



Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985
(301) 496-9836 (Phone)
(301) 496-9839 (Fax)
nih/oba.od.nih.gov

December 17, 2013

[redacted by agreement]

Vice Chancellor for Research and Dean of the Graduate School
University of Wisconsin
333 Bascom Hall
500 Lincoln Drive
Madison, WI 53706-1380

Dear [redacted by agreement]

We are writing in regard to two incidents involving recombinant research with highly pathogenic avian influenza (HPAI) H5N1 that have occurred recently in the ABSL3+ laboratory of Dr.

[redacted by agreement] After reviewing the details of these two incidents, NIH has significant concerns relating to the University of Wisconsin's apparent lack of a dedicated quarantine facility other than the researcher's home. We also have concerns relating to the biosafety practices associated with these incidents. Our concerns are detailed below.

Lack of a dedicated quarantine facility

In the needlestick incident that occurred on November 16, 2013, a decision was made to home quarantine the individual because the route of exposure (needlestick) was not expected to place the researcher at high risk for infection and this influenza strain, which contained the HA gene from H5N1, was determined not to be a mammalian-transmissible strain. However, in conversations with the University of Wisconsin Alternate Responsible Official, [redacted by agreement]

[redacted by agreement] regarding this incident, [redacted by agreement] informed us that all researchers exposed to H5N1 would be quarantined at home, regardless of the risk of infection or whether the strain was mammalian-transmissible or not.

In a subsequent phone conversation with the University of Wisconsin Senior Associate Dean for Research, [redacted by agreement], the policy for home isolation for all incidents was reiterated to us. We were told by [redacted by agreement] that the decision was based upon consultation with University of Wisconsin infectious disease experts and the state health department. We were also informed that the use of a hospital room for quarantine was rejected due to the stress it would place on the laboratory worker.

December 16, 2013

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The University of Wisconsin's policy on home quarantine communicated to us by [redacted by agreement] is not in keeping with what was communicated to us in [redacted by agreement] application to the Department of Health and Human Services to perform research with mammalian transmissible strains of HPAI H5N1. In a May 6, 2013, plan provided to NIH, Dr. [redacted by agreement] indicated that he had access to a "designated quarantine apartment" in which researchers could be placed for 10-14 days in the event of an accidental exposure (Attachment: A). [redacted by agreement] have indicated to OBA that there was a miscommunication between the PI and the University of Wisconsin administration regarding the availability and appropriateness of such a quarantine apartment.

The University of Wisconsin's policy on home quarantine is inconsistent with the requirements for this research under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, and under the terms agreed to by the University as a condition of funding this project. The University of Wisconsin must find a dedicated facility outside of the individual's permanent residence (1) in which an individual exposed to mammalian-transmissible HPAI H5N1 can be safely isolated for up to 10 days, and (2) that can be decontaminated easily after the individual's departure. An isolation room in a hospital would also be appropriate. An individual's permanent residence is not appropriate when the risk of infection is high. For high risk exposures, it is critical to isolate the individual in a structure that does not have shared air exchange and can be quickly and efficiently decontaminated in the case of infection. In addition, if this structure is outside of a health care facility, there needs to be a plan in place regarding how this researcher could be safely transported to an isolation room in a health care facility, should he or she develop clinical symptoms, without the risk of exposure to other individuals.

Concerns relating to biosafety practices

In addition to the quarantine issue, NIH has significant concerns regarding the biosafety practices associated with both of the recent incidents.

The November 16, 2013, needlestick incident occurred when the researcher used a needle to collect tissue culture supernatant in violation of the University of Wisconsin's own policies, which only permits needles to be used in the ABSL3+ laboratory to anesthetize research animals, draw blood from research animals, or inoculate eggs. It was unclear from the University's response why this individual was using a needle for this type of procedure.

The University of Wisconsin report regarding the November 9, 2013, HPAI H5N1 spill described the researcher as having two to three inches of exposed skin between where his tyvek suit ended and his shoe covers began. While it was reported that none of the spilled material landed on the researcher's bare skin, we made it clear in our letter (Attachment: A) and in a phone conversation with [redacted by agreement] that having bare skin in the ABSL3+ laboratory was unacceptable under the containment requirements for this research specified in the *NIH Guidelines*. During that phone conversation, [redacted by agreement] stated that the ABSL3+ laboratory had recently undergone a Select Agent inspection and the report from that inspection did not specifically mention a prohibition against working in the ABSL3+ laboratory

December 16, 2013

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with bare skin. We have discussed the issue of bare skin in the ABSL3+ laboratory with the United States Department of Agriculture (USDA) Select Agent Program, and they are in agreement that bare skin is unacceptable at this level of containment.

Attachments B and Attachment C to this letter contain the NIH response to both H5N1 incidents. These letters contain requests for action regarding the quarantine situation and our biosafety concerns. We would appreciate any assistance you can provide to ensure that these requests are answered by December 23, 2013.

Finally, if your response is not received by this date or if does not fully address the issues we have described regarding a dedicated quarantine facility and inappropriate biosafety practices, as required by the terms and conditions of grant award, NIH will institute enforcement action(s) for the NIH grant.

