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

January 8, 2014

James Turk, M.S., ASP
Biological Safety Officer
University of Wisconsin
30 East Campus Mall
Madison, Wisconsin 53715

Dear Mr. Turk:

Thank you for your November 29, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a November 22, 2013, incident in which a University of Wisconsin researcher was stuck by a microinjector that malfunctioned. According to your report, the researcher was using a microinjector to perform injections on a roundworm. During the injection, pressure built up in the line. When the researcher attempted to remove the glass needle, it shot out of the apparatus and pricked the tip of his finger. As a result, the researcher was potentially exposed to plasmid DNA used for transgene expression in roundworms. The DNA also contained ampicillin resistance genes. The researcher reported to the University of Wisconsin Hospital emergency room for follow up care. At the hospital, the researcher received a tetanus shot and antibiotics.

In response to this incident, the researcher will be retrained in the appropriate use of sharps and in particular, the microinjector. It appears from your response that the BL1 laboratory in which this incident occurred did not have a robust emergency response plan in place. As a result, it appears there was some confusion on the part of the researcher about the risks posed by his research, and hence, how he should have responded to the exposure. Please note that Section IV-B-2-b-(6) of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* requires Institutional Biosafety Committees (IBC) to adopt emergency plans that cover accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research. With this said, it is OBA's expectation that every laboratory conducting research with recombinant or synthetic nucleic acid molecules will have an appropriate emergency response plan in place tailored to the activities in that specific laboratory. We recommend reviewing the existing emergency response plans for this laboratory and amend them as necessary. After the plans have been amended, the members of the laboratory staff should receive training on the plan such that emergencies can be responded to appropriately.

No further information regarding this incident is requested at this time. You may 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

cc: Judith Kimble, Ph.D., Principal Investigator, University of Wisconsin
Daniel Uhlrich, Ph.D., Associate Vice Chancellor for Research Policy, University of Wisconsin
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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January 8, 2014

Despina Felis, M.S., RBP
Biosafety Officer
Boston Children's Hospital
300 Longwood Avenue
Boston, MA 02115

Dear Ms. Felis:

Thank you for your October 15, 2013, and November 5, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an October 14, 2013, incident in which a Boston Children's Hospital employee stuck her finger with a syringe containing a human cell line transfected with a viral vector containing Sendai virus. According to your report, the injury occurred as the researcher was attempting to recap the syringe. Immediately following the needlestick, the researcher washed her finger with soap and water and reported to the Boston Children's Hospital Occupational Health Services for medical evaluation.

In response to this incident, the Boston Children's Hospital biosafety officer retrained the researcher on the appropriate use of sharps. In addition, it was decided by the Institutional Biosafety Committee that the procedure being performed did not require the recapping of syringes, and the practice should be discontinued.

The Boston Children's Hospital response appears appropriate. No further information regarding this incident 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

cc: William Lorenzen, Radiation Safety Officer, Boston Children's Hospital
Simon Dove, Ph.D., Professor of Pediatrics, Boston Children's Hospital
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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January 8, 2014

Kalpana Rengarajan, Ph.D., M.P.H., RBP
Biosafety Officer
Emory University
1762 Clifton Road NE, Suite 1200
Mailstop 0940-001-1AB
Atlanta, GA 30322

Dear Dr. Rengarajan:

Thank you for your October 22, 2013, and November 18, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an October 22, 2013, incident in which a postdoctoral fellow stuck herself with a syringe containing AAV-9 tagged with a green fluorescent protein. The incident occurred as the fellow was inserting a catheter into the spinal canal of a rat. When the fellow inserted the needle into the catheter, the needle went through the tube and stuck her finger. Immediately following the incident, the fellow washed the wound site with soap and water and sought medical treatment at the Emory University Employee Health Services. The fellow received a tetanus shot, but no additional medical treatment was deemed necessary.

In response to this incident, the laboratory will switch to blunt tipped needles. Additionally, the use of forceps will be required when performing a catheterization. These changes have been incorporated into the policies and procedures manual of the laboratory.

