.<br>Urbana, IL. 61802 |
| **Date of incident:** | June 2019- April 2021 |
| **Name of Principal Investigator:** | Dr. Justin Rhodes |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☒Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐YES ☒NO<br><br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☐BL2 ☐BL2+ (describe specific enhancement in report)<br>☐BL3 ☐BL3+ (describe specific enhancement in report)<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III D-4<br>Section III D-2 |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Attempted knock out of Short-wavelength sensitive opsin and RH2b opsin genes of Amphiprion ocellaris via CRISPR/Cas9. Recent work involved developing transgenic fish that express channelrhodopsin in GnRH neurons via Tol2 transposase. |

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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)

The PI has been attempting to generate transgenic Amphiprion ocellaris (anemonefish) via various methods without the prior approval of the IBC. There was a previous, now discontinued, failed attempt to generate KO animals via CRISPR/Cas9 the summers of 2019 and 2020. This work would have been classified under Sections III D-2 and D-4. In January, the lab began work to generate fish that express channelrhodopsin in GnRH neurons. Recently fertilized eggs would be injected with capped RNA for the tol2 transposase along with a plasmid containing desired constructs for transfection. The lab had begun testing this method using GFP.

The Division of Research Safety was notified by the IACUC office of this work on April 27. The BSO notified the PI of the registration requirements and work was stopped immediately. Work will not resume until review and discussion by the IBC on June 8. This IBC chairs have been notified and the rest of the IBC will be informed on at the monthly meeting on May 11.

The university requires that all lab workers take *Laboratory Safety Training* and all laboratorians working with recombinant material take *NIH Guidelines Overview* training before work can begin. The PI took those trainings, prior to beginning work, on May 15, 2017 and May 30, 2017, respectively. Additionally, the university requires these trainings to be repeated every three years so the PI repeated them in May of 2020, while KO work was ongoing.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO |
| **Please describe the root cause of this incident:** | The PI was not clear on how these experiments applied to the NIH Guidelines. |

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 stopped work on April 27. The PI has submitted a registration to the IBC to be reviewed and discussed on June 8. The Division of Research Safety met with the PI on April 30, 2021 to explain how this work is classified under the NIH guidelines. Prior to approval of the work, the PI will be required to repeat the *NIH Guidelines Overview* training.

- **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:** Arseneau, Linda Marie <lmarsene@illinois.edu>
**Sent:** Wednesday, May 5, 2021 4:07 PM
**To:** NIH guidelines
**Cc:** DRS-IBC; Maddox, Carol W; Kraft, Mary L; Rhodes, Justin S; Miller, Monica A
**Subject:** Report of Failure to Obtain IBC Approval -Rhodes
**Attachments:** 2021-04 Rhodes Lab NIH Incident Report.pdf

Dear OSP,
On behalf of the IBC co-chairs, please find the attached incident report regarding a Principal Investigator, Dr. Justin Rhodes, who did not receive IBC approval prior to initiating experiments that fell under sections III D-2a and III D-4a of the NIH Guidelines. The PI has since submitted a registration and is currently going through the IBC approval process.

Please feel free to contact me or the Chairs 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

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## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, May 6, 2021 2:26 PM
**To:** Ghosh, Sajal K; NIH guidelines
**Cc:** IBC; Mellouk, Kathryn M.; Richmond, Pamela J; Hutchinson, Jennifer M; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: BU Incident Report 4.14.2021

Dear Dr. Sajal Ghosh,

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:** Ghosh, Sajal K <sajal@bu.edu>
**Sent:** Wednesday, May 5, 2021 10:04 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** IBC <IBC@bu.edu>; Mellouk, Kathryn M. <kateski@bu.edu>; Richmond, Pamela J <pamelajr@bu.edu>; Hutchinson, Jennifer M <jhutch@bu.edu>; Ghosh, Sajal K <sajal@bu.edu>
**Subject:** BU Incident Report 4.14.2021

To Whom It May Concern,

Attached please find report for an incident that occurred on 4/14/2021 at 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, Cell: Redacted by agreement
Email: sajal@bu.edu; ibc@bu.edu

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| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☒YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Boston University |
| **Date of Report:** | 5/5/2021 |
| **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<br>Boston, MA 02118 |
| **Date of incident:** | 4/14/2021 |
| **Name of Principal Investigator:** | Tsuneya Ikezu, MD, PhD. |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant or contract number: 1RF1- AG054199-01*<br>*NIH funding institute or center: NIA*<br>*NIH program officer (name, email address): Austin Jyan-Yu Yang (yangj13@mail.nih.gov)* |

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this** | ☒YES ☐NO |

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| | |
|---|---|
| **research?** | If yes, date of approval: 10/04/2019 |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Sections III-D-1-a, III-D-2-a, III-D-4-a, III-E-1; Appendix-B-II-D, Appendix G-II-B |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☒State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Recombinant AAV vectors that conditionally express green florescence protein (GFP) and Tau P301L mutant under the control of *Cre-Lox* system. |

DESCRIPTION OF INCIDENT:

On April 14, 2021, a graduate student accidentally stuck his left middle knuckle with a glass capillary tube containing recombinant Adeno-associated viruses. He was preparing to make an intracranial stereotactic injection in a mouse when he inadvertently raised his arm near the stereotactic machine (where the glass capillary tube was setup and had not yet touched the mouse). At the time of the incident, the student was wearing appropriate personal protective equipment (double gloves, coveralls, shoe covers and a face mask). He washed his hands immediately with soap and water and was seen in Research Occupational Health for evaluation and counseling and was provided a Tdap vaccination. That same day he went to the emergency room for further evaluation and on 4/16/21 was seen by Research Occupational Health staff for follow-up and reported the wound was healing well. In an animal model, Cre-recombinase is expressed conditionally in the presence of tamoxifen, allowing expression of GFP and Tau P301L genes in the AAV vector. However, AAVs are not known to cause disease in humans; the AAV vectors cannot express GFP and Tau P301L genes in humans without the presence of Cre-recombinase.

The student'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<br>Reviewed at the April 2021 IBC meeting. |
| **Please describe the root cause of this incident:** | Lack of conscientiousness. |

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:

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The student was advised to complete the Sharps Safety Training and he indicated he will be more conscientious in the future.

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## Hunter, Renee (NIH/OD) [C]

**From:** Ghosh, Sajal K <sajal@bu.edu>
**Sent:** Wednesday, May 5, 2021 10:04 AM
**To:** NIH guidelines
**Cc:** IBC; Mellouk, Kathryn M.; Richmond, Pamela J; Hutchinson, Jennifer M; Ghosh, Sajal K
**Subject:** BU Incident Report 4.14.2021
**Attachments:** BU Incident Report 4.14.2021.pdf

To Whom It May Concern,

Attached please find report for an incident that occurred on 4/14/2021 at 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, Cell: Redacted by agreement
Email: sajal@bu.edu; ibc@bu.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, July 7, 2021 2:40 PM
**To:** ANDREA N LADD; NIH guidelines
**Cc:** Jeri Barak-Cunningham; STEPHANIE G KUTZ; Christopher Strang; Tucker, Jessica (NIH/OD) [E]; Young, Cari (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 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:** Friday, June 4, 2021 6:51 PM
**To:** Harris, Kathryn (NIH/OD) [C] <HarrisKath@mail.nih.gov>; NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Jeri Barak-Cunningham <jeri.barak@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 incident reported on 05/12/21 (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:

- Jeri Barak-Cunningham, 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., RBP*
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, May 12, 2021 7:55 AM
**To:** harriskath@mail.nih.gov; NIHGuidelines@od.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

Kathryn or Whom It May Concern,

We were notified today of an exposure to a recombinant microbe from a sharps injury in one of our BSL2 laboratories. The employee was directed to Occupational Medicine 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., RBP*
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

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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Wisconsin-Madison |
| **Date of Report:** | 05/12/21 (initial email to OSP)<br>06/04/21 (full 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<br>30 East Campus Mall<br>Madison, WI 53715 |
| **Date of incident:** | 05/11/21 |
| **Name of Principal Investigator:** | John-Demian Sauer |
| **Is this an NIH-funded project?** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☒Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval: 02/28/19 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA<br><br>Not applicable |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *Listeria monocytogenes* strain 10403s with an integrated transposon carrying erythromycin resistance and a plasmid with kanamycin resistance; this mutant was obtained from a transposon mutagenesis library screening for attenuation |

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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.**

**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:** disposable gloves

**Event description:** The employee was performing tissue culture work in a biosafety cabinet in the evening. After aspirating medium from cells infected with Listeria using a glass Pasteur pipet, the employee's hand slipped and the pipet hit the employee's hand, breaking the glass and puncturing the skin.

Note: The tissue culture media contained $1x10^7$ CFU/ml Listeria monocytogenes. Assuming contact with approximately 1 μl, the maximum exposure is estimated to be $1x10^4$ CFU.

**Immediate follow-up and medical follow-up:** The employee immediately removed their gloves and went to the laboratory sink. They expressed the wound and applied alcohol, then flushed the wound with soap and water for 15 minutes and applied a bandage. 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<br>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 June 2, 2021. |
| **Please describe the root cause of this incident:** | Root cause is the use of glass pipets that easily break and proximity of the glass to the employee's hand. |

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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 laboratory will replace glass Pasteur pipets with shatterproof plastic pipets to avoid similar injuries 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:** ANDREA N LADD <andrea.ladd@wisc.edu>
**Sent:** Friday, June 4, 2021 6:51 PM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Jeri Barak-Cunningham; STEPHANIE G KUTZ; Christopher Strang
**Subject:** Incident report attached
**Attachments:** Sauer_051121_OSP Reportable.docx

Dear Kathryn or Whom It May Concern,

Please find attached the incident report for the incident reported on 05/12/21 (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:

- Jeri Barak-Cunningham, 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., RBP*
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/(608) 575-3738 mobile
andrea.ladd@wisc.edu

---

**From:** ANDREA N LADD
**Sent:** Wednesday, May 12, 2021 7:55 AM
**To:** harriskath@mail.nih.gov; NIHGuidelines@od.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

Kathryn or Whom It May Concern,

We were notified today of an exposure to a recombinant microbe from a sharps injury in one of our BSL2 laboratories. The employee was directed to Occupational Medicine 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.

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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., RBP*
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/(608) 575-3738 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:** Wednesday, May 12, 2021 8:55 AM
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Kristen Bernard; STEPHANIE G KUTZ; Christopher Strang
**Subject:** initial notification of incident

Kathryn or Whom It May Concern,

We were notified today of an exposure to a recombinant microbe from a sharps injury in one of our BSL2 laboratories. The employee was directed to Occupational Medicine 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., RBP*
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/(608) 575-3738 mobile
andrea.ladd@wisc.edu

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 1:06 PM
**To:** Bell, Theresa (NIH/NCI) [C]; NIH guidelines
**Cc:** Bray, Terri (NIH/NCI) [C]; Kitta, Wendy (NIH/NCI) [C]; Witte, Theodore (NIH/NCI) [C]; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident report-NCI at Frederick

Dear Theresa Bell,

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

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**From:** Bell, Theresa (NIH/NCI) [C] <belltd@mail.nih.gov>
**Sent:** Friday, May 14, 2021 1:34 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Bray, Terri (NIH/NCI) [C] <terri.bray@nih.gov>; Kitta, Wendy (NIH/NCI) [C] <wendy.kitta@nih.gov>; Bell, Theresa (NIH/NCI) [C] <belltd@mail.nih.gov>; Witte, Theodore (NIH/NCI) [C] <theodore.witte@nih.gov>
**Subject:** Incident report-NCI at Frederick

Good morning,
Please accept the attached Incident Report related to a recent injury with a scalpel contaminated with non-human primate material.

As a follow-up to the report, both primates involved with the incident were tested and confirmed negative for the presence of Herpes B Virus for swabs; however, one of the serology test results is still pending (initially came back indeterminate). As more information becomes available on this testing, I will provide an update.

We look forward to your reply and answering any additional questions you may have.

Thank you.