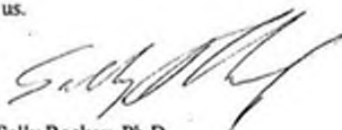
Redacted by agreement

Principal Investigator. Such actions could include disallowance of costs, suspension, or termination of the grant award.

If you have any questions, please feel free to contact us.



Amy P. Patterson, M.D.
Associate Director for Science Policy
National Institutes of Health



Sally Rockey, Ph.D.
Deputy Director for Extramural Research
National Institutes of Health

cc: Redacted by agreement

Capt. Robbin Weyant, Ph.D., Director, Division of Select Agents and Toxins, CDC
Freeda E. Isaac, D.V.M., Director, Agriculture Select Agent Program, USDA APHIS
Jacqueline Corrigan-Curay, J.D., M.D., Acting Director, Office of Biotechnology Activities, NIH



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National Institutes of Health
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Bethesda, MD 20892-7985
(301) 496-9838 (Phone)
(301) 496-9839 (Fax)
<http://osp.od.nih.gov>

October 28, 2016

Name Ph.D., CBSP
Director, Office of Biological and Chemical Safety
Environmental Health and Safety
Washington University
660 South Euclid Avenue
Campus Box 8229
St. Louis, MO 63110

Dear Dr. Name

Thank you for your September 30, 2016, and October 13, 2016, reports to the National Institutes of Health (NIH) Office of Science Policy (OSP) regarding a September 24, 2016, incident in which a graduate student grazed her hand with a needle while administering an antibody to mice infected with Chikungunya virus (CHIKV) in a biosafety level (BL) 3 laboratory at Washington University.

From your report, we understand that the student grazed her finger while handling the needle after performing an injection. She was wearing appropriate personal protective equipment (PPE), including double gloves, at the time of the incident, but the needle broke through both pairs of gloves. She immediately washed her hands with soap and water.

On September 28, 2016, the student developed a fever with severe body aches. On September 29, 2016, she presented with a macular rash which worsened throughout the day. That evening she reported her symptoms and the needle stick to the principal investigator (PI) and went to the hospital. She was kept in hospital overnight for observation, and the following day was seen by an infection disease specialist who sent blood to the state laboratories for CHIKV testing. She was released from hospital that day.

By October 2, 2016, the fever and rash had gone and the student did not develop arthralgia or arthritis, which is often associated with Chikungunya fever. However, she did receive positive CHIKV qPCR results from the Infectious Disease clinic.

In response to this incident, the PI met with all laboratory personnel to discuss the proper reporting of personnel exposures and the processes in place for reporting incidents. The Department of Environmental Health and Safety will add additional slides about sharps safety to the annual laboratory training.

No further information about this incident is required at this time. However, we are concerned that an exposure incident occurred in a BL3 laboratory and went unreported for four days. We recommend that the requirement to immediately report any overt or potential exposure be stressed to all personnel working in high containment. We also recommend evaluating exactly how the injury occurred, including how the

Name

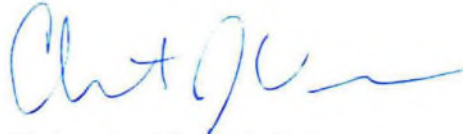
Ph.D., CBSP

October 28, 2016

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student was handling the needle after conducting the injection. The student may require additional hands on training on how to safely handle sharps. Needles should be discarded in an appropriate sharps container immediately after use to minimize the potential for a stick. The use of safety needles, where the needle can be sheathed immediately after use should also be considered. 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.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Chris Viggiani', with a long horizontal flourish extending to the right.

Christopher Viggiani, Ph.D.
Program Director, Biosafety and Biosecurity Policy
Biosafety, Biosecurity and Emerging Biotechnology
Policy Division, NIH

cc: Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH
Jessica Tucker, Ph.D., Director, Biosafety, Biosecurity and Emerging Biotechnology Policy
Division, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Biosafety,
Biosecurity and Emerging Biotechnology Policy Division, NIH
Laura Cochran, Program Assistant (contractor), Biosafety, Biosecurity and Emerging
Biotechnology Policy Division, NIH

Harris, Kathryn (NIH/OD) [C]

From: [Name]@wustl.edu>
Sent: Thursday, October 13, 2016 5:17 PM
To: Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report of potential exposure
Attachments: Incident Report Follow Up 161013.pdf

Kathryn,

Attached, please find the completed final report for this exposure. Please let me know if I can provide any additional information.