The Emory University response to this incident appears appropriate. We require no additional information 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: Kris West, J.D., M.S. Associate Vice President, office of Research Compliance, Emory University
Gary Miller, Ph.D., Institutional Biosafety Committee Chair, Emory University
Nicholas Boulasi, M.D., Ph.D., associate Professor of Neurosurgery, Emory University
Patty Olinger, RBP, Director, Environmental Health and Safety Office, Emory University
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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January 13, 2014

Angela Birnbaum, M.P.H., RBP
Senior Biosafety Officer
Harvard University
46 Blackstone Street
Cambridge, MA 02139

Dear Ms. Birnbaum

Thank you for your November 14, 2013, and December 6, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a November 11, 2013, incident in which a researcher at Harvard University stuck herself with a syringe containing transformed HEK-203 cells. According to your report, the researcher was adding cell lysate to a tube containing the HEK-293 cells when she noticed a clog in the needle. She removed the needle from the tube to clear the clog, and upon reinserting the needle, stuck herself in the finger. Immediately following the incident, the researcher cleaned the wound site for 15 minutes with soap and water. She then sought medical attention at the Harvard University Health Services. After reviewing the circumstances of this incident, the occupational health physician considered it a low-risk exposure, and determined that further treatment was not necessary.

In response to this incident, the laboratory will eliminate the use of sharps for this procedure. In addition, the use of a separating column will be employed for all actions that involve the lysing of cells.

The Harvard University response to this incident appears appropriate. We require no additional information 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: Rebecca Caruso, M.P.H., Associate Director, Biological Safety Office,
Harvard Medical School
Susan Westmoreland, V.M.D., Acting Chair, Division of Comparative Pathology,
New England Primate Research Center
R. Paul Johnson, M.D., Interim Director, New England Primate Research Center
Alexander McAdam, Chair, Committee on Microbiological Safety, Harvard Medical School
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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January 13, 2014

Nanette Moss, M.S., CIH
Biosafety Officer
Harvard Medical School
77 Avenue Louis Pasteur
Boston, MA 02115

Dear Ms. Moss:

Thank you for your December 2, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a November 26, 2013, incident in which a researcher at Harvard Medical School stuck herself with a syringe containing blood from a mouse that was previously administered lymphocytic choriomeningitis virus (LCMV).

According to your report, the researcher was harvesting lymphoid organs from a mouse and was using a needle to pin down its paws onto a dissection board. The incident occurred at the end of the procedure when the researcher was removing the needle. The mouse had been administered the recombinant LCMV twelve days earlier. The LCMV strain was engineered to express a red fluorescence protein. Immediately following the incident, the researcher performed first aid measures then went to the Harvard University Health Services for medical treatment. An acute serum for LCMV was drawn. The researcher was educated on the symptoms of LCMV infection and provided with a phone number to call if symptoms developed. The researcher is not immunocompromised or pregnant. A subsequent serum draw was scheduled for one month post-exposure.

In response to this incident, the procedures for appropriately securing research animals for dissection, was reviewed with the researcher. To prevent further incidents of this nature from reoccurring, the biosafety officer has discussed alternative practices with the principal investigator for securing mice during dissection, including the use of solid plastic boards with laboratory tape so that sharps would not be necessary.

The Harvard Medical School response to this incident appears appropriate. We require no additional information 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: Rebecca Caruso, M.P.H., Associate Director, Biological Safety Office,
Harvard Medical School
Ulrich Von Andrian, M.D., Professor of Immunopathology, Harvard Medical School
Timothy Gondre-Lewis, Ph.D., Program Officer, NIAID
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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January 14, 2014

Juan Sanchez, Ph.D.
Vice President for Research
FAC 29, Suite 426
P.O. Box 7996, G1400
The University of Texas at Austin
Austin, TX 78713-7996

Dear Dr. Sanchez:

Thank you for your November 22, 2013, initial notification and January 2, 2012, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a laboratory worker was exposed to recombinant *Vibrio cholera*.

From your report, we understand that the laboratory worker was closing the lid on a tube containing the *V. cholera* when she felt a splash hit her eye. Although the individual was wearing gloves and a laboratory coat, eye protection was not being worn at the time of the incident. The employee immediately stopped work, rinsed the eye, and was evaluated by staff in the Occupational Health Program (OHP). OHP referred the employee to a clinic where she was prescribed an antibiotic. In response to this incident, laboratory staff has been retrained on the use of appropriate personal protective equipment, including eye and face protection, when manipulating pathogens.