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Frederick National Laboratory

**Theresa D. Bell, MPH, PMP, RBP, CBSP, SM(NRCM)**
**Program Manager and Biological Safety Officer**
Environment Health and Safety Directorate

office: 301-846-5038 / cell: Redacted by agreement
belltd@nih.gov *[Contractor]*
Post Office Box B, Frederick, MD 21702
frederick.cancer.gov

The Frederick National Laboratory for Cancer Research is operated by Leidos Biomedical Research, Inc. for the National Cancer Institute.

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# Incident Report

Redacted by agreement

## iption of Incident - What Happened

An FNLCR staff scientist was exposed to the infectious virus SIVmac239NIR, in building [redacted] room [redacted] on April 20, 2021. The employee had used a disposable scalpel in room [redacted] to slice lymph node biopsies obtained from non-human primates (NHPs) actively [redacted] with the virus. There was no sharps disposal container in this room. She re-[redacted] the contaminated scalpels, reinserted them into their packaging, and then placed them in a styrofoam box. She then left the laboratory containment area and transported the box to room [redacted] which required descending a public stairwell, and entering the laboratory containment area of [redacted]. Having entered room [redacted] she then grasped the scalpels by their handles while they were still sheathed and encased in the packaging. A scalpel slid free of the sheath and packaging and the blade made incidental contact with her left palm, slicing through the nitrile laboratory exam glove and flesh. She immediately washed the wound with a povidone-iodine scrub and reported to OHS. OHS provided post exposure prophylaxis for SIV and Herpes B Virus exposure.

The virus involved in the incident, SIVmac239NIR, is modified by deletion of the nef gene and the insertion of the iRFP713 gene and is therefore subject to section III-D-3-b of the NIH Guidelines as a Risk Group 3 agent. This incident is being reported to the Office of Science Policy as required by Appendix G, section II-C-2-q.

The introduction of the virus to the NHPs was performed under the approved Bethesda NIH IACUC animal study proposal, AVP-076. The injured scientist's Principal Investigator (PI), Dr. Jeffrey Lifson has an approved IBC registration (2018-23-A10) at NCI at Frederick for the receipt and manipulation of NHP tissues and generation of recombinant viruses using Biosafety Level 2 practices. Although the approved IBC registration noted above does not specifically refer to SIVmac239NIR in the laboratory's list of approved viral genes and viruses, the IBC registration does include language approving research with retroviruses to include SIV and SIV chimeras. The IBC registration also includes language indicating that the viruses will be injected into non-human primates and that tissue samples will be returned to Frederick for further processing and analysis.

The injured scientist is enrolled in the following FNLCR medical/training surveillance programs: Animal Exposure Program, Blood and Body Fluids and OPIM, Non-human Primate Handlers, and Viral Vector Training. She has completed all required initial and annual refresher trainings associated with these programs.

## Incident Causes - Why Incident Happened

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- Failure of the employee to comply with the requirements for containment and disposal of contaminated sharps.
- Failure of the employee to comply with previous management directive to place a sharps disposal container in room [redacted]
- Failure by management to ensure that employees comply with safety requirements.

[redacted]

**Follow-up Actions - What is Being Done & Lessons Learned**

- A sharps disposal container has been placed in room [redacted] EHS will confirm that this sharps container is located inside the primary containment device where the work is performed.
- The injured scientist and her work group will be retrained by EHS. This individualized training will emphasize appropriate disposal, transport, and decontamination practices.
- The IBC and Biological Safety Officer will reevaluate the laboratory's use of sharps and adherence to approved practices.

| | | | |
|---|---|---|---|
| Report Number | | IR-006622 | |
| Organization | | LDOS | |
| Injury? | Yes | Property Damage/Loss? | No |
| OSHA Recordable? | Yes | Estimate ($) | |
| DART? | No | Incident Date | 04/20/2021 |
| First Aid? | No | Report Date | |

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Bell, Theresa (NIH/NCI) [C]
**Sent:** Friday, May 14, 2021 1:34 PM
**To:** NIH guidelines
**Cc:** Bray, Terri (NIH/NCI) [C]; Kitta, Wendy (NIH/NCI) [C]; Bell, Theresa (NIH/NCI) [C]; Witte, Theodore (NIH/NCI) [C]
**Subject:** Incident report-NCI at Frederick
**Attachments:** IncidentReport_IR-006622.7 for May 2021.pdf

Good morning,
Please accept the attached Incident Report related to a recent injury with a scalpel contaminated with non-human primate material.

As a follow-up to the report, both primates involved with the incident were tested and confirmed negative for the presence of Herpes B Virus for swabs; however, one of the serology test results is still pending (initially came back indeterminate). As more information becomes available on this testing, I will provide an update.

We look forward to your reply and answering any additional questions you may have.

Thank you.

Frederick National Laboratory

**Theresa D. Bell, MPH, PMP, RBP, CBSP, SM(NRCM)**
**Program Manager and Biological Safety Officer**
Environment Health and Safety Directorate
office: 301-846-5038 / cell: Redacted by agreement
belltd@nih.gov *[Contractor]*
Post Office Box B, Frederick, MD 21702
frederick.cancer.gov

The Frederick National Laboratory for Cancer Research is operated by Leidos Biomedical Research, Inc. for the National Cancer Institute.

POWER of Community

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 1:25 PM
**To:** Kathryn Obrien; NIH guidelines
**Cc:** Erick Guandique; Ekaterina Semenyuk; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Incident Report for University of Southern California

Dear Dr. Kate O'Brien,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). 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
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:** Kathryn Obrien <kathryno@usc.edu>
**Sent:** Monday, May 17, 2021 11:33 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Erick Guandique <eguandiq@usc.edu>; Ekaterina Semenyuk <semenyuk@usc.edu>
**Subject:** Incident Report for University of Southern California

Hello,

Please, find attached an incident report involving a researcher that was bitten by a transgenic mouse.

Please, let me know if you need anything else.

Thank you,
Kate

**Kate O'Brien, PhD, RBP (ABSA)** | Biosafety Officer & High Containment Officer

Obtained via FOIA by Judicial Watch Inc.

Environmental Health & Safety
kathryno@usc.edu
Desk: 323-442-2204
Cell: Redacted by agreement

USC University of Southern California

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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Southern California, Los Angeles |
| **Date of Report:** | 05/11/2021 |
| **Reporter name and position:** | Ekaterina Semenyuk, Safety Specialist I |
| **Telephone number:** | 323-229-4733 |
| **Email address:** | semenyuk@usc.edu |
| **Reporter mailing address:** | 2001 N Soto Street, SBA #329<br>Los Angeles, CA 90032 |
| **Date of incident:** | 05/07/2021 |
| **Name of Principal Investigator:** | Dr. Caleb Finch |
| **Is this an NIH-funded project?** | ■YES ☐NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:* 1RF1AG051521-01;<br>*NIH funding institute or center: NIH, NIA*<br>*NIH program officer (name, email address): Wise, Bradley* |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>■ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ ■ YES ☐ NO<br>If yes, date of approval: 02/01/2021 |
| **What was the approved biosafety level of the research?** | ■ BL1<br>☐ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III F-8 **Appendix C-VII:** |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Transgenic i-TLR4-KO mouse containing Cre(CX3CR1)=/-;fl(TLR4)+/+ |

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 trained by USC Department of Animal Research on animal techniques was handling mice in the vivarium. He was wearing a disposable gown, face mask and two pairs of gloves. There were two more people in the animal room with the technician. The animal line that he was using had been genetically modified to carry Cre and floxed TLR4 gene. The technician was sorting out mice that had not received any injections. The researcher states that he was checking the ear tags, when one of the mice bit his left index finger. He removed the gloves, washed the wound with soap and water for about 2-3 minutes, and cleaned with alcohol. He went to the Kaiser Permanente Urgent Care facility where he was attended to by a physician and was prescribed antibiotics.
The list of training received by the researcher:
**03/25/2020** 18th EDITION OF THE GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS (2011); A2 - INTRO TO ANIMAL CARE LAWS, REG; ASEPTIC TECHNIQUE FOR RODENT SURVIVAL SURGERY; MOUSE; NON SURG-REQ. ANESTHESIA; COMMON COMPLIANCE ISSUES (e-learning); WORKING WITH CONTROLLED SUBSTANCES; Rodent Reproduction and Colony Management (e-learning).
**03/26/2020** Basic lab animal care and use training (e-learning and hands –on).

Obtained via FOIA by Judicial Watch Inc.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ■YES ☐NO |
| **Please describe the root cause of this incident:** | **Unknown cause** |

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 researcher is going to receive a refresher training on handling transgenic mice.**

- **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:** Kathryn Obrien <kathryno@usc.edu>
**Sent:** Monday, May 17, 2021 11:33 AM
**To:** NIH guidelines
**Cc:** Erick Guandique; Ekaterina Semenyuk
**Subject:** Incident Report for University of Southern California
**Attachments:** Incident-Reporting-USC 12may21.pdf

Hello,

Please, find attached an incident report involving a researcher that was bitten by a transgenic mouse.

Please, let me know if you need anything else.

Thank you,
Kate

**Kate O'Brien, PhD, RBP (ABSA)**| Biosafety Officer & High Containment Officer
Environmental Health & Safety
kathryno@usc.edu
Desk: 323-442-2204
Cell: Redacted by agreement

USC University of Southern California

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 1:15 PM
**To:** Harding, Beverly; NIH guidelines
**Cc:** IBO; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Attention NIH Incident Reporting

Dear Beverly Harding,

Thank you for your below reports to the National Institutes of Health (NIH) Office of Science Policy (OSP). 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/OD/NIH
Phone: 301-402-7465
Mobile: Redacted by agreement
michelle.mckinney@nih.gov

---

**From:** Harding, Beverly <beverlyh@pitt.edu>
**Sent:** Monday, May 17, 2021 12:51 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** IBO <ibo@pitt.edu>
**Subject:** Attention NIH Incident Reporting

Hi Dr. Harris and NIH Staff,

Please find the attached Incident Reporting form and Summary statement.

Thank you,
Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
University of Pittsburgh
ibo@pitt.edu or beverlyh@pitt.edu
412-383-1766

Obtained via FOIA by Judicial Watch Inc.

# Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

**Instructions for Completing this Template**

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid*

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.

*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**

| | |
|---|---|
| **Does this incident involve** | ☒YES ☐NO |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **research subject to the *NIH Guidelines*?** | If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Pittsburgh |
| **Date of Report:** | 5/17/21 |
| **Reporter name and position:** | Beverly Harding |
| **Telephone number:** | 412-383-1766 |
| **Email address:** | beverlyh@pitt.edu |
| **Reporter mailing address:** | University of Pittsburgh<br>Office of Research Protections<br>Institutional Biosafety Division<br>Suite 202 Heiber Building<br>3500 Fifth Avenue<br>Pittsburgh, PA 15213 |
| **Date of incident:** | Incidences of use of the AAV8 between 1/16/2018-2/5/2019 under ABSL-1 containment |
| **Name of Principal Investigator:** | Stephen Meriney |
| **Is this an NIH-funded project? This WAS funded 08/01/2014-05/31/2019. The grant is now expired.** | ☒YES ☐NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:1R01NS090644*<br>*NIH funding institute or center:NINDS*<br>*NIH program officer (name, email address):Yuan Liu,* |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| | *liuyuan@ninds.nih.gov* |

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☒Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐YES ☐NO<br><br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | ☒BL1<br>☐BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or** | AAV8 virus used to transfect Rapsyn-GCamp6 – a fluorescent calcium reporter. |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **synthetic material involved in 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)
- 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)

(*Provide a description of the incident and the responses to correct any future issues*)

Between in late 2018 and early 2019 a protocol modification that had been approved by the IACUC was performed on mice. Specifically, instead of the original approved approach of using electroporation to deliver DNA (rapsyn-GCamp6) to the inside of muscle cells, an AAV8 virus was used for transfection. The IACUC reviewed and approved of this change before any surgeries were performed. The surgeries were performed using gowns, masks, gloves, and shoe covers, and all viral material was inactivated using bleach and disposed of as indicated in the IACUC protocol. Unfortunately, the investigator did not submit a modification to the IBC protocol to indicate this change from electroporation to viral transfection. This was an oversight. No such use of viral transfection has occurred since early 2019. The NIH grant that was funding this research has since ended.