-Susan

[Name] PhD, CBSP
Director, Office of Biological & Chemical Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: [Name]@wustl.edu; Web: ehs.wustl.edu

From: Harris, Kathryn (NIH/OD) [C] [mailto:HarrisKath@mail.nih.gov]
Sent: Friday, October 07, 2016 8:40 AM
To: [Name]
Subject: RE: Report of potential exposure

Dear [Name]

Thanks for the update. It would be helpful if you could compile a formal final report regarding the event, immediate actions taken and actions to prevent similar accidents. Our new incident reporting template articulating the kinds of information a report should contain is available at

http://osp.od.nih.gov/sites/default/files/resources/Incident%20Reporting%20Template%20-%202016_2.docx

Thanks,

Kathryn

From: [Name] [mailto:[Name]@wustl.edu]
Sent: Friday, October 07, 2016 9:33 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: [Name]@wustl.edu>
Subject: RE: Report of potential exposure

Yesterday afternoon, the PI contacted me to let me know that the student involved has recovered and is back at work. The student never developed arthritis or joint swelling but the PCR results for Chikungunya were positive. Now that the student is recovered, I have asked the PI to talk with her to get more details on the circumstances surrounding the incident and what can be done to prevent similar incidents in the future. I have also stressed the importance of reporting any exposures or potential exposures immediately. I will pass along any additional information as it becomes available but please let me know if there are other items you would like addressed.

[Name]

Name PhD, CBSP
Director, Office of Biological & Chemical Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: Name@wustl.edu; Web: ehs.wustl.edu

From: Name
Sent: Friday, September 30, 2016 6:55 PM
To: NIHGuidelines@od.nih.gov
Cc: Name
Subject: Report of potential exposure

I am writing to report a potential exposure to recombinant DNA. On September 30th, I was contacted by a principal investigator whose graduate student had been admitted to the ER on the night of September 29th with high fever, muscle aches, and rash. On the 30th, the student told the PI that on September 24th she had sustained a scratch with a needle used to inject antibodies into a mouse that had been previously infected with a recombinant clone of Chikungunya virus (la Reunion 2006 strain). The student did not see any blood from the scratch so she did not report it or seek medical attention. The student has not received a diagnosis yet but the Infectious Diseases division of the hospital as well as Occupational and Student Health have been contacted for consultations.

At this time, I do not have any additional details. I am gathering information about the circumstances surrounding the exposure as well as the student's current condition and diagnosis and will pass that information along as soon as I can. The Co-Chairs of the IBC have been notified of this situation and the full committee will discuss the potential exposure at the next scheduled IBC meeting on October 19th.

I will be out of the office for the ABSA conference next week but will be checking email frequently to monitor this situation. I'm also copying Name Associate Biological & Chemical Safety Officer, who will be able to assist you in my absence.

-Susan

Name PhD, CBSP
Biological & Chemical Safety Officer, Washington University
660 South Euclid Avenue, Campus Box 8229
St. Louis, MO 63110
Phone (314) 747-0309; Fax (314) 362-6786
Email: Name@wustl.edu; Web: <http://ehs.wustl.edu>

**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

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If no, this incident does not require reporting to OSP
Institution Name:	Washington University in St. Louis
Date of Report:	10/13/16
Reporter name and position:	<div>Name</div> Biological Safety Officer
Telephone number:	314-747-0309
Email address:	<div>Name</div> @wustl.edu
Reporter mailing address:	660 S. Euclid Ave Campus Box 8229 St. Louis, MO 63110
Date of incident:	9/24/16
Name of Principal Investigator:	<div>Name</div> MD, PhD
Is this an NIH-funded project?	YES xNO If yes, please provide the following information (if known) <i>NIH grant of contract number:</i> <i>NIH funding institute or center:</i> <i>NIH program officer (name, email address):</i>

What was the nature of the incident?	<input type="checkbox"/> Failure to follow approved containment conditions <input type="checkbox"/> Failure to obtain IBC approval <input type="checkbox"/> Incomplete inactivation <input type="checkbox"/> Loss of containment <input type="checkbox"/> Loss of a transgenic animal <input checked="" type="checkbox"/> Personnel exposure <input type="checkbox"/> Spill <input type="checkbox"/> Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	x <input type="checkbox"/> YES <input type="checkbox"/> NO If yes, date of approval: Renewed 8/29/16
What was the approved biosafety level of the research?	<input type="checkbox"/> BL1 <input type="checkbox"/> BL2+ <input checked="" type="checkbox"/> BL3 <input type="checkbox"/> BL3+ <input type="checkbox"/> BL4
What section(s) of the <i>NIH Guidelines</i> is the research subject to?	III-D-1-b, III-D-4-a
Has a report of this incident been made to other agencies? If so, please indicate	<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> CDC <input type="checkbox"/> USDA <input type="checkbox"/> FDA <input type="checkbox"/> EPA <input type="checkbox"/> OSHA </div> <div> <input type="checkbox"/> Funding agency/sponsor <input type="checkbox"/> State or local Public Health <input type="checkbox"/> Law enforcement <input type="checkbox"/> Other (please describe): </div> </div>
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Chikungunya virus (recombinant strain: LR OPY2006)



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)

The incident took place in our ABSL3 laboratory space (inside a biosafety cabinet) on Saturday 9/24/16. A graduate student was administering antibody to mice infected with CHIKV-LR2006 strain via an intraperitoneal route at a time point where infectious virus would still be present in the mice. There were no other lab members present at the time, and proper BSL3 personal protective equipment was in use at the time of the incident (double gowns, double gloves, double shoe covers, hair net, and face mask). All lab personnel that use the BSL3 space have had proper training in accordance with national and institutional guidelines.