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

Sincerely,

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

Cc: Dennis Nolan, Biological Safety Officer, University of Texas at Austin
Alan Lloyd, Chair, Institutional Biosafety Committee, University of Texas at Austin
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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January 14, 2014

Matthew Anderson, Ph.D.
Biosafety Officer
Environmental Health and Safety
University of Nebraska – Lincoln
3630 East Campus Loop
Lincoln, NE 68583-0824

Dear Dr. Anderson:

Thank you for your December 17, 2013, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to Section III-D-1-a of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) was conducted without submission of a protocol registration for review and approval by the University of Nebraska – Lincoln Institutional Biosafety Committee (IBC).

In response to this incident, the investigator was sent a letter from the IBC detailing his responsibilities under the *NIH Guidelines* and was instructed to stop all recombinant work until IBC approval was obtained. The investigator has submitted a registration to the IBC that was expected to be reviewed by the committee at its January 13, 2014 meeting. The investigator and his laboratory staff will be required to take *NIH Guidelines* training as a condition of any IBC approval that is granted for the work.

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

Sincerely,

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

Cc: Regina Werum, Ph.D., Associate Vice Chancellor for Research, University of Nebraska – Lincoln
Amit Mitra, Ph.D., IBC Chair, University of Nebraska – Lincoln
Brenda Osthus, Director, Environmental Health and Safety, University of Nebraska – Lincoln
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
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January 14, 2014

Stacey A. Kraemer, Ph.D., CBSP
Biosafety Officer
Office of Environment, Health and Safety
University of California Los Angeles
501 Westwood Plaza, 4th Floor
Los Angeles, CA 90095-1605

Dear Dr. Kraemer:

Thank you for your December 17, 2013, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to Section III-D-1-a of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) was conducted without submission of a protocol registration for review and approval by the University of California, Los Angeles Institutional Biosafety Committee (IBC).

From your report, we understand the work was being conducted by a postdoctoral fellow who mistakenly believed that a previous IBC approval obtained for the same research while working in the laboratory of another investigator was sufficient. In response to this incident, all work that had not been reviewed and approved by the IBC in accordance with the *NIH Guidelines* has been suspended. A registration has been submitted to the IBC and is expected to be reviewed by the committee at its January 16, 2014, meeting.

No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Alyse DiStefano, IBC Administrator, University of California, Los Angeles
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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January 14, 2014

Eric Stefansson
Biosafety Programs Manager
Research and Occupational Safety
University of Washington
Environmental Health and Safety Department
201 Hall Health Center
Mail Stop: 354400
Seattle, WA 98195-4400

Dear Mr. Stefansson:

Thank you for your November 27, 2013, initial notification and December 27, 2013, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a laboratory worker was exposed to vesicular stomatitis virus (VSV) expressing simian immunodeficiency virus (SIV) proteins.

From your report, we understand that a research scientist sustained a needlestick while removing a needle from a blood collection tube holder after drawing blood from a macaque that had previously been vaccinated with the recombinant VSV and then challenged with SIV. The individual was wearing appropriate personal protective equipment, including double gloves, coveralls, face shield, and surgical mask at the time of the incident.

Immediately following the injury, the individual stopped work, washed the wound for 15 minutes, went to the and emergency room, and was administered a single dose of post-exposure prophylaxis (Truvada for SIV exposure). The individual was also seen by a virologist five days after the incident as part of standard exposure incident follow-up.

In response to this incident, all staff have been retrained in the procedure to discard intact blood collection tube holders with the syringe attached immediately after a single use.

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

Sincerely,

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

Cc: Katia Harb, Assistant Director, Environmental Health and Safety, University of Washington
David Emery, Ph.D., IBC Chair, University of Washington
Jude Van Buren, Dr.P.H., M.P.H., Director, Environmental Health and Safety, University of Washington
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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January 14, 2014

Eric Stefansson
Biosafety Programs Manager
Research and Occupational Safety
University of Washington
Environmental Health and Safety Department
201 Hall Health Center
Mail Stop: 354400
Seattle, WA 98195-4400

Dear Mr. Stefansson:

Thank you for your October 30, 2013, initial notification and November 26, 2013, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a laboratory worker sustained a needlestick injury while injecting replication competent Herpes Simplex Virus (HSV) 1 expressing thymidine kinase and td-Tomato into an anesthetized transgenic mouse.

From your report, we understand that the employee was performing a whisker pad injection when her hand slipped and she stuck her finger. Immediately following the injury, the individual scrubbed the wound with soap and water for 15 minutes. The employee notified her supervisor and also called the Employee Health Center who advised her to monitor the wound. Several days later the employee observed swelling and a vesicle at the injury site. She was examined at the Employee Health Center and was referred for PCR, culture, and blood testing. The results of the all tests PCR, culture, and serology, were positive for HSV. The employee was prescribed topical antiviral treatment and will have follow-up serological testing.