This issue was detected when a modification was sought to this IACUC protocol to add a new funding source, a new lab person, and a change in the anesthetic used for surgery. The review caught the oversight in the IBC protocol regarding the use of viral transfection. The investigator responded by submitting a modification request to the IBC that included the use of the viral transfection method for any future experiments.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES ☒NO |
| **Please describe the root cause of this incident:** | Oversight |

**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):**

This issue was detected when a modification was sought to this IACUC protocol to add a new funding source, a new lab person, and a change in the anesthetic used for surgery. The review caught the oversight in the IBC protocol regarding the use of viral transfection. The investigator responded by submitting a modification request to the IBC that included the use of the viral transfection method for any future experiments.

The ORP Divisions for IBC and IACUC support have met to discuss procedures and processes within the review for both committees to ensure collaboration and coordination for protocol modifications to be consistent between the two divisions. This was determined to be a one-off rare instance where the coordination has now been clarified and strengthened. No further action was required of the investigator.

Obtained via FOIA by Judicial Watch Inc.

- ***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.



May 17, 2021

Dear Dr. Harris/NIH OSP Incident Reporting,

The incident report is to inform the NIH OSP of the IBC deliberation of incidents under 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 May 10, 2021 IBC meeting. The initial reporting forms were reviewed by the committee.

To summarize the non-compliance incident (IR-21-05), the University of Pittsburgh's IBC became aware that the investigator failed to apply for IBC review for a downgrade of a strain of AAV. An incident inquiry was sent to the investigator upon IBC Staff notification. The investigator has since submitted the incident form and an IBC application (modification of existing protocol) to cover the work described. The committee determined that the incident did not require any additional actions, as the investigator provided understanding of the requirements. The modification to the original protocol was approved at BSL-1/ABSL-1 containment, according to NIH requirements and the IBC recommendations for work with AAV vectors.

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
412-383-1766

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Harding, Beverly <beverlyh@pitt.edu>
**Sent:** Monday, May 17, 2021 12:51 PM
**To:** NIH guidelines
**Cc:** IBO
**Subject:** Attention NIH Incident Reporting
**Attachments:** IR-21-05 S. Meriney 05-17-21 report.docx; OSP Summary for IR-21-05 University of Pittsburgh 05-17-21.doc

Hi Dr. Harris and NIH Staff,

Please find the attached Incident Reporting form and Summary statement.

Thank you,
Beverly Harding, MSL
Director, Institutional Biosafety Division
Office of Research Protections
University of Pittsburgh
ibo@pitt.edu or beverlyh@pitt.edu
412-383-1766

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Johnson,Christine <Christine.Johnson@ColoState.EDU>
**Sent:** Tuesday, May 18, 2021 12:03 PM
**To:** Harris, Kathryn (NIH/OD) [C]
**Cc:** Johnson,Christine; Chen,Chaoping; Dobos,Karen; Moritz,Rebecca
**Subject:** initial incident report - CSU 042221

Dear Dr. Harris,

I hope that you are doing well. On April 22, 2021 our office became aware of a project involving transgenic drosophila being conducted without IBC approval. I am submitting this email as an initial report as we are still gathering the information needed to fill out the Template for Reporting Incidents Subject to the NIH Guidelines. I will submit the full report as soon as possible.

Best regards,
Christy

**Christine M. Johnson, MS, RBP**
Senior IBC Coordinator
Research Integrity & Compliance Review Office
2011 Campus Delivery | Fort Collins, CO 80523-2011
200D University Services Center | Colorado State University
Office: (970) 491-1553 | Direct: (970) 491-8690 | https://www.research.colostate.edu/ricro/ibc/

*"We must find time to stop and thank the people who make a difference in our lives."*
**–John F. Kennedy**

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 12:51 PM
**To:** Schlimgen, Ryan J.,Ph.D.; NIH guidelines
**Cc:** Thadhani, Ravi Ishwar,M.D.,M.P.H.; Moriarty, Allison P.; Mitchell, Mary; Gelfand, Jeffrey A.,M.D.; Widlund, Hans,Ph.D.; Gilbert, Kathleen Marie; Hunter, Claire; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Mass General Brigham NIH Guidelines Incident Notification

Dear Dr. Ryan Schlimgen,

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:** Schlimgen, Ryan J.,Ph.D. <RSCHLIMGEN@PARTNERS.ORG>
**Sent:** Wednesday, May 19, 2021 11:28 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Thadhani, Ravi Ishwar,M.D.,M.P.H. <RTHADHANI@mgh.harvard.edu>; Moriarty, Allison P. <AMORIARTY@BWH.HARVARD.EDU>; Mitchell, Mary <MMITCHELL14@PARTNERS.ORG>; Gelfand, Jeffrey A.,M.D. <JGELFAND@mgh.harvard.edu>; Widlund, Hans,Ph.D. <HWIDLUND@BICS.BWH.HARVARD.EDU>; Gilbert, Kathleen Marie <kmgilbert@bwh.harvard.edu>; Hunter, Claire <CHUNTER5@PARTNERS.ORG>
**Subject:** Mass General Brigham NIH Guidelines Incident Notification

Dear Office of Science Policy,

On behalf of the Mass General Brigham IBC Chair, Dr. Gelfand, I am submitting a letter that notifies you and describes a violation of the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules that was identified at Brigham and Women's Hospital on April 19, 2021. Details of the incident are included in the attached letter.

If you have any questions, please let me know.

Sincerely,
Ryan

Obtained via FOIA by Judicial Watch Inc.

Ryan J. Schlimgen, Ph.D.
he/him/his
Director of Biosafety, Research Compliance Mass General Brigham
Export Control Officer, Research Compliance Mass General Brigham

**Mass General Brigham**
399 Revolutions Drive, Suite 765, Somerville, MA 02145
T 857-282-1799, M Redacted by agreement F 857-282-5681
massgeneralbrigham.org



The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Mass General Brigham Compliance HelpLine at http://www.massgeneralbrigham.org/complianceline . If the e-mail was sent to you in error but does not contain patient information, please contact the sender and properly dispose of the e-mail.

Please note that this e-mail is not secure (encrypted). If you do not wish to continue communication over unencrypted e-mail, please notify the sender of this message immediately. Continuing to send or respond to e-mail after receiving this message means you understand and accept this risk and wish to continue to communicate over unencrypted e-mail.

Obtained via FOIA by Judicial Watch Inc.

Mass General Brigham

INSTITUTIONAL BIOSAFETY COMMITTEE

May 19, 2021

Office of Science Policy
National Institutes of Health
6705 Rockledge Dr #750
Bethesda, MD 20817

Dear NIH Office of Science Policy:

In accordance with the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*) Section IV-B-1-j, we are reporting a violation of the *NIH Guidelines* Section III-D, "Experiments that Require Institutional Biosafety Committee Approval Before Initiation." The research that was initiated prior to IBC approval was supported by Internal Funds at Brigham and Women's Hospital (BWH).

On April 19, 2021, the BWH Biosafety Officer determined that a BWH Investigator had generated transgenic Zebrafish using recombinant nucleic acid molecules without prior review and approval by the Mass General Brigham Institutional Biosafety Committee (IBC) which acts as the IBC for BWH. The Investigator had registered and been approved by the IBC for *in-vitro* work with recombinant nucleic acid molecules under *NIH Guidelines* Section III-E. The investigation of the incident revealed that in preliminary discussions between the previous BWH Biosafety Officer and the Investigator, it was determined that the use of morpholinos to generate genetically modified zebrafish did not fall under the *NIH Guidelines.* Unfortunately, this discussion and determination overshadowed other methods of creating genetically modified zebrafish used by the Investigator (these methods did fall under *NIH Guidelines* Section III-D-4) and at that time the work was not registered or approved by the IBC.

To address this oversight, we instituted the following corrective actions. First, the Investigator immediately registered the work which was reviewed and approved at the next scheduled IBC meeting on April 26, 2021. The committee approved the research at Biosafety Level 1 (BL1) and Animal Biosafety Level 1 (BL1-N) under *NIH Guidelines* Section III-D-4. Second, we audited all other Zebrafish research across Mass General Brigham and found no other discrepancies. Third, the Mass General Brigham Director of Biosafety and the Hospital Biosafety Officers discussed the incident to refresh themselves on policy and procedures to help ensure this oversight does not reoccur. Finally, we will educate members of the IACUC and the IBC about the requirements. Additionally, Investigators and Laboratory Staff will be trained through our required (and revised) general laboratory biosafety course.

This oversight was for low-risk research, as it was approved by the IBC at BL1 and BL1-N, which did not result in overt exposures or releases. All animal work was properly registered and reviewed by the IACUC.

Should you require more details or have follow-up questions or concerns, please contact the Director of Biosafety, Ryan Schlimgen, at rschlimgen@partners.org.

Sincerely,

Redacted by agreement

Jeffrey Gelfand, MD, Chair of the Mass General Brigham IBC

Obtained via FOIA by Judicial Watch Inc.



CC:

Ryan Schlimgen, Ph.D., Director of Biosafety, Mass General Brigham
Hans Widlund, Ph.D., Vice-Chair of the Mass General Brigham IBC
Kathleen Gilbert, Biosafety Officer, Brigham and Women's Hospital
Mary Mitchell, Chief Research Compliance Officer, Mass General Brigham
Ravi Thadhani, M.D., Chief Academic Officer, Mass General Brigham
Allison Moriarty, VP Research Operation, Brigham and Women's Hospital

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Schlimgen, Ryan J.,Ph.D. <RSCHLIMGEN@PARTNERS.ORG>
**Sent:** Wednesday, May 19, 2021 11:28 AM
**To:** NIH guidelines
**Cc:** Thadhani, Ravi Ishwar,M.D.,M.P.H.; Moriarty, Allison P.; Mitchell, Mary; Gelfand, Jeffrey A.,M.D.; Widlund, Hans,Ph.D.; Gilbert, Kathleen Marie; Hunter, Claire
**Subject:** Mass General Brigham NIH Guidelines Incident Notification
**Attachments:** NIH OSP - MGB Incident Notification Letter.pdf

Dear Office of Science Policy,

On behalf of the Mass General Brigham IBC Chair, Dr. Gelfand, I am submitting a letter that notifies you and describes a violation of the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules that was identified at Brigham and Women's Hospital on April 19, 2021. Details of the incident are included in the attached letter.

If you have any questions, please let me know.

Sincerely,
Ryan

Ryan J. Schlimgen, Ph.D.
he/him/his
Director of Biosafety, Research Compliance Mass General Brigham
Export Control Officer, Research Compliance Mass General Brigham

**Mass General Brigham**
399 Revolutions Drive, Suite 765, Somerville, MA 02145
T 857-282-1799, M Redacted by agreement F 857-282-5681
massgeneralbrigham.org

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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Harris, Kathryn (NIH/OD) [C]
**Sent:** Tuesday, June 15, 2021 4:36 PM
**To:** Fernandez, Javier; NIH guidelines
**Cc:** McKinney, Michelle (NIH/OD) [E]
**Subject:** RE: Incident Report: Dosing Error with Oncolytic Adenovirus Melanoma Vaccine

Dear Javier:

Thank you for your May 22, 2020 report to the NIH Office of Science Policy (OSP) regarding an incident involving a dosing error during an oncolytic adenovirus melanoma vaccine clinical trial at Cedars-Sinai Medical Center.

In April 2019, NIH revised the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) to streamline oversight of human gene transfer research. Section IV-B-2-b of the current *NIH Guidelines*, states (in part) that for recombinant or synthetic nucleic acid molecule research involving human research participants, the Institutional Biosafety Committee's assessment should be focused on biosafety issues (e.g., administration, shedding). IBC oversight may conclude after the last participant is administered the final dose of product. However, IBCs may choose to establish other end points for oversight, based on their biosafety assessment of the proposed research.

In addition, with the 2019 amendment to the *NIH Guidelines*, NIH OSP no longer accepts safety reports for human gene transfer protocols. Further information about the 2019 amendments to the *NIH Guidelines* can be found at: https://osp.od.nih.gov/biotechnology/nih-guidelines/

From your report we understand the incident has been reported to the Food and Drug Administration (FDA), the sponsor of the trial, and the IRB. No further information is required by NIH OSP.