She grazed a finger on her left hand while handling the needle after an IP injection. The needle did break through both sets of gloves (by visible inspection), but there was no visible sign of blood (i.e. it didn't seem like a deep needle stick). The student washed her hands with soap and water immediately following the needle stick.

Wednesday evening (9/28/16 - 4 days post needle stick) the graduate student started running a fever and had severe body aches and chills. Thursday morning (9/29/16) she presented with a macular rash, which progressively worsened throughout the day. Thursday evening she reported her symptoms and needle stick incident to her PI and checked into the ER for treatment. She was kept overnight for observation and was given ibuprofen for the fever and pain and fluids for hydration. On Friday 9/30/16 she was seen by the Infectious Disease consult service and blood was sent to the state labs for CHIKV tests. She was released from the hospital that Friday afternoon.


By Sunday (10/2/16) her rash and fever were gone, and she was back at work on Tuesday 10/4/16. Ultimately, she experienced only 3 days of more severe symptoms, and she never developed the arthralgia and arthritis often associated with chikungunya fever. On Thursday 10/6/16 she did receive positive CHIKV qPCR results from the Infectious Disease clinic.

Has the IBC reviewed this incident?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> 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):

Prior to this incident, EH&S distributed a sharps safety reminder through the University's Research News tool. The day prior to the incident, EH&S sent annual safety and compliance reports to all department chairs and business managers in departments that have laboratories and clinics. The report highlighted needle stick trends, asking departments to focus on reducing needle sticks and other common injuries, and asked department chairs to pay special attention to prompt reporting of any potential exposure to recombinant DNA-containing material, as required by NIH. Following this incident, the PI discussed proper reporting of personnel exposure in a lab meeting with all members of the lab and procedures in place for reporting such incidents were reviewed with all members of the lab being present. EH&S will also add additional slides about sharps safety to the annual laboratory safety training. The IBC will discuss at the October meeting what other educational steps can be taken to minimize the chance of sharps 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.

Harris, Kathryn (NIH/OD) [C]

From: [Name]@wustl.edu>
Sent: Friday, October 07, 2016 9:33 AM
To: NIH guidelines
Cc: [Name]
Subject: RE: Report of potential exposure

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[Name]

[Name] PhD, CBSP
Director, Office of Biological & Chemical Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: [Name]@wustl.edu; Web: ehs.wustl.edu

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Sent: Friday, September 30, 2016 6:55 PM
To: NIHGuidelines@od.nih.gov
Cc: [Name]
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I will be out of the office for the ABSA conference next week but will be checking email frequently to monitor this situation. I'm also copying [Name] Associate Biological & Chemical Safety Officer, who will be able to assist you in my absence.

[Name]

[Name] PhD, CBSP
Biological & Chemical Safety Officer, Washington University
660 South Euclid Avenue, Campus Box 8229
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Email: [Name]@wustl.edu; Web: <http://ehs.wustl.edu>

Harris, Kathryn (NIH/OD) [C]

From: [Name]@wustl.edu>
Sent: Friday, September 30, 2016 7:55 PM
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Cc: [Name]
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[Name]

[Name] PhD, CBSP
Biological & Chemical Safety Officer, Washington University
660 South Euclid Avenue, Campus Box 8229
St. Louis, MO 63110
Phone (314) 747-0309; Fax (314) 362-6786
Email: [Name]@wustl.edu; Web: <http://ehs.wustl.edu>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

September 21, 2011

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985
(301) 496-9838 (Phone)
(301) 496-9839 (Fax)
<http://oba.od.nih.gov/oba>

Name

M.S., CIH, CBSP

Institutional Biosafety Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place
Box 1155
Atran-Berg Building B2 Room 56D
New York, NY 10029

Dear Mr. Name:

Thank you for your September 2, 2011, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a September 2, 2011, incident in which a researcher at the Mount Sinai School of Medicine was bitten by a ferret that had been previously inoculated with a recombinant form of 1918 influenza virus. The inoculation occurred approximately three days prior to this incident. According to your report, the researcher immediately washed the wound with 70-percent alcohol, showered out of the facility, and contacted the biological safety officer. The researcher was examined by the occupational health physician and was administered the 2011 batch of the Valence influenza vaccine and prescribed a course of Tamiflu. As per Mount Sinai protocol, the researcher was quarantined at home for seven days following the exposure. According to your report, it was verified that the researcher lived alone before being discharged to home-quarantine. The researcher was also instructed to use an N95 respirator if, during the home-quarantine, he needed outside medical assistance. The researcher was also instructed to take his temperature in the morning and evening and report the results, via telephone, to the occupational health physician. The likelihood of illness from this exposure was judged to be remote, but the researcher was monitored until the incubation period for disease had passed. The researcher subsequently showed no symptoms of illness and returned to work on September 9, 2011.