In response to this incident, the IBC suspended the research because the IBC registration had incorrectly identified the agent as replication incompetent. The investigator must resubmit an IBC application with the correct information for IBC review. In addition, the attending veterinarian has reviewed safe injection and sharps procedures with the employee.

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

Sincerely,

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

Cc: Katia Harb, Assistant Director, Environmental Health and Safety, University of Washington
David Emery, Ph.D., IBC Chair, University of Washington
Jude Van Buren, Dr.P.H., M.P.H., Director, Environmental Health and Safety, University of Washington
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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January 16, 2014

Bruce J. Brown, M.P.H., CBSP
Director, Environmental Health and Safety
University of Texas Health Science Center at Houston
1851 Crosspoint Ave
OCB 1.330
Houston, TX 77054

Dear Mr. Brown:

Thank you for your December 6, 2013, and December 12, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a December 3, 2013, incident in which a research assistant cut her finger while cleaning a cryostat that had been used to slice tissue samples taken from a rat that had been administered human mesenchymal embryonic stem cells (MESC) transduced with a lentiviral vector. According to your report, the incident occurred because the research assistant failed to remove the blade from the cryostat before beginning the disinfection process. Due to the depth of the cut, the research assistant immediately went to the occupational health center for treatment. At the occupational health center, the wound was cleaned and the research assistant received stitches. The occupational health physician took a baseline blood draw and a follow-up blood draw was scheduled for June 2014.

After reviewing the circumstances of this incident, it was determined by the biosafety staff that a lack of concentration on the part of the research assistant led her to forget to remove the blade of the cryostat before beginning disinfection. In order to prevent this from reoccurring, a sign will be placed on the cryostat instructing the user that the blade must be removed prior to any disinfection.

While reviewing this incident, the biosafety staff noted that the laboratory was approved to use a murine retrovirus, but not the lentivirus used to transduce the MESC. As a result the principal investigator was instructed to stop the research involving lentivirus vectors, and add an amendment to his Institutional Biosafety Committee registration. This amendment will be reviewed by the IBC at its January 2014 meeting.

The University of Texas Health Science Center at Houston response to this incident appears appropriate. We require no additional information 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: Robert Emery, Dr.P.H., Vice President of Safety, Health, Environment and Risk Management
University of Texas Health Science Center at Houston
Rachel Gamble, Safety Specialist, University of Texas Health Science Center at Houston
Brett Haltiwanger, Ph.D., Safety Specialist, University of Texas health Science Center at Houston
Yong Li, Ph.D., M.D., Associate Professor, Department of Pediatric Surgery
University of Texas Health Science Center at Houton
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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January 16, 2014

W. Dean Rupp, Ph.D.
Chairperson, Institutional Biosafety Committee
Yale University
135 College Street, Suite 100
New Haven, CT 06510

Dear Dr. Rupp:

Thank you for your October 21, 2013, and November 4, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an incident in which a principal investigator (PI) failed to notify the Yale University Institutional Biosafety Committee that he had initiated an experiment subject to Section III-E-1 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*).

According to your report, the PI was maintaining approximately 8 percent of the HIV genome in cell culture. The PI mistakenly thought this research was exempt under Appendix C-I of the *NIH Guidelines*. The PI did not understand that this exemption does not apply to RG3 agents. When the Yale Environmental Health and Safety Office learned of this, they ordered the research be halted. The PI was required to submit an IBC registration for the research, which was reviewed at the October 2013 IBC meeting.

In response to this incident, the Yale biosafety officer met with the PI to review the requirements of the *NIH Guidelines* and the necessity of registering research with the IBC. The laboratory staff were also retrained on the requirements of the *NIH Guidelines*.