Regards,

Dr. Kathryn Harris

---

**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Saturday, May 22, 2021 7:34 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** Re: Incident Report: Dosing Error with Oncolytic Adenovirus Melanoma Vaccine

Dear Dr. Harris,

I just noticed an error on the report form that I submitted to you on 5/20/2021.

In the section for "Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)," it was indicated that the material involved was a "Personalized" vaccine, which is not the case. I am attaching the corrected report form to this email.

Obtained via FOIA by Judicial Watch Inc.

I apologize for the trouble; please let me know if you need additional information.

Regards,

Javier

Javier P. Fernandez, MS, RAC, CSP, CBSP
Biosafety Officer, Environmental Health and Safety
Javier.Fernandez@cshs.org

Cedars-Sinai
8700 Beverly Boulevard, TSB-190 : Los Angeles CA 90048
office 310-423-4336 : cedars-sinai.org

---

**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Thursday, May 20, 2021 12:27 PM
**To:** NIHGuidelines@od.nih.gov <NIHGuidelines@od.nih.gov>
**Subject:** Incident Report: Dosing Error with Oncolytic Adenovirus Melanoma Vaccine

Dear Dr. Harris,

Attached is an Incident Report for a Dosing Error at one of our sites that resulted from an Administrative Error by the Sponsor.

Please let me know if you need additional information.

Regards,

Javier

Javier P. Fernandez, MS, RAC, CSP, CBSP
Biosafety Officer, Environmental Health and Safety
Javier.Fernandez@cshs.org

Cedars-Sinai
8700 Beverly Boulevard, TSB-190 : Los Angeles CA 90048
office 310-423-4336 : cedars-sinai.org

Obtained via FOIA by Judicial Watch Inc.

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Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ▣ YES ☐ NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Cedars-Sinai Medical Center |
| **Date of Report:** | 2021/03/15 |
| **Reporter name and position:** | Javier P. Fernandez (Biosafety Officer) |
| **Telephone number:** | (310) 423-4336 |
| **Email address:** | Javier.Fernandez@cshs.org |
| **Reporter mailing address:** | 8700 Beverly Boulevard<br>TSB-190<br>Los Angeles, CA 90048 |
| **Date of incident:** | 2021/01/12 |
| **Name of Principal Investigator:** | Mark Faries, M.D. |
| **Is this an NIH-funded project?** | ☐ YES ▣ NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☒ Other (please describe): Dosing error with presonalized mRNA cancer vaccine |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒ YES ☐ NO<br>If yes, date of approval: 2019/04/16 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☒ BL2 ☐ BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐ BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐ State or local Public Health<br>☒ FDA ☐ Law enforcement<br>☐ EPA ☒ Other (please describe): WIRB<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Personalized mRNA cancer vaccine |

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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)

The filing of this incident report with NIH has been delayed and could not be submitted within the required 30 days due to the following factors:

- The incident was discovered during a review of documentation several weeks after the date of the incident.
- Several institutional departments had to gather required information from the clinical site involved to help assess the incident and determine the necessary corrective and preventive measures.

Please see attached description of incident (**Description_of_Incident_Cedars_Sinai_Dosing_Error_mRNA_Cancer_Vaccine**).

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | Scheduling, Pharmacy, and Infusion errors described in attached file (**Description_of_Incident_Cedars_Sinai_Dosing_** |

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 see the attached file, which includes a description of the CAPA measures taken by the institutions to correct and prevent the problems identified (**Description_of_Incident_Cedars_Sinai_Dosing_Error_mRNA_Cancer_Vaccine**).

- **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.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☐YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Cedars-Sinai Medical Center |
| **Date of Report:** | 2021/03/15 |
| **Reporter name and position:** | Javier P. Fernandez (Biosafety Officer) |
| **Telephone number:** | (310) 423-4336 |
| **Email address:** | Javier.Fernandez@cshs.org |
| **Reporter mailing address:** | 8700 Beverly Boulevard<br>TSB-190<br>Los Angeles, CA 90048 |
| **Date of incident:** | 2021/01/12 |
| **Name of Principal Investigator:** | Mark Faries, M.D. |
| **Is this an NIH-funded project?** | ☐YES ☐NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☒ Other (please describe): Dosing error with presonalized mRNA cancer vaccine |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ☐NO<br>If yes, date of approval: 2019/04/16 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☒ BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☒ FDA ☐Law enforcement<br>☐ EPA ☒Other (please describe):<br>☐ OSHA WIRB |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Personalized mRNA cancer vaccine |

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 filing of this incident report with NIH has been delayed and could not be submitted within the required 30 days due to the following factors:

- The incident was discovered during a review of documentation several weeks after the date of the incident.
- Several institutional departments had to gather required information from the clinical site involved to help assess the incident and determine the necessary corrective and preventive measures.

Please see attached description of incident (**Description_of_Incident_Cedars_Sinai_Dosing_Error_mRNA_Cancer_Vaccine**).

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☒YES ☐NO |
| **Please describe the root cause of this incident:** | Scheduling, Pharmacy, and Infusion errors described in attached file (**Description_of_Incident_Cedars_Sinai_Dosing_** |

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 see the attached file, which includes a description of the CAPA measures taken by the institutions to correct and prevent the problems identified (**Description_of_Incident_Cedars_Sinai_Dosing_Error_mRNA_Cancer_Vaccine**).

- **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:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Saturday, May 22, 2021 7:34 PM
**To:** NIH guidelines
**Subject:** Re: Incident Report: Dosing Error with Oncolytic Adenovirus Melanoma Vaccine
**Attachments:** NIH_Incident_Report_Dosing_Error_Oncolytic_Adenovirus_Melanoma_Vaccine_2021_05_22.pdf

Dear Dr. Harris,

I just noticed an error on the report form that I submitted to you on 5/20/2021.

In the section for "Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)," it was indicated that the material involved was a "Personalized" vaccine, which is not the case. I am attaching the corrected report form to this email.

I apologize for the trouble; please let me know if you need additional information.

Regards,

Javier

Javier P. Fernandez, MS, RAC, CSP, CBSP
Biosafety Officer, Environmental Health and Safety
Javier.Fernandez@cshs.org

Cedars-Sinai
8700 Beverly Boulevard, TSB-190 : Los Angeles CA 90048
office 310-423-4336 : cedars-sinai.org

---

**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Thursday, May 20, 2021 12:27 PM
**To:** NIHGuidelines@od.nih.gov <NIHGuidelines@od.nih.gov>
**Subject:** Incident Report: Dosing Error with Oncolytic Adenovirus Melanoma Vaccine

Dear Dr. Harris,

Attached is an Incident Report for a Dosing Error at one of our sites that resulted from an Administrative Error by the Sponsor.

Please let me know if you need additional information.

Regards,

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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Fernandez, Javier <Javier.Fernandez@cshs.org>
**Sent:** Thursday, May 20, 2021 3:28 PM
**To:** NIH guidelines
**Subject:** Incident Report: Dosing Error with Oncolytic Adenovirus Melanoma Vaccine
**Attachments:** NIH_Incident_Report_Dosing_Error_Oncolytic_Adenovirus_Melanoma_Vaccine_2021_05_19.pdf

Dear Dr. Harris,

Attached is an Incident Report for a Dosing Error at one of our sites that resulted from an Administrative Error by the Sponsor.

Please let me know if you need additional information.

Regards,

Javier

Javier P. Fernandez, MS, RAC, CSP, CBSP
Biosafety Officer, Environmental Health and Safety
Javier.Fernandez@cshs.org

Cedars-Sinai
8700 Beverly Boulevard, TSB-190 : Los Angeles CA 90048
office 310-423-4336 : cedars-sinai.org

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Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 1:55 PM
**To:** Cook, Susan; NIH guidelines
**Cc:** Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Preliminary exposure notification

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 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:** Cook, Susan <shcook@wustl.edu>
**Sent:** Monday, May 24, 2021 3:05 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Subject:** RE: Preliminary exposure notification

Attached, please find the completed incident report for this exposure. 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)

---

**From:** Cook, Susan
**Sent:** Friday, May 21, 2021 2:04 PM
**To:** NIHGuidelines@od.nih.gov
**Subject:** Preliminary exposure notification

I'm writing to provide a preliminary notification of an exposure to a recombinant Toxoplasma gondii. The PI is traveling but will complete the incident report as soon as possible.

Obtained via FOIA by Judicial Watch Inc.

-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<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | Washington University in St. Louis |
| **Date of Report:** | May 21, 2021 |
| **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<br>660 S. Euclid Ave<br>St. Louis, MO 63110 |
| **Date of incident:** | May 19, 2021 |
| **Name of Principal Investigator:** | David Sibley |
| **Is this an NIH-funded project?** | xYES ☐NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:* R01AI118426<br>*NIH funding institute or center: NIAID*<br>*NIH program officer (name, email address):* Deirdre A. Joy, djoy@mail.nih.gov |

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>X Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO If yes, date of approval:<br><br>Most recent renewal 3/15/2021 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐State or local Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | *T. gondii*: strain RH/Cas9P2A::CAT, DHFR-TS* |

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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)

On May 19th 2021 at 5pm a male staff scientist in the lab was passing Toxoplasma by scraping and syringe lysing (using blunt needles) infected host cell (Human foreskin fibroblasts) monolayers and putting the parasites on a fresh monolayer of host cells. The work was done while wearing gloves in a certified BSL2 biosafety cabinet located in the tissue culture room. During the syringe lysis step the individual accidentally stabbed himself with the blunt needle. The needle pierced the glove and left a small scrape on his index finger. The individual immediately removed the glove, washed the area with water and soap for 5min. Following the wash, he sterilized the scrape with single use rubbing alcohol pads. The individual informed his PI. The PI contacted the OHS and the following morning the individual was put on a prophylactic antibiotic treatment (Clindamycin 300mg and Sulfadiazine 500mg, 4 times a day for 14 days). Additionally, antibody levels were measured on the same morning and the individual will continue the drug treatment and antibody monitoring for the following 14 days. The training for the whole lab, which also included the individual above regarding safe work with Toxoplasma was conducted via Zoom on May 15th 2021. There were no deviations from standard operating procedures (SOPs) and no deviation from the IBC approved containment level.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | X YES ☐NO<br>Discussed with IBC chairs on May 20, 2021. Will be discussed with the full committee at the next meeting on June 16, 2021. |
| **Please describe the root cause of this incident:** | Better caution should be exercised when working with Toxoplasma and 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):

We will discuss this incident at the next IBC meeting to determine if any changes to procedures or training are needed.

- **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:** Monday, May 24, 2021 3:05 PM
**To:** NIH guidelines
**Subject:** RE: Preliminary exposure notification
**Attachments:** Incident-Reporting-Template_WUSTL_210521.pdf

Attached, please find the completed incident report for this exposure. 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)

---

**From:** Cook, Susan
**Sent:** Friday, May 21, 2021 2:04 PM
**To:** NIHGuidelines@od.nih.gov
**Subject:** Preliminary exposure notification

I'm writing to provide a preliminary notification of an exposure to a recombinant Toxoplasma gondii. The PI is traveling but will complete the incident report as soon as possible.

-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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## Hunter, Renee (NIH/OD) [C]

**From:** Cook, Susan <shcook@wustl.edu>
**Sent:** Friday, May 21, 2021 3:04 PM
**To:** NIH guidelines
**Subject:** Preliminary exposure notification

I'm writing to provide a preliminary notification of an exposure to a recombinant Toxoplasma gondii. The PI is traveling but will complete the incident report as soon as possible.