The actions taken in response to this incident by Mount Sinai Medical Center appear appropriate. No further information is required at this time. Please contact OBA staff by email at oba@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Jacqueline Corrigan-Curay, M.D., J.D.
Acting Director
Office of Biotechnology Activities

Name

M.S., CIH, CBSP

September 21, 2011

Page 2

cc:

Name

M.D., Ph.D., Assistant Professor of Medicine, Mount Sinai School of Medicine

Name

Senior Director, Environmental Health and Safety, Mount Sinai School of Medicine

Amy P. Patterson, M.D., Associate Director for Science Policy, NIH

Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH

Ryan Bayha, Outreach and Education Analyst, Office of Biotechnology Activities, NIH

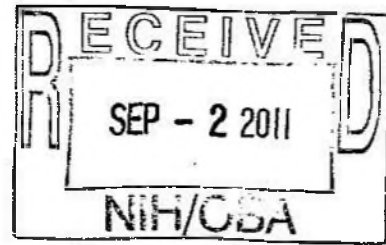
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

9/21



MOUNT SINAI
SCHOOL OF
MEDICINE

FAX



DATE September 2, 2011

TO Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

FAX# 301- 496-9839 (fax).

SUBJ: Mount Sinai School of Medicine /SA&T Renewal

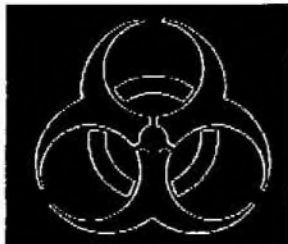
NO. OF PAGES + COVER 1+1

COMMENTS:

See Attached Letter for information regarding Ferret bite with Modified
GMO 1918 Influenza; CDC has also been notified through the Select
Agent Program: Expanded contact info at bottom of letter

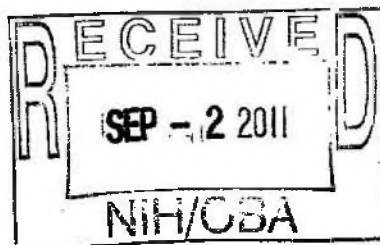
Name MS, CIH, CBSP, SM(NRM)

Institutional Biosafety Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place
Box 1162
Atran Berg B2—56D
New York, New York 10029
212 241 5169 phone
212 241 6695 Fax





MOUNT SINAI
SCHOOL OF
MEDICINE



Institutional Biosafety Program

September 2, 2011
National Institutes of Health / Office of Biotechnology

Greetings:

I received a call at @14 58 hrs from [Name] stating that he had been bitten by a ferret, 3 days post-inoculation with a mutant form of the 1918 (Spanish) Influenza. At present he is waiting to be seen by Dr. [Name] the Alternate Responsible Official, BSL-3 Director and ID Physician in order to be evaluated.

[Name] is up to date on his flu shot, and noted that the ferret's incisor barely broke the skin of his left thumb (hands were double-gloved). He immediately washed the site with 70% alcohol, showered out of the facility as per standard protocol and contacted me. I in turn notified Dr. [Name] who will relay back to me his findings.

Since this is a genetically modified Influenza, I have to notify the NIH Office of Biotechnology Activities as well as the Centers for Disease Control. Realistically, if we were to see an infection it would take two-four days incubation time. Bite-wound inoculation is not a standard exposure route, and [Name] stated that the ferret was not moribund, but to the contrary was energetic and healthy (not displaying any signs of illness). We will institute the standard operating procedure of checking daily for elevated temperature / fever, sore throat and the usual flu-like symptoms. [Name] will also have to begin taking Tamiflu prophylactically.

Dr. Daefler stated to me he is on call all weekend as part of his rotation in Infectious Disease, and would be able to monitor [Name] closely over the weekend if any illness develops. The likelihood is extremely remote, but we will not be sure until [Name] is past the incubation period without any sequelae.

I will keep you updated with regard to any further developments. At present, I will relay exactly what I reported to you to the two agencies.

[Name]

[Name] MS, MSHS, CIH, CBSP, SM(NRM)

Institutional Biosafety Officer
Environmental Health and Safety

Tel: 212 241 5169

Pager: [Personal Info]

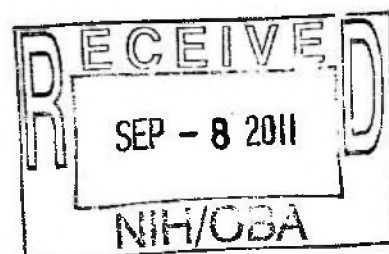
Fax: 212 241 6695

BB: [Personal Info]



**MOUNT SINAI
SCHOOL OF
MEDICINE**

FAX



DATE September 8, 2011

TO **Ryan T. Bayha**
Outreach and Education Analyst
Office of Biotechnology Activities
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(301) 496-9838 (phone)
(301) 496-9839 (fax)

FAX# (301) 496-9839

SUBJ: RE: Form 3 Report - Name **Ferret Bite-9/2/2011**

NO. OF PAGES + COVER 1+2=3

COMMENTS: Select Agent Form 3 Completed for the incident reported by Fax and phone.