The Yale University response to this incident appears appropriate. We require no additional information 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc Benjamin Fontes, Biological Safety Officer, Yale University
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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January 16, 2014

L. William Cashdollar, Ph.D.
Biosafety Officer
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226-0509

Dear Dr. Cashdollar:

Thank you for your December 20, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a December 19, 2013, incident in which a graduate student at the Medical College of Wisconsin scratched his finger on a screw top used to secure a culture tube containing a recombinant form of *Borrelia burgdorferi.*

According to your report, the student was in the process of examining cultures of tissue harvested from mice that had been administered *B. burgdorferi* two weeks earlier. This recombinant strain of *B. burgdorferi* was not infectious in mice, but used to generate a targeted mutation in which single chromosomal gene had been replaced by an antibiotic resistance cassette. Towards the end of the experiment, the student noticed he was bleeding from a scrape on his finger. The student assumed the scrape came from handling the striations on the screw top of the culture tube. The student washed his hands with soap and water for approximately five minutes, put on gloves and completed the experiment. The student then contacted the laboratory principal investigator (PI) to report the incident. At the time of the incident, the Medical College of Wisconsin Occupational Health Services was closed. Taking into account that the agent involved in this incident does not cause lethal disease and is treatable, the PI instructed the student to report to the Occupational Health Services early the next morning. That following day, the student consulted with the occupational health physician who recommended a post-exposure treatment plan. The incident was determined to be a low-risk potential exposure as it was unlikely the student touched any of the culture.

In your report, you state that the student involved in this incident was not wearing gloves. Furthermore, you state that the laboratory in question has a policy which describes the use of gloves as optional when handling strains not known to be infectious in mice. Your report states that this policy will be reviewed in the course of the investigation of this incident. The Medical College of Wisconsin policy of allowing researchers the option of not using gloves is not in keeping with the requirements of Appendix G-II-B-2 of the *NIH Guidelines for Research*

Involving Recombinant or Synthetic Nucleic Acid Molecules. It is OBA's expectation that all researchers working under BL2 containment will wear the appropriate personal protective equipment, including gloves. In addition, the Medical College of Wisconsin response to this incident did not include any details regarding the steps that will be taken to prevent these types of incidents from reoccurring.

Based on the information in your report, we cannot conclude whether the Medical College of Wisconsin response to this incident was appropriate. Please provide OBA with a plan for how the Medical College of Wisconsin will ensure that all researchers working under BL2 containment conditions will wear gloves. Additionally, provide us with information on what actions the Medical College of Wisconsin is taking to preclude these types of incidents from reoccurring. Please provide this information no later than **February 5, 2014**.

If you have any questions, 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: Rebecca Seevers, CIH, Director, Environmental Health and Safety, Medical College of Wisconsin
David Gutterman, M.D., Senior Associate Dean for Research, Medical College of Wisconsin
Dara Frank, Ph.D., Professor of Microbiology, Medical College of Wisconsin
David Wilcox, Ph.D., IBC Chair, Medical College of Wisconsin
Jenifer Coburn, Ph.D., Professor of Medicine, Medical College of Wisconsin
Joseph Breen, Ph.D., Program Officer, NIAID, NIH
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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January 24, 2014

Eric Stefansson
Biosafety Programs Manager
Research and Occupational Safety
University of Washington
Environmental Health and Safety Department
201 Hall Health Center
Mail Stop: 354400
Seattle, WA 98195-4400

Dear Mr. Stefansson:

Thank you for your December 6, 2013, initial notification and January 16, 2014, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a veterinary technician was received a deep cut from an intravenous (IV) injection needle that had been used in a lentivirus-infected macaque.

From your report, we understand that the injury occurred while administering propofol to the animal through an IV route. The animal had been sedated with ketamine, but was still moving and pulled out the IV needle during the supplemental propofol injection. The individual was wearing appropriate personal protective equipment, including gloves, coveralls, eye protection, and surgical mask at the time of the incident.

Immediately following the injury, the individual cleaned the wound and went to the University of Washington Medical Center emergency room for follow up care. At the emergency room, post-exposure prophylaxis was administered. A baseline serology taken on the individual was negative for SHIV and the animal was tested, and found to be negative for simian herpesvirus. The injured individual will have follow up serologies for SHIV at 1, 3, 6, and 13 month intervals post-exposure.

In response to this incident, an alternative drug will be used during the initial sedation procedure if it is known that ketamine is not completely effective with a particular animal. If the animal is still showing significant movement after sedation, the animal will be sedated further with gas anesthetic to completely immobilize it before using a needle for IV propofol administration.