-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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Thursday, June 3, 2021 1:43 PM
**To:** Zara Llewellyn; NIH guidelines
**Cc:** Katia Harb; Lesley Decker; Steve Libby; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: University of Washington - NIH reportable incident

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:** Monday, May 24, 2021 8:18 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Katia Harb <kharb@uw.edu>; Lesley Decker <lldecker@uw.edu>; Steve Libby <slibby@uw.edu>
**Subject:** University of Washington - NIH reportable incident

Dear NIH,

Please find attached a report involving an incident subjected to the NIH 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
Interim 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)

**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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of Washington |
| **Date of Report:** | 5/24/2021<br>NIH was informed of the incident via phone on 05/19/2021 |
| **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<br>Environmental Health and Safety Department (EH&S)<br>Research and Occupational Safety Section<br>1705 NE Pacific Street<br>Box 357165<br>Seattle, WA 98195-7165 |
| **Date of incident:** | March 2, 2021 |
| **Name of Principal Investigator:** | N/A |
| **Is this an NIH-funded project?** | ☐YES ☐NO<br>UKNOWN – Since the contents of the waste could not be accounted for, there is not a particular NIH-funded project associated with the incident.<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| | |
|---|---|
| **What was the nature of the incident?** | ☐ Failure to follow approved containment conditions<br>☐ Failure to obtain IBC approval<br><br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>X Other (please describe): Potential release of biohazardous waste to landfill |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | X YES ☐NO<br>The research associated with the recovered waste was approved by the IBC on September 16, 2020. All research at UW with biohazards and recombinant or synthetic DNA/RNA are reviewed and approved by EH&S and the IBC. |
| **What was the approved biosafety level of the research?** | X BL1<br>X BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br><br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Sections III-E and III-F potentially apply to the waste that was recovered and returned for autoclaving.<br><br>Sections III-D, III-E, III-F could potentially apply to waste that could not be accounted for. |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☐Funding agency/sponsor<br>☐ USDA X State or local Public Health: Seattle King County Public Health<br>☐ FDA ☐Law enforcement<br>☐ EPA ☐Other (please describe):<br>☐ OSHA |

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| | |
|---|---|
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | For the pipet boxes that were located and returned for autoclaving, the contents were pipets used in a BSL1 lab for work with reagents and potentially recombinant or synthetic DNA/RNA.<br><br>For the unrecovered or unaccounted for biohazardous waste, the contents are unknown. Labs in the building are approved for research with biohazardous agents including recombinant RG1 and RG2 organisms, viral vectors and recombinant or synthetic DNA/RNA. |

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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)

Improper removal and disposal of biohazardous waste occurred on March 2, 2021 at a University of Washington autoclave room. Approximately 12 bags and boxes of untreated (not sterilized) biohazardous waste were reported missing from an autoclave room by autoclave staff at the University. The Custodians report collecting only autoclaved waste (red bags with autoclave tape with black stripes indicating it was sterilized). After discovery of the incident, the trash compactor that was used for treated and regular waste from the building was secured, and a contractor was hired to sort through the compactor and find untreated biohazardous waste. The contractor found eight untreated pipet boxes, and an EH&S biosafety officer returned them to the autoclave facility for sterilization. There were conflicting accounts from the involved parties and ultimately, the reported missing waste cannot be accounted for. There were no known exposures or injuries.

The autoclave facility staff alerted the University's waste management unit on Wednesday, March 3, in order to close the waste compactor where trash is taken. The trash compactor was closed that day. EH&S was notified on Thursday, March 4, from the custodial unit about potentially untreated biohazardous waste collected from an autoclave facility. That day, EH&S contacted the autoclave facility for information about the incident. At approximately 4:00 p.m. on Tuesday, March 2, 2021 an autoclave facility employee reportedly left for the day with bags and boxes of non-sterilized biohazardous waste in the autoclave facility.

The autoclave facility employee reported that there was a full bin and at least six tubs of biohazardous waste awaiting sterilization when they left. When the staff member returned the next morning at approximately 10:20 a.m., all the untreated waste was gone. The employee contacted the custodial supervisor to alert them. The custodial staff stated a swing shift employee collected treated waste with autoclave tape that had changed color from neutral to black stripes after 8 p.m. The staff employee stated the waste could not have been autoclaved that evening as the autoclave log sheets indicate the autoclave were not used that evening, and that there were no staff trained to use the autoclave present. The autoclave facility is a shared facility with another department (department2). Department2 stated that their staff cannot access the room after 6:00 p.m.

A contractor was brought in to sort through the contents of the trash compactor and retrieve the untreated biohazardous waste. On March 19, the contractor arrived, and locked and tagged out the compactor for safety entry. The contractor group then entered the compactor to remove all content in order to identify potentially untreated biohazardous waste. An EH&S biosafety officer was present to assist in identifying treated or untreated biohazardous waste. After all contents of the compactor were removed, eight untreated biohazardous pipet boxes were found. An EH&S biosafety officer returned the boxes to the autoclave facility. Each box had autoclave tape that indicated no autoclaving had been performed. The boxes were labeled with the lab name. The lab confirmed that these pipet boxes were used with biohazardous materials. The boxes were intact, and no untreated waste had been released. No other untreated waste or biohazard bags were found in the trash compactor.

An EH&S biosafety officer visited the autoclave facility on March 23. The practices for sterilizing and handling biohazardous waste were found to be in compliance with University, state and local

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regulations. Appropriate safety practices were in place and followed, and training was documented. Untreated biohazardous waste is collected in a large green bin prior to autoclaving. If there is more waste than can fit, waste is placed into tubs on the floor. After autoclaving, the staff take the treated waste on a cart directly to the trash compactor. They do not store treated waste in the autoclave facility.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES X☐NO<br>It will be reported to the IBC at the next meeting on June 16, 2021. |
| **Please describe the root cause of this incident:** | The same green bins were being used to store both untreated (unautoclaved) and treated (autoclaved) waste by two different departments in the shared autoclave facility. Despite custodial staff being trained on the procedures of the autoclave facility and labeling on the bins of treated or untreated biohazardous waste, there is a potential for confusion. |

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 has recommended the following changes to the autoclave facility and is following up to ensure the items are addressed:

1) Change the autoclave facility procedures for storing untreated biohazardous by:
   a) Ensure all untreated biohazardous waste is stored in containers marked with a biohazard symbol. Use a large red bin with biohazard stickers to collected untreated biohazardous waste from department labs. Use one or two additional red bins with biohazard stickers for overflow as needed instead of tubs on the floor. Continue to use a sign with a biohazard symbol indicating no collection by custodians. Use a red octagon (stop sign shape) to indicate to custodians not to collect. All staff working in the autoclave facility should be trained in these procedures.
      - As of April 29, 2021, the autoclave facility purchased 110-gallons-worth of red bins to replace the 45-gallon green bin and will make sure they are clearly marked and that there is an empty bin available at the end of the workday.

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b) Use a log to document when and how much waste Genome Sciences labs leave in S030 for autoclaving.







*New biohazardous waste collection bins for the department in the autoclave facilities.*

2) EH&S is working with the custodial unit and autoclave facility staff to provide additional training to custodians working in buildings with biohazards to recognize untreated biohazardous waste. Both department report that the custodial teams servicing the buildings have recently changed. EH&S is working with UW Facilities and Custodial Services to review training related to biohazards with custodial staff and help provide re-training.
   - As of May 12, 2021, EH&S is currently in review of the training materials used to train custodial staff on biohazards, biohazardous waste and treated (autoclaved) waste.

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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:** Zara Llewellyn <zaral@uw.edu>
**Sent:** Monday, May 24, 2021 8:18 PM
**To:** NIH guidelines
**Cc:** Katia Harb; Lesley Decker; Steve Libby
**Subject:** University of Washington - NIH reportable incident
**Attachments:** Final_NIH report_ UW Mixed waste compactor.pdf

Dear NIH,

Please find attached a report involving an incident subjected to the NIH 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
Interim 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:** Antony Schwartz, PhD
**To:** Harris, Kathryn (NIH/OD) [C]; NIH guidelines
**Cc:** Frothingham, Richard; Wayne Thomann; Mary Brock; Andrea Vogel
**Subject:** Preliminary Report: Ankle Exposure to Lentiviral Vector
**Date:** Thursday, June 3, 2021 5:37:01 PM

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Dr. Harris,

We received a report today that the intact skin on an individual's ankle was exposed to lentiviral vector when he spilled a plate containing the material. The work was conducted in a BSL-2 laboratory. We're in the process of collecting additional information for a final report that will be reviewed at the upcoming IBC meeting before we send it to you.

Thank you and please let us know if you have any questions.

Best regards,
Antony

**Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA)**
Duke University | Duke University Health System
Occupational and Environmental Safety Office (OESO)

Assistant Director, OESO
Director, Biological Safety | Biosafety Officer | Responsible Official
Adjunct Assistant Professor, Dept. of Family Medicine and Community Health

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:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, July 7, 2021 2:32 PM
**To:** Pearce, Ericka Elizabeth; NIH guidelines
**Cc:** Brennan, Catherine; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: Updated report

Dear Ericka Pearce,

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:** Pearce, Ericka Elizabeth <epearce@unc.edu>
**Sent:** Wednesday, June 16, 2021 1:25 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Brennan, Catherine <crbrennan@ehs.unc.edu>
**Subject:** Updated report

Dear OSP,
Please replace the report that I sent with the one attached. There was a mistake on the date of the accident and when it was reported to EHS. The date should be June 2nd and not May 28th, 2021.

Best regards,
Ericka

UNC Chapel Hill **Environment Health & Safety/Risk Management**
**Ericka E. Pearce, MS, CBSP**
Biosafety Program Manager/Officer
Office: 919-962-5722
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)

**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*?** | **X** YES ☐NO<br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of North Carolina--Chapel Hill (UNC-CH) |
| **Date of Report:** | June 14, 2021 |
| **Reporter name and position:** | Ericka Pearce, Biological Safety Officer |
| **Telephone number:** | 919-962-5722 (office); 919-869-5874 (cell) |
| **Email address:** | Epearce@unc.edu |
| **Reporter mailing address:** | Environment, Health and Safety/Risk Management<br>1120 Estes Drive Ext.<br>Chapel Hill, NC 27599-1650 |
| **Date of incident:** | 06/02/2021 |
| **Name of Principal Investigator:** | Brian Conlon, PhD |
| **Is this an NIH-funded project?** | YES **X** NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

| | |
|---|---|
| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>**X** Personnel exposure |

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| | |
|---|---|
| | ☐Spill<br>☐Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | **X** YES ☐NO<br>If yes, date of approval: 05/10/2020 |
| **What was the approved biosafety level of the research?** | ☐BL1<br>**X** BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐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<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | C57BL/6 wild-type mice infected with *Staphylococcus aureus* strain HG003* containing a tetracycline-inducible Green Fluorescent Protein(GFP) plasmid. The recombinant organism was received from a UNC collaborator.<br><br>*Parental strain NCTC8325; Reference strain HG003 for regulation and virulence studies |

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐YES **X** NO<br>Will be presented and reviewed at the monthly (July 2021) meeting. |
| **Please describe the root cause of this incident:** | Hand/arm position fatigue using the biosafety cabinet while performing an animal procedure. |

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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.**

**Incident Description:**

At approximately 4:00 PM on June 2, 2021, a Researcher was working with experimental mice within a biological safety cabinet (BSC) when the incident occurred. The mice were previously infected with a GFP-labeled strain of *Staphylococcus aureus*. The Researcher was working in the appropriate ABSL2 room within the animal facility and was wearing the prescribed personal protective equipment (PPE) for work including: two pairs of nitrile gloves, a lab coat, sleeve covers, hair bonnet and shoe covers. Based on the location, work practices and PPE used, there was no indication of a deviation from previous IBC approvals. The Researcher stated that they were prepping anesthetized mice for perfusion with phosphate-buffered saline (PBS) when the needlestick occurred. For this perfusion, they were using a Becton-Dickinson (BD) Precision Glide 26G needle attached to a 50 mL syringe. The Researcher further explained that their arms were suspended in the air (within the BSC) which led to fatigue. The Researcher was injecting PBS at the apex of the left ventricle (heart) using their right hand, while holding the mouse heart with tweezers in the left hand. They explained since there was no support for their arms, their hands became shaky, and they accidentally stuck their left middle finger as a result.