Name **MS, CIH, CBSP, SM(NRCM)**
Institutional Biosafety Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place
Box 1162
Atran Berg B2--56D
New York, New York 10029
212 241 5169 phone
212 241 6695 Fax





REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0578-0213
OMB NO. 0920-0578
EXP DATE 12/31/2011

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC within 7 days of the theft, loss or release.

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3852
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2098
Email: lsrat@cdc.gov

SECTION 1 - TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Mount Sinai School of Medicine		2. Entity registration number (if applicable): CDC050563	
3. Entity address (NOT a post office address): One Gustave L. Levy Place		4. City: New York City	5. State: NY
7. Responsible Official (RO) or Facility Director First: <u>Name</u> MI: <u>Name</u> Last: <u>Name</u>		6. Telephone #: <u>212 241 5169</u>	
9. FAX #: <u>212 241 6695</u>		10. E-mail address: <u>Name</u> @msm.edu	
11. RO or Facility Director address (NOT a post office address): Same as entity Box 1162		12. City: New York City	13. State: NY
14. Zip Code: 10028		14. Zip Code: 10028	
15. Type of incident: <input type="checkbox"/> Theft <input type="checkbox"/> Loss <input type="checkbox"/> Release	16. Immediate notification provided to: <input type="checkbox"/> APHIS <input checked="" type="checkbox"/> CDC	17. Date of immediate notification: 09/02/2011	18. Type of immediate notification: <input checked="" type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of theft/loss/release of select agents and toxins at this entity: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (If yes, please provide additional details in an attachment.)			

SECTION 2 - TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (attach additional sheets if necessary)

	20. Select agents and/or toxins:	21. Characterization of agent:	22. Number of vials:	23. Form (powder/liquid/slant):	24. Volume or wt of vial contents (e.g., mL, mg, ng):
A	Reconstructed 1918 influenza virus	3-days post inoculation /ferret	0		0.00
B					
C					
D					

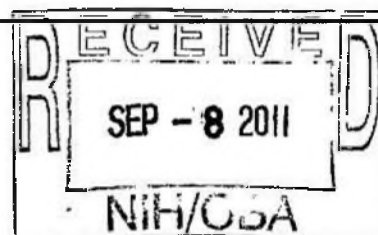
25. Date and time of incident: 09/02/2011	26. Date of last inventory:	27. Name of principal investigator responsible for laboratory with select agents and toxins: First: Adolfo MI: Last: Garcia-Sastre	
28. Location of incident (building and room #): Annenberg 17	29. Location of incident (within room (e.g., freezer, incubator)): 294 DD	30. Biosafety level of laboratory where incident occurred: ABSL3	31. Agent was recovered (theft/loss): <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes

32. Provide a detailed summary of events including a timeline of events and name and telephone numbers of agencies notified. The summary should also include description of containers (e.g., size, color, type, brand, and any symbols or markings), supporting documentation (e.g., access and inventory records), identified weaknesses, and any corrective actions taken (attach additional sheets if necessary):

I received a call at @14 58 hrs from Name stating that he had been bitten on the left thumb (@ 13 30 hrs by a ferret, which was 3 days post-inoculation with a mutant form of the 1918 (Spanish) Influenza. The incisor broke through the double set of gloves and scored the skin (not a deep puncture wound). He provided first aid by expressing the wound and washing with 70% ethanol, and showered out of the EPF facility as per protocol. He was seen by Dr. Name, the Alternate Responsible Official, BSL-3 Director and ID Physician who started Dr. Name on Tamiflu and administered the newly received Influenza vaccine (2011 valence) that is being administered to health care providers. Name received the mandatory flu vaccine in October, 2010. As of today (9/7/2011) there have been no sequelae, however he is in quarantine until 9/7/2011 and reporting his health status twice per diem to Dr. Simon Daefler.

☐ Continued as an attachment

(CDC Adobe Acrobat 9.0 Electronic Version, 1/2009)



SECTION 3 - IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION AND INCLUDE A COPY OF THE RELEVANT APHIS/CDC FORM 2	
33. Transfer authorization number from APHIS/CDC Form 2: NA	34. Date shipped:
35. Name of carrier:	36. Airway bill number/bill of lading number/tracking number:
37. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary): Not Applicable	
38. Package with select agents and toxins received by requestor: <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, date of receipt:	39. Package with select agents and toxins appears to have been opened: <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, include in explanation above for Box #37)
40. Sender was contacted regarding incident: <input type="checkbox"/> No <input type="checkbox"/> Yes	41. Carrier/courier was contacted regarding incident: <input type="checkbox"/> No <input type="checkbox"/> Yes

SECTION 4 - TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS
42. Hazards posed by release: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (If Yes, explain. Attach additional sheets if necessary.) Potential for infection with 1918 Influenza; route of exposure and load of potential 1918 Influenza virus has little potential to cause an active infection. Nonetheless, this incident is being tracked as a significant exposure until the full 7 days is reached.
43. Exposures: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.) One individual was bitten by an inoculated ferret, 3-days post inoculation.
44. Area was decontaminated: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (If Yes, explain. Attach additional sheets if necessary.) Individual provided immediate wound cleaning and antiseptics, followed by mandatory shower-out decontamination.
45. Medical treatment was provided: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (If Yes, explain. Attach additional sheets if necessary.) Tamiflu regimen plus inoculation with 2011 Valence Influenza Vaccine.