The mouse that was involved in the incident was a commercial C57BL/6N mouse that had previously been injected with a recombinant *Staphylococcus aureus* HG003 expressing green fluorescent protein (GFP). After the injury occurred, the Researcher immediately removed their outer gloves and exited the BSC. They noticed the wound was bleeding and sprayed the inner gloves. The Researcher removed the inner gloves and immediately pressed the site of the wound to squeeze out the blood and to stop the bleeding. They washed with soap and water for a couple of minutes. After the Researcher finished with the mouse and cleaned up the animal work, they returned to their main laboratory and notified the Supervisor of the incident. Following instructions from their Supervisor, the Researcher then called the University Employee Occupational Health Clinic (UEOHC) for medical assessment. Since the clinic was closed at the time (after hours), the Researcher was referred to and reported to the UNC Emergency Department for medical follow up.

**Incident Investigation and Discussion:**

On June 4, 2021, personnel from Environment Health and Safety (EHS) Biosafety met by video conference and spoke with the Researcher and the Principal Investigator (PI) about the incident. The Researcher was up-to-date and compliant on all their requisite EHS training. Please see below, the documentation of the researcher's biosafety and related trainings:

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Show Training: Current | All

| Course No. | Course Name | Training Date | Retrain/Exp. Date | Instructor |
|---|---|---|---|---|
| **EHS** | | | | |
| 1685 | LAB ENVIRONMENT - NEW EMPS | 02-05-2021 | N/A | SELF STUDY TEST |
| 1801 | ANNUAL LSP REVIEW WITH PI | 02-05-2021 | 02-05-2022 | CONLON (Marsico Hall) |
| 4100 | Introduction to Biosafety | 02-05-2021 | N/A | SELF STUDY TEST |
| 4101 | Biosafety Cabinets | 02-05-2021 | N/A | SELF STUDY TEST |
| 4108 | BIOLOGICAL SAFETY - BSL2 | 02-05-2021 | N/A | SELF STUDY TEST |
| 4123 | AUTOCLAVE SELF STUDY | 02-05-2021 | N/A | SELF STUDY TEST |
| 4140 | BBP CLASS/SELF-STUDY 1910.1030 | 02-05-2021 | 02-05-2022 | SELF STUDY TEST |
| 42201 | HAZCOM 2012 - GHS | 02-05-2021 | N/A | SELF STUDY TEST |
| 42261 | FORMALDEHYDE | 02-05-2021 | N/A | SELF STUDY TEST |
| 5520 | MANAGING LAB GENERATED HAZWAST | 02-05-2021 | N/A | SELF STUDY TEST |
| 5525 | Lab Waste - Subpart K | 02-05-2021 | N/A | SELF STUDY TEST |
| 60001 | PPE (LAB) | 02-05-2021 | 02-05-2022 | CONLON |

The Researcher has worked in this specific laboratory since February 2021 and was cleared through the UEOHC as an animal handler. As part of their animal handling training, the Researcher watched a training video and read relevant papers on performing a cardiac perfusion in mice. They stated that for basic mouse techniques (e.g., injections, dissection, etc.) they completed in-person training given by another researcher in the lab on 2/18/2021. As part of their animal handler approval, they completed the *Mouse Handling and Techniques Class* given by animal care staff on 2/23/2021. For isoflurane vaporizer training (anesthesia during perfusion), the Researcher was also trained in person by animal care staff on 3/9/2021. The Researcher did not indicate that there was any deviation from the standard operating procedures at the time of the incident.

It should be mentioned that when a laboratorian gets a sharps injury while in the lab, they should rinse their wound with soap and water for at least five minutes. Additionally, when a laboratorian is injured or involved in an incident while working in the lab, the laboratorian should stop their experiment and seek medical attention as soon as possible after an incident has occurred. Both the Researcher and the PI mentioned they will investigate better methods of balancing arms/hands while handling the mice in the future. It was also mentioned during the initial meeting that the Researcher could rest one elbow at a time, without disaffecting airflow in the BSC, and to reduce any incidence of fatigue.

**Recommendations and Corrective Steps:**

As part of the corrective and preventative actions to be taken, an internal Incident Report will be submitted by EHS to the Principal Investigator (PI) detailing the incident and including recommendations for the lab to follow to mitigate future reoccurrence of the incident. Additionally, the incident was reported as per reporting requirements and was resolved according to lab standard operating procedures. Therefore, no shortcomings in these areas were identified as part of the incident investigation.

In consultation with EHS Biosafety, The PI will review the incident with all lab members, focusing on identifying and implementing mouse handling techniques and reviewing these documents for retraining:

Obtained via FOIA by Judicial Watch Inc.

- Laboratory Safety Manual: Chapter 14 - Safe Handling of Laboratory Animals
  https://unc.policystat.com/policy/5819143/latest/
- "Hand Washing" section listed in the UNC Biological Safety Manual
  https://unc.policystat.com/policy/5858176/latest/#autoid-qn4ey
- Review the "Preventing Cuts and Punctures" PDF
  https://ehs.unc.edu/files/2015/09/cuts_punctures.pdf

The PI was also encouraged to investigate alternative methods and aids for handling mice such as arm rests. There are arm rests configured for use in a BSC (see link) that do not impede airflow.
https://www.fishersci.com/shop/products/accessories-series-1300-class-ii-type-a2-biological-safety-cabinets/p-4529309

The PI and or his/her designee is expected to address all changes and recommendations by June 25, 2021.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Pearce, Ericka Elizabeth <epearce@unc.edu>
**Sent:** Wednesday, June 16, 2021 1:25 PM
**To:** NIH guidelines
**Cc:** Brennan, Catherine
**Subject:** Updated report
**Attachments:** 06-02-2021 needle stick NIH report_final .pdf

Dear OSP,
Please replace the report that I sent with the one attached. There was a mistake on the date of the accident and when it was reported to EHS. The date should be June 2nd and not May 28th, 2021.

Best regards,
Ericka

UNC Chapel Hill **Environment Health & Safety/Risk Management**
**Ericka E. Pearce, MS, CBSP**
Biosafety Program Manager/Officer
Office: 919-962-5722
Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Pearce, Ericka Elizabeth <epearce@unc.edu>
**Sent:** Thursday, June 3, 2021 1:38 PM
**To:** NIH guidelines
**Cc:** Brennan, Catherine; Cyr, Douglas M.
**Subject:** Preliminary report of incident

Dear NIH Office of Science Policy,

I am writing to notify you of a laboratory incident that occurred at University of North Carolina-Chapel Hill. It was determined that the incident is subject to the reporting requirements as defined by the NIH Guidelines Appendix G-II-B-2-k, and occurred as a result of working with a recombinant microorganism. The following is a summary of information we have gathered, and a full report will be forthcoming. Please do not hesitate to contact me if you have any questions.

Date of incident: June 2, 2021
Reported to supervisor/EHS: June 2, 2021
Location: Genetic Medicine Building
Department: Microbiology and Immunology
Individual involved: Post-doctoral Research Associate
Incident type: Puncture from tweezers
Agent/Material: blood/body fluids from infected mouse (*Staphylococcus aureus*, strain HG003 with tet-inducible GFP)
Approved BSL: BSL2/ABSL2
Amount of inoculum: negligible
First Aid/post-exposure medical follow up: Yes, performed post exposure first-aid and reported to emergency department

Best regards,
Ericka Pearce

UNC Chapel Hill **Environment Health & Safety/Risk Management**
**Ericka E. Pearce, MS, CBSP**
Biosafety Program Manager/Officer
Office: 919-962-5722
Cell: Redacted by agreement

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, July 7, 2021 2:25 PM
**To:** Major, Sheryl; NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; John Kelsoe; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: UCSD Incident 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 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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Friday, June 4, 2021 7:18 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** McMahill, Angela <amcmahill@ucsd.edu>; Scott, Lance <lscott@ucsd.edu>; John Kelsoe <jkelsoe@ucsd.edu>
**Subject:** UCSD Incident 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 Section III-D-3. This report describes an incident where a lab was working with a viral vector at BSL-2 prior to IBC approval. This incident will be discussed with the Institutional Biosafety Committee on June 11, 2021.

Please let me know if you have any questions regarding this report.
Best,

Sheryl Major

Sheryl Major
Biosafety Officer (BSO)
High Containment Officer (HCO)

Obtained via FOIA by Judicial Watch Inc.

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, 201**

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | X YES ☐NO<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | University of California, San Diego |
| **Date of Report:** | 06/04/2021 |
| **Reporter name and position:** | Sheryl Major, Biosafety Officer |
| **Telephone number:** | (858) 822-2493 |
| **Email address:** | smajor@ucsd.edu |
| **Reporter mailing address:** | 9500 Gilman Drive #0090<br>La Jolla, CA 92093 |
| **Date of incident:** | 5/12/2021 |
| **Name of Principal Investigator:** | Dr. John Rice Kelsoe Jr. |
| **Is this an NIH-funded project?** | ☐YES X NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>X Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☐ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES X NO<br>If yes, date of approval: |
| **What was the approved biosafety level of the research?** | BL1<br>BL2 ☐BL2+ (describe specific enhancement in report)<br>☐ BL3 ☐BL3+ (describe specific enhancement in report)<br>☐ 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<br>☐ USDA ☐ State or local Public Health<br>☐ FDA ☐ Law enforcement<br>☐ EPA ☐ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | This lab is working with a pCSC-prox1-eGFP vector in human established cell lines. This is a third generation, HIV-based, self-inactivating lentiviral vector. In the pCSC backbone, a portion of the human prox1 promoter drives the expression of eGFP. No prox1 is expressed. |

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**

**DESCRIPTION OF INCIDENT**: (use additional space as necessary)

During a routine audit, it was discovered on 5/12/2021 that this laboratory had initiated work with a viral vector prior to obtaining IBC approval. This lab was found to be working with a pCSC-prox1-eGFP vector in human established cell lines. This is a third generation, HIV-based, self-inactivating lentiviral vector. In the pCSC backbone, a portion of the human prox1 promoter drives the expression of eGFP. No prox1 is expressed. The plasmid contains the HIV LTRs, Prox1-eGFP and the antibacterial selection cassette. The laboratory did have an active Biological Use Authorization (BUA) but was not approved to conduct any work covered under Section III-D of the NIH Guidelines, and their approved biosafety level for the authorization was BSL-1. Upon notification, the laboratory immediately ceased work with the vector and submitted an amendment to their existing authorization for use of the vector and cells [submission date 05/13/2021]. Scheduled date of review is the next scheduled IBC meeting on 6/11/2021. Approval and finalization of the biosafety level are pending IBC review.

One researcher was found to be conducting work with the vector. The researcher had completed the mandatory biosafety training for work with recombinant and synthetic nucleic acids [completed 09/06/2020] and for human cell lines [completed 09/06/2020]. Work with the vector and cells was confirmed as having been conducted in a biosafety cabinet [most recent certification date 04/2021]. Standard PPE in the form of a laboratory coat, safety glasses, and disposable gloves was worn. The tissue culture room in which the work was conducted met the BSL-2 facilities criteria outlined in the BMBL 6$^{th}$ edition. The biosafety officer evaluated the current work practices, facility containment, engineering controls, personal protective equipment, and waste management, and agrees with the labs proposed biosafety level of BSL-2.

The BSO conducted retraining of the PI regarding PI responsibilities and materials which require IBC approval prior to start of work [completed 05/13/2021]. Retraining of the researcher regarding materials which require IBC approval prior to start of work was conducted on 5/12/2021. This incident will be reported to the UC San Diego IBC on 6/11/2021.

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| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES X NO |
| **Please describe the root cause of this incident:** | PI did not realize the lentiviral vector was not described in the active BUA. |

**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):

Amendment to the Biological Use Authorization (BUA) was submitted on 05/13/2021 to include the work with the lentiviral vector. The Principal Investigator and the Biosafety Officer conducted a retraining regarding research materials and procedures that require IBC oversight. Retraining of the researcher regarding materials which require IBC approval prior to start of work was conducted on 5/12/2021.

The protocol will be reviewed at the June 11, 2021 IBC meeting and the incident reported to the IBC on the same day.

- **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:** Major, Sheryl <smajor@ucsd.edu>
**Sent:** Friday, June 4, 2021 7:18 PM
**To:** NIH guidelines
**Cc:** McMahill, Angela; Scott, Lance; John Kelsoe
**Subject:** UCSD Incident Report to the NIH
**Attachments:** 2021.05.19_NIH_Incident_Report_Kelsoe.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 Section III-D-3. This report describes an incident where a lab was working with a viral vector at BSL-2 prior to IBC approval. This incident will be discussed with the Institutional Biosafety Committee on June 11, 2021.

Please let me know if you have any questions regarding this report.
Best,

Sheryl Major

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.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, July 7, 2021 2:38 PM
**To:** Smith, Sherika; NIH guidelines
**Cc:** Robbins, Mark; Tucker, Jessica (NIH/OD) [E]; Young, Cari (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]
**Subject:** RE: UofSC Incident Report

Dear Sherika 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 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:** Smith, Sherika <SMITHS69@mailbox.sc.edu>
**Sent:** Wednesday, June 9, 2021 6:13 PM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Robbins, Mark <MROBBINS@mailbox.sc.edu>
**Subject:** UofSC Incident Report

NIH Office of Science Policy:

I have attached a report for an incident that occurred at the University of South Carolina School of Medicine on 6/8/2021 involving recombinant AAV. If you have any questions or need additional information, please let me know.

Thank you,

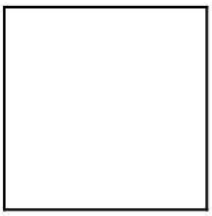
**Sherika Smith**
**Biosafety Officer**

O: 803-777-1625 | C: Redacted by agreement
smiths69@mailbox.sc.edu | sc.edu/ehs/biosafety

Environmental Health & Safety

Obtained via FOIA by Judicial Watch Inc.

University of South Carolina
Benson Building, Rm 306A



Obtained via FOIA by Judicial Watch Inc.

UNIVERSITY OF SOUTH CAROLINA

# Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

## 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. Report any incident involving recombinant or synthetic nucleic acids to the Biosafety Office as soon as possible for further investigation.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*). Please complete all fields as fully as possible.

Completed reports should be sent to Sherika Smith at smiths69@mailbox.sc.edu and Mark Robbins at mrobbins@mailbox.sc.edu

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Does this incident involve research subject to the *NIH Guidelines*?** | ☐YES ☐NO<br>**If no, this incident does not require reporting to OSP** |
| **Date of Report:** | 06/08/2021 |
| **Reporter name and position:** | Javier P. Fernandez (Biosafety Officer) |
| **Telephone number:** | (803) 777-1625 |
| **Email address:** | Javier.Fernandez@cshs.org |
| **Date of incident:** | 06/08/2021 |
| **Name of Principal Investigator:** | Mark Faries, M.D. |
| **Is this an NIH-funded project?** | ☐YES ☐NO<br>If yes, please provide the following information (if known)<br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*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<br>☐ Failure to obtain IBC approval<br>☐ Incomplete inactivation<br>☐ Loss of containment<br>☐ Loss of a transgenic animal<br>☐ Personnel exposure<br>☐ Spill<br>☒ Other (please describe): |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☐ YES ☐ NO<br>If yes, date of approval: 02/24/2021 |
| **What was the approved biosafety level of the research?** | ☐ BL1<br>☒ BL2 ☐ BL2+<br>☐ BL3 ☐ BL3+<br>☐ BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-D-4a |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐ CDC ☒ Funding agency/sponsor<br>☐ USDA ☐ State or local Public Health<br>☒ FDA ☐ Law enforcement<br>☐ EPA ☒ Other (please describe):<br>☐ OSHA |
| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | Replication-deficient non-pathogenic adeno-associated virus (rAAV). All elements of the WT-AAV are deleted. Vector cassette contains ITRs (inverted repeats). Helper function provided by pHelper cassette and serotype-specific cassette expressing Rep-Cap proteins of the virus. The animal brain (source of AAV exposure) was injected with purified viral particles (Risk Group 1). There is no known risks associated with accidental human exposure to AAV. |

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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)

On 1/11/21 at approximately 5:00 PM, the personnel (PhD student) was exposed to a cell suspension containing a human breast cancer cell line through a small splash of liquid in her left eye while in her laboratory (a BSL-2 area). She approximates that the volume was around 10-20 ul (a small droplet). She was performing tissue culture work and was splitting the MDA-MB-468 (ATCC HTB-132) human cell line. While working, she felt some of the cell suspension splashed into her left eye. She immediately washed her eye out with water in the bathroom. The splash occurred when the personnel was disposing of the serological pipette that she had used to transfer the cell suspension. The tip of the pipette got stuck in the metal grate in the front of the biosafety cabinet where the air flows out from and some of the liquid on the pipette tip splashed into her eye.

The cell suspension contained DMEM (Dulbecco's Modified Eagle Medium) with 10% FBS (fetal bovine serum), 1% Pen/Strep (Penicillin Streptomycin) and also contained 0.25% trypsin (5 ml media to 1 ml trypsin total) and the cell density of the suspension was 1.13x10^3 cells/ul. Per the safety data sheet (attachment available) on ATCC for the cell line, its states "This cell line is not known to cause disease in healthy adult humans. These cells have not been screened for Hepatitis B, human immunodeficiency viruses or other adventitious agents, unless otherwise reported on the Certificate of Analysis." The cells were from a common lab stock. The personnel does not have the lot number for the cells that she was growing and therefore could not download the Certificate of Analysis. She was able to find a COA for a recent stock of MDA-MB-468 cells that was recently ordered from ATCC as a representative document (attachment available).

The cells that the personnel was working with were previously transduced on 12/1/20 (approximately 40 days before the exposure incident) with a lentiviral vector containing a doxycycline-inducible construct; the cells had undergone antibiotic selection and were now passage 3. She has saved the rest of the original cell suspension in two 2 ml aliquots stored at 4*C and -80*C in case the samples can be tested for the presence of any infectious agents.

The incident was reported by the exposed personnel via e-mail to the Environmental Health & Safety e-mail address on 1/12/21 at 12:07 AM. It was forwarded in the morning to the Biosafety Program and Employee Health Services Deputy Medical Director. Employee Health Services advised the employee that her case will be assessed under Mount Sinai's BBFE (Blood or Body Fluid* Exposure) protocol and will monitor her for any infectious disease exposures, and advise her to visit their office for clinical evaluation. The employee made an appointment for 1:30 PM on this same date (1/12/21) for clinical evaluation.

The Biosafety Program Director asked the employee to provide more information about the lentiviral vector that was utilized. The personnel stated that it was 2nd generation lentiviral system from Addgene that was not replicative and had been modified for laboratory use. She made the vector using a transfer plasmid (psPAX2), which is listed as a 2nd generation plasmid. Per Addgene literature, "For safety reasons, transfer plasmids are all replication incompetent and may contain an additional deletion in the 3'LTR, rendering the virus “self-inactivating” (SIN) after integration." Additionally, "Unless recombination occurs between the packaging, envelope, and transfer vectors, and the resulting construct is packaged into a viral particle, it is not possible for viruses normally produced from these systems to replicate and produce more virus after the initial infection. Detailed information from AddGene is available here: https://www.addgene.org/guides/lentivirus/

Per review of training records for the employee, while she has completed and is up-to-date the 5 "core" (minimally required) Environmental Health & Safety trainings and other specialized safety trainings, she has not completed Bloodborne Pathogens Training.

Obtained via FOIA by Judicial Watch Inc.

| | |
|---|---|
| **Has the IBC reviewed this incident?** | ☐ YES ▣ NO |
| **Please describe the root cause of this incident:** | When disposing of the serological pipette that was had used to transfer the cell suspension, the tip of the pipette got stuck in the metal grate in the front of the biosafety cabinet where the air flows out from and some of the liquid on the pipette tip splashed into her eye. |

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 need for an alternative to blade removal was identified during the investigation and a noted potential solution was having a device designed by the department's machine shop manager that would allow the holder to be removed without the user's hand coming as close to the blade. If this is not feasible, the lab will purchase cut resistant gloves to reduce the risk of a sharps injury and exposure. The lab will also develop an SOP specifically for the vibratome that will included information pertaining to the safe removal of the holder and blade. The lab will send a copy of the finalized SOP to the Biosafety Officer for review by 6/16/21.
The IBC will be provided with a copy of this incident report at the next convened meeting.

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** Smith, Sherika <SMITHS69@mailbox.sc.edu>
**Sent:** Wednesday, June 9, 2021 6:13 PM
**To:** NIH guidelines
**Cc:** Robbins, Mark
**Subject:** UofSC Incident Report
**Attachments:** rSNA Incident- 6-8-21.pdf

NIH Office of Science Policy:

I have attached a report for an incident that occurred at the University of South Carolina School of Medicine on 6/8/2021 involving recombinant AAV. If you have any questions or need additional information, please let me know.

Thank you,

**Sherika Smith**
**Biosafety Officer**

O: 803-777-1625 | C: Redacted by agreement
smiths69@mailbox.sc.edu | sc.edu/ehs/biosafety

Environmental Health & Safety
University of South Carolina
Benson Building, Rm 306A

Obtained via FOIA by Judicial Watch Inc.

## Hunter, Renee (NIH/OD) [C]

**From:** McKinney, Michelle (NIH/OD) [E]
**Sent:** Wednesday, July 7, 2021 2:44 PM
**To:** Garry Coulson, Ph.D, RBP; NIH guidelines
**Cc:** Chris Jenkins, PHD, MPH, RBP, CHMM; Marala McCallister, AHM, CMBC, SSMBB; Patrick Conley, MS, CBSP, NREMT, Licensed EMT and Mold Consultant; Nicholas Noriea, PhD, MCS, RBP; Marilyn LG Lamm, Ph.D.; Goldberg, Sharon; Cochrane, Monica L; Tucker, Jessica (NIH/OD) [E]; Young, Cari (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 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:** Garry Coulson, Ph.D, RBP <gcoulson@clinicalbiosafety.com>
**Sent:** Thursday, June 10, 2021 11:07 AM
**To:** NIH guidelines <NIHguidelines@od.nih.gov>
**Cc:** Chris Jenkins, PHD, MPH, RBP, CHMM <cjenkins@clinicalbiosafety.com>; Marala McCallister, AHM, CMBC, SSMBB <mmccallister@sabaiglobal.com>; Patrick Conley, MS, CBSP, NREMT, Licensed EMT and Mold Consultant <pconley@clinicalbiosafety.com>; Nicholas Noriea, PhD, MCS, RBP <nnoriea@clinicalbiosafety.com>; Marilyn LG Lamm, Ph.D. <mlamm@clinicalbiosafety.com>; Goldberg, Sharon <Sharon.Goldberg@usoncology.com>; Cochrane, Monica L <Monica.Cochrane@usoncology.com>
**Subject:** NIH Incident Report

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

In fulfillment of our responsibility as an externally-administered Institutional Biosafety Committee (IBC) under the *NIH Guidelines* (2019) Section IV-B-2, please find enclosed an incident report regarding research covered under Section III-C of the *NIH Guidelines*.

Please let me know if you have any questions regarding the provided incident report.

Kind regards,
Garry

Obtained via FOIA by Judicial Watch Inc.