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, and 42 CFR 73

Signature of Respondent:

Name

Title: Biosafety officer and RO

Typed or printed name of Respondent:

Name

MS, MSHS, CBSP, SM(NRCM)

Date: 09/07/2011

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

APHIS/CDC FORM 3 (12/31/2011)

Публикации на The Intercept о нарушениях, допущенных в американских лабораториях



THE GRADUATE STUDENT was alone in the lab on a Saturday, handling a mouse infected with a debilitating virus, when the needle slipped. She wore two gowns, two pairs of shoe covers, a hair net, a face mask, and two pairs of gloves. Gingerly, she had pointed the needle at the mouse's abdomen and injected the antibody. The animal was infected with a recombinant strain of Chikungunya virus, a mosquito-borne pathogen that has sparked epidemics in Africa and the Caribbean. Chikungunya can wreak havoc in other regions when the right kind of mosquito is present; in 2007 and 2017 there were [outbreaks in Italy](#), and in 2014 the virus [hit Florida](#), [infecting 11 people](#) who had not recently traveled abroad. In January 2016, nine months before the researcher stood in the lab that weekend, a locally acquired infection was [diagnosed in Texas](#).

Рис. 9. Публикация на сайте американской некоммерческой новостной организации The Intercept «В американских биолaborаториях сотни несчастных случаев остались нераскрытыми для общественности. Часть 1. Эксперименты с катастрофой»



A

THE MOMENT that the ferret bit him, the researcher was smack in the middle of Manhattan, in a lab one block from Central Park's East Meadow. It was the Friday afternoon before Labor Day in 2011, and people were rushing out of the city for a long weekend. Three days earlier, the ferret had been inoculated with a recombinant strain of 1918 influenza, which killed between 20 and 50 million people when it swept through the world at the end of World

War I. To prevent it from sparking another pandemic, 1918 influenza is studied under biosafety level 3 conditions, the second-tightest of biosafety controls available. The researcher at Mount Sinai School of Medicine (now Icahn School of Medicine at Mount Sinai) was wearing protective equipment, including two pairs of gloves. But the ferret bit hard enough to pierce through both pairs, breaking the skin of his left thumb.

Рис.10. Публикация на сайте американской некоммерческой новостной организации The Intercept «В американских биологических лабораториях сотни несчастных случаев остались нераскрытыми для общественности. Часть 2. Эксперименты с катастрофой»



The Intercept

HIGH CONTAINMENT

Lab That Created Ebola Didn't Disclose 'Significant' Research

Photography

Experimenting With Disaster

Part 3

[EXPAND ALL PARTS](#)

In America's biolabs, hundreds of accidents have gone undisclosed to the public.

I

T STARTED WITH a bold idea. "Someone finally convinced me to do something really, really stupid," virologist Ron Fouchier [told Scientific American](#) in 2011. Fouchier, of Erasmus Medical Center in Rotterdam, and another scientist, Yoshihiro Kawaoka of the University of Wisconsin–Madison, had separately tweaked the H5N1 virus — an influenza that primarily infects birds — in a way that made it spread more easily in ferrets. H5N1 is a

prime pandemic candidate, and ferrets are often used as proxies for humans in flu experiments. When word got out that the two scientists were planning to publish papers detailing their experiments, making a blueprint available to the world, the outcry was extreme. The scientists were trying to better understand H5N1 in order to prevent a pandemic, but critics worried that their experiments could instead cause one — or provide would-be bioterrorists with an outbreak manufacturing guide.

Рис.11. Публикация на сайте американской некоммерческой новостной организации The Intercept «В американских биологических лабораториях сотни несчастных случаев остались нераскрытыми для общественности. Часть 3. Эксперименты с катастрофой»

Согласно опубликованной информации на сайте американской некоммерческой новостной организации The Intercept (в ней обзор более 5500 страниц материалов, полученных от Национальных институтов здравоохранения США согласно американскому закону о свободе информации), было выявлено «множество инцидентов и неудач» в ходе исследований в местных лабораториях, большинство из которых связаны со «смертельно опасными вирусами».

В частности, выявлены сотни несчастных случаев, зарегистрированных в биолaborаториях по всей территории Соединенных Штатов за последние восемнадцать лет. Многие инциденты не привели к причинению вреда местным гражданам. Однако, некоторые заканчивались тем, что ученые либо заболели сами, либо подвергали общество потенциальному воздействию пандемических патогенов

В одном из упомянутых случаев аспирант-исследователь Вашингтонского университета в Сент-Луисе (штат Миссури, США) лечила мышь, зараженную вирусом Чикунгунья, и случайно проколола себе иглой палец через два слоя защитных перчаток. Укол не вызвал кровотечения, и поэтому студентка не придавала этому значения и продолжила свой день, не рассказав об этом своим руководителям. В последующие дни она заболела вирусом и только тогда поведала о том, что произошло в лаборатории.