Garry Coulson, Ph.D, RBP
IBC Chair, Clinical Biosafety Services
16759 Main Street, Suite 208
Wildwood, MO 63040
Tel: 1-888-442-2472xx730
Email: gcoulson@clinicalbiosafety.com
Web: www.clinicalbiosafety.com




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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<br><br>If no, this incident does not require reporting to OSP |
| **Institution Name:** | VA Cancer Specialists<br>Fairfax, VA 22031 |
| **Date of Report:** | 6/09/2021 |
| **Reporter name and position:** | Garry Coulson, IBC Chair, Clinical Biosafety Services |
| **Telephone number:** | 1-888-442-2472 |
| **Email address:** | gcoulson@clinicalbiosafety.com |
| **Reporter mailing address:** | Clinical Biosafety Services<br>16759 Main Street<br>Suite 208<br>Wildwood, MO 63040 |
| **Date of incident:** | 4/21/2021 and 4/28/2021 |
| **Name of Principal Investigator:** | Dr. Alexander Spira |
| **Is this an NIH-funded project?** | ☐YES ☒NO<br><br>If yes, please provide the following information (if known)<br><br>*NIH grant of contract number:*<br>*NIH funding institute or center:*<br>*NIH program officer (name, email address):* |

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| **What was the nature of the incident?** | ☐Failure to follow approved containment conditions<br>☐Failure to obtain IBC approval<br>☐Incomplete inactivation<br>☐Loss of containment<br>☐Loss of a transgenic animal<br>☐Personnel exposure<br>☐Spill<br>☒Other (please describe): Dosed subjects at new location prior to IBC review |
| **Did the Institutional Biosafety Committee (IBC) approve this research?** | ☒YES ☐NO<br><br>If yes, date of approval:<br>The externally-administered IBC initially reviewed and approved the Redacted by agreement clinical trial on 11/16/2018, with subsequent annual reviews of this trial on 11/06/2019 and 12/7/2020.<br><br>The externally-administered IBC initially reviewed and approved the Redacted by agreement clinical trial on 08/13/2020, with a subsequent review of the trial on 11/09/2020. |
| **What was the approved biosafety level of the research?** | ☐BL1<br>☒BL2 ☐BL2+<br>☐BL3 ☐BL3+<br>☐BL4 |
| **What section(s) of the *NIH Guidelines* is the research subject to?** | Section III-C |
| **Has a report of this incident been made to other agencies? If so, please indicate** | ☐CDC ☐Funding agency/sponsor<br>☐USDA ☐State or local Public Health<br>☐FDA ☐Law enforcement<br>☐EPA ☐Other (please describe):<br>☐OSHA |

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| **Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)** | ***PROPRIETARY INFORMATION***<br>Clinical Trial – Redacted by agreement<br>• Redacted by agreement Recombinant, replication-defective adenovirus Redacted by agreement<br>Redacted by agreement<br>•<br>Clinical Trial – Redacted by agreement<br>Redacted by agreement<br>• Redacted by agreement Allogenic CD34+ cells transduced with 3rd generation replication-defective, self-inactivating lentiviral vectors Redacted by agreement<br>Redacted by agreement |

**DESCRIPTION OF INCIDENT:**

Redacted by agreement

An externally administered Clinical Biosafety Services ("CBS") Institutional Biosafety Committee ("IBC"), reviewed and approved the Redacted by agreement and Redacted by agreement human gene transfer ("HGT") clinical trials at VA Cancer Specialists located at 8503 Arlington Blvd, Suite 400, Fairfax, VA, 22031. These two trials were initially reviewed and approved by the IBC on 11/16/2018 and 8/13/2020, respectively. Additionally, both trials were approved at biosafety level 2 (BSL-2) under the direction of Dr. Alexander Spira.

On 4/13/2021, VA Cancer Specialists completed their relocation to a new facility at 8613 Lee Hwy, Fairfax, VA, 22031. Following their move to the new location, VA Cancer Specialists began preparing the required documents to initiate a formal review of their new facilities by the IBC. Such documents included, but were not limited to, biosafety checklists, standard operating procedures (SOPs), site maps, biohazard signs and photographs. It is important to note that

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most of these documents could not be generated until the move was complete and new facility was opened for patient care.

Unfortunately, due to extenuating circumstances Redacted by agreement Redacted by agreement for VA Cancer Specialists, there were some unintentional delays in generating the necessary documentation required for scheduling the convened IBC meeting. During this period, while documents were still being gathered for the IBC meeting, one study subject for each of the above-referenced trials Redacted by agreement and Redacted by agreement Redacted by agreement scheduled to be dosed with the aforementioned study agents.

Out of an abundance of concern for the patients' well-being, health and safety, the VA Cancer Specialists elected to proceed with dosing of the two study subjects prior to receiving formal approval of the new facility by the IBC. One subject enrolled in the trial was dosed on 4/21/2021, and the other subject enrolled in the Redacted by agreement trial was dosed on 4/28/2021. In both cases, the study agents were prepared and administered according to the established biosafety SOP approved by the IBC. The study agents for both trials were prepared in a biological safety cabinet (BSC) by trained study staff wearing personal protective equipment (PPE) consisting of a disposable gown, gloves, mask, head cover and foot covers, as per the approved SOP. During administration of the study agents, study staff wore PPE consisting of disposable gown, gloves, procedure mask and eye protection, as per the approved SOP. All disposable PPE and contaminated materials were disposed of in labeled biohazard waste containers, as per the approved SOP. All sharps were immediately disposed of in sharps containers, as per the approved SOP. During preparation and administration of the study agents, there was no loss of containment, spills or occupational exposures to report. Study staff were trained and experienced in the procedures being conducted, and were current with their applicable bloodborne pathogens (BBP) training.

Redacted by agreement

By 5/14/2021, the VA Cancer Specialists had generated all the required documentation, and an IBC meeting was scheduled to review the change in facilities on 5/21/2021. During the convened meeting on this date, the IBC reviewed the new facilities and determined that the new facilities and arrangements at the site were equivalent to the approved "old" facilities, and that there was no significant difference between the two sites. The Committee unanimously approved the new site for both clinical trials. Additionally, the Committee also recognized the difficulties VA Cancer Specialists faced in managing a move to new facilities while keeping the safety of patients and study participants a priority and was sympathetic to the challenging decision the site had to make regarding compliance and the wellbeing of study participants enrolled in these clinical trials.

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| **Has the IBC reviewed this incident?** | ☒YES ☐NO<br><br>The externally-administered IBC for the study site reviewed this incident on 5/21/2021. |
| **Please describe the root cause of this incident:** | Transitioning patient-care facilities is a not a trivial logistical and operational process. Unfortunately, due to the nature of such transitions, timelines for occupancy consistently shift and the collection of site-specific information ahead of time (ie. prior to moving into the facility) is not always feasible or possible. This posed unique challenges in scheduling of a convened IBC meeting prior to the required dosing of patients already enrolled in the clinical trials, and for whom rescheduling may not have been feasible from a critical patient care perspective.<br><br>Scheduling of the IBC was also delayed by an extended Redacted by agreement who was most familiar with the IBC and the required site documents needed for IBC review. Following a brief internal review, CBS identified a few internal procedures that covering communications and coordination with VA Cancer Specialists that may have contributed to a Change in Research process delay. |

**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 action to mitigate any potential reoccurrence of the incident, VA Cancer Specialists has already identified three (3) additional site contacts and will train them on the CBS IBC review process and documentation. This would eliminate potential delays in the collection of information in the event that the primary site contact is unavailable to assist CBS prepare for an IBC meeting. Additionally, CBS will work with the site to increase communication and coordination of site activities to ensure the prompt notification to the site's IBC regarding any potential changes to the site or trial that would require prior review and approval. This increase in communication and coordination will provide CBS an opportunity to perform an expedited *ad hoc* review for preliminary or conditional approval (see below for details).

In addition to the measures taken by the institution (VA Cancer Specialists), Clinical Biosafety

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Services will also review the incident internally and identify potential procedural avenues for expediting a trial review in extenuating circumstances such as this. Such avenues may include a preliminary *ad hoc* review of available information to grant the site conditional approval. An additional approach, which may be coupled to the first approach, may be to preliminarily accept Site and/or Principal Investigator assurances that i) the new facilities are equivalent to the approved facilities, ii) approved engineering controls (e.g. BSCs or CACIs) are in place at the new facility, and iii) that the approved Standard Operating Procedures (SOPs) for handling the study agent at the new site will remain unchanged from the approved SOP.

Following granting of conditional approval through either of these avenues, the Study Site would still be required to have a full, formal review at a convened IBC meeting as soon as feasible thereafter for final approval by the IBC.

The Study Site will be requested to train the newly-identified Site Contact backups by 7/2/2021. CBS will perform an internal review of the incident and identify potential procedural avenues for responding to such unique situations to assist clinical trial sites in maintaining compliance with the *NIH Guidelines.* The anticipated date for completion of this activity is 7/2/2021.

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## Hunter, Renee (NIH/OD) [C]

**From:** Garry Coulson, Ph.D, RBP <gcoulson@clinicalbiosafety.com>
**Sent:** Thursday, June 10, 2021 11:07 AM
**To:** NIH guidelines
**Cc:** Chris Jenkins, PHD, MPH, RBP, CHMM; Marala McCallister, AHM, CMBC, SSMBB; Patrick Conley, MS, CBSP, NREMT, Licensed EMT and Mold Consultant; Nicholas Noriea, PhD, MCS, RBP; Marilyn LG Lamm, Ph.D.; Goldberg, Sharon; Cochrane, Monica L
**Subject:** NIH Incident Report
**Attachments:** NIH Incident Report_06092021.pdf

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

In fulfillment of our responsibility as an externally-administered Institutional Biosafety Committee (IBC) under the *NIH Guidelines* (2019) Section IV-B-2, please find enclosed an incident report regarding research covered under Section III-C of the *NIH Guidelines*.

Please let me know if you have any questions regarding the provided incident report.

Kind regards,
Garry

Garry Coulson, Ph.D, RBP
IBC Chair, Clinical Biosafety Services
16759 Main Street, Suite 208
Wildwood, MO 63040
Tel: 1-888-442-2472xx730
Email:gcoulson@clinicalbiosafety.com
Web: www.clinicalbiosafety.com

Clinical Biosafety Services

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# Accessibility Report

**Filename:**
usc_template_for_rsna_incident_reporting_fillable.pdf

**Report created by:**

**Organization:**

[Enter personal and organization information through the Preferences > Identity dialog.]

## Summary

The checker found problems which may prevent the document from being fully accessible.

- Needs manual check: 2
- Passed manually: 0
- Failed manually: 0
- Skipped: 2
- Passed: 27
- Failed: 1

## Detailed Report

### Document

| Rule Name | Status | Description |
|---|---|---|
| Accessibility permission flag | Passed | Accessibility permission flag must be set |
| Image-only PDF | Passed | Document is not image-only PDF |
| Tagged PDF | Passed | Document is tagged PDF |
| Logical Reading Order | Needs manual check | Document structure provides a logical reading order |
| Primary language | Passed | Text language is specified |
| Title | Passed | Document title is showing in title bar |
| Bookmarks | Passed | Bookmarks are present in large documents |
| Color contrast | Needs manual check | Document has appropriate color contrast |

### Page Content

| Rule Name | Status | Description |
|---|---|---|
| Tagged content | Passed | All page content is tagged |
| Tagged annotations | Passed | All annotations are tagged |
| Tab order | Passed | Tab order is consistent with structure order |
| Character encoding | Passed | Reliable character encoding is provided |
| Tagged multimedia | Passed | All multimedia objects are tagged |
| Screen flicker | Passed | Page will not cause screen flicker |
| Scripts | Passed | No inaccessible scripts |
| Timed responses | Passed | Page does not require timed responses |
| Navigation links | Passed | Navigation links are not repetitive |

### Forms

| Rule Name | Status | Description |
|---|---|---|
| Tagged form fields | Passed | All form fields are tagged |
| Field descriptions | Passed | All form fields have description |

### Alternate Text

| Rule Name | Status | Description |
|---|---|---|
| Figures alternate text | Passed | Figures require alternate text |

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| Nested alternate text | Passed | Alternate text that will never be read |
| Associated with content | Passed | Alternate text must be associated with some content |
| Hides annotation | Passed | Alternate text should not hide annotation |
| Other elements alternate text | Skipped | Other elements that require alternate text |

## Tables

| Rule Name | Status | Description |
|---|---|---|
| Rows | Passed | TR must be a child of Table, THead, TBody, or TFoot |
| TH and TD | Passed | TH and TD must be children of TR |
| Headers | Passed | Tables should have headers |
| Regularity | Failed | Tables must contain the same number of columns in each row and rows in each column |
| Summary | Skipped | Tables must have a summary |

## Lists

| Rule Name | Status | Description |
|---|---|---|
| List items | Passed | LI must be a child of L |
| Lbl and LBody | Passed | Lbl and LBody must be children of LI |

## Headings

| Rule Name | Status | Description |
|---|---|---|
| Appropriate nesting | Passed | Appropriate nesting |

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