В других установленных случаях выявлено множество неудач: неисправное оборудование; пролитые мензурки; трансгенные грызуны; бегущие по коридору; обезьяна, получившая успокоительное и, придя в сознание, прокусившая руку исследователю.

Как сообщает The Intercept, даже самые защищенные лаборатории не застрахованы от несчастных случаев. Некоторые из выявленных в ходе расследования случаев произошли в лабораториях уровня биобезопасности BSL-3, где должны применяться очень строгие меры предосторожности.

Среди несчастных случаев в американских лабораториях также числятся следующие:

- В 2013 г. исследователь из Университета штата Канзас (Манхэттен, США) уколол палец во время забора анализа крови у курицы, зараженной птичьим гриппом H5N1. Ученый передал использованный шприц ассистенту, который затем вернул его иглой наружу, проткнув перчатки ученого насквозь. Исследователю прописали Тамифлю на одну неделю и велели немедленно сообщить о повышении температуры. Университет штата Канзас не ответил на просьбу прокомментировать ситуацию.

- В период с апреля 2013 по март 2014 гг. Университет Северной Каролины в Чапел-Хилл (США) сообщил о пяти побегах мышей, в том числе одной особи, которая была заражена атипичной пневмонией четырьмя днями ранее.

- In 2013, a researcher at Kansas State University in Manhattan, Kansas, [pricked their finger while drawing blood](#) from a chicken infected with H5N1 avian influenza. The scientist had handed a used syringe to an assistant while trying to get a better grasp of the chicken's jugular vein. The assistant returned it needle side out, piercing through the scientist's gloves. The researcher was prescribed Tamiflu for one week and told to immediately report a fever. Kansas State University did not respond to a request to comment.
- Between April 2013 and March 2014, the University of North Carolina at Chapel Hill [reported five mouse escapes](#), including one of an animal that had been infected with SARS four days earlier. In a letter to NIH, a biosafety specialist argued that the frequency of escapes was due to the "complex research taking place at our institute" rather than a failure of training, noting that several teams at the university use a breed of transgenic mouse known for its unpredictable behavior. After the SARS-infected mouse darted under lab equipment, researchers cornered it with a broom and returned it to its cage. The University of North Carolina did not respond to a request to comment.

Рис. 12. Публикация на сайте американской некоммерческой новостной организации The Intercept о случаях, подтверждающих отсутствие контроля за НИОКР, а также нарушения биобезопасности в США

- В 2018 г. сотрудник Центра оценки и исследований биологических препаратов Управления по контролю качества пищевых продуктов и лекарственных средств США в Силвер-Спринг, штат Мэриленд, заразился инфекцией МРСЗ (Метициллин-резистентный золотистый стафилококк).
- В начале 2020 г. в условиях нехватки респираторов и масок, вызванных пандемией, лаборатория Университета Тафтса (США) проводила эксперименты с вирусом гриппа H3N2 без надлежащего оборудования. Студент пролил пробирку с небольшим количеством вируса, потенциально подвергнув опасности пять человек. Изначально никто не был в масках. H3N2 является вирусом сезонного гриппа и не считается опасным патогеном, но в электронном письме Тафтсу администратор НИИ указал на ряд допущенных ошибок. К ним относятся непредоставление лабораторией средств индивидуальной защиты, отсутствие надлежащих знаков безопасности и неспособность исследователей обратиться за надлежащей медицинской помощью после контакта с вирусом. Администратор НИИ также рекомендовал, чтобы главный исследователь прошел переподготовку. Университет Тафтса отказался от комментариев.

- In 2018, a researcher at the Food and Drug Administration's Center for Biologics Evaluation and Research in Silver Spring, Maryland, [contracted a MRSA infection](#), a condition that can become severe if left untreated, after working with the antibiotic-resistant bacteria MRSA in the lab. The researcher could not recall any mishaps that would have led to infection, a situation that experts say is common with laboratory-acquired infections. The FDA center did not respond to a request to comment.
- In early 2020, amid the shortage in respirators and masks brought on by the pandemic, a lab at Tufts University conducted low-risk experiments with the H3N2 flu virus without proper equipment. A student [spilled a test tube](#) containing a small amount of virus, potentially exposing five people. None were initially wearing masks. (Two later put them on to clean up the spill.) H3N2 is a seasonal flu virus and not considered a dangerous pathogen, but in an email to Tufts, an administrator at NIH highlighted a series of omissions and errors. These included the lab's failure to provide personal protective equipment, a lack of proper safety signage, and the failure of researchers to seek appropriate medical care after being exposed to the virus. The NIH administrator also recommended that the principal investigator be retrained. Tufts declined to comment.

Рис. 13. Публикация на сайте американской некоммерческой новостной организации The Intercept о случаях, подтверждающих отсутствие контроля за НИОКР, а также нарушения биобезопасности в США