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

Sincerely,

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

Cc: Katia Harb, Assistant Director, Environmental Health and Safety, University of Washington
David Emery, Ph.D., IBC Chair, University of Washington
Jude Van Buren, Dr.P.H., M.P.H., Director, Environmental Health and Safety, University of Washington
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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January 24, 2014

Christine T. McFarland, Ph.D.
Biosafety Officer
Office of Research Compliance and Biosafety
Texas A&M University
750 Agronomy Road, Suite 3501
1186 TAMU
College Station, TX 77843-1186

Dear Dr. McFarland:

Thank you for your November 1, 2013, notification and January 6, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to Section III-D-4 of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) was conducted without approval by the Texas A&M University (TAMU) Institutional Biosafety Committee (IBC).

From your report, we understand that the investigator administered an adeno-associated viral vector construct to a dog. The investigator had received approval for the animal protocol from the TAMU Institutional Animal Care and Use Committee, but the protocol was never reviewed by the IBC.

In response to this incident, the IBC conducted an investigation and also determined that other recombinant work had been conducted without IBC review and approval as required by TAMU policy. Furthermore, research with recombinant materials had taken place in an unapproved and uninspected laboratory space, and the PI had not completed training on the *NIH Guidelines*, which is required at TAMU for all investigators who conduct research subject to the *NIH Guidelines*.

In response to this incident, the PI was instructed not to conduct any further recombinant research in any TAMU laboratory or facility until an IBC registration for all research was submitted, reviewed, and approved by the IBC. In order for approval to be obtained, the IBC will require that all laboratory and animal facilities used for research be inspected for compliance with appropriate biosafety standards. TAMU will also require that the PI, along with all the laboratory personnel, complete appropriate biosafety training.

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

Sincerely,

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

Cc: Garry Adams, D.V.M., Ph.D., Professor, TAMU
Joe Kornegay, Ph.D., Professor, TAMU
Evelyn Castiglioni, Ph.D., Professor, TAMU
Glen Laine, Ph.D., Professor, TAMU
Bhanu Chowdhary, Ph.D., Professor, TAMU
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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January 24, 2014

Stephanie Roberts
Associate Director for Research Compliance
Indiana University-Purdue University Indianapolis
509 E. Third Street
Bloomington, IN 47401

Dear Ms. Roberts:

Thank you for your January 17, 2014, response to our December 19, 2013, letter requesting additional information regarding an incident at Indiana University-Purdue University Indianapolis (IUPUI) in which a research protocol falling under Section III-D-1 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) was incorrectly classified as exempt and was initiated without proper review and approval by the Institutional Biosafety Committee (IBC).

In our letter we asked IUPUI to provide:

- Documentation and a description or examples of training given to IBC members at the time they are appointed to the committee.
- A description or copy of the training that has been provided to IBC members since the July 2013 incident.
- A copy of materials used to train investigators on the review requirements of the *NIH Guidelines*.
- A copy of the current IUPUI IBC registration form.

We have reviewed the documentation you provided and understand that the IBC member training will be updated to reflect the recent expansion in the scope of the *NIH Guidelines*. We also understand that the IBC is in the process of updating the IBC registration document to make it easier for the investigators to complete the form, identify where their research falls under the *NIH Guidelines*, and provide the necessary information required for the IBC to conduct a complete review.

In your letter, you state that at the time the initial submission was made to the IBC for the research that was misclassified, the investigator was not required to take any training on the requirements of the *NIH Guidelines*. We understand that the IBC has since reviewed the requirements for training on the *NIH Guidelines* and has implemented *NIH Guidelines* training for anyone listed on an IBC-registered protocol.

No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Chinghai Kao, Ph.D., IBC Chair, IUPUI
James Klenner, Biological Safety Manager, IUPUI
Eric Swank, J.D., Interim Assistant Vice President for Research, IUPUI
Ruben Vidal, Ph.D., IBC Vice Chair, IUPUI
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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February 3, 2014

Kara Manning Drolet, Ph.D.
Associate Director, Research Integrity Office
Oregon Health and Science University
Mail Code L106RI
3181 SW Sam Jackson Park Road
Portland, OR 97239

Dear Dr. Drolet:

Thank you for your December 27, 2013, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* was conducted without submission of a protocol registration for review and approval by the Institutional Biosafety Committee (IBC). According to your report, the incident involved baculovirus expression in mammalian cells.

In response to this incident, the investigator submitted a protocol modification detailing the recombinant DNA work to the IBC. The protocol was reviewed and approved by the IBC on December 10, 2013. In addition, all personnel working on the project will be required to take training on the responsible conduct of research involving recombinant or synthetic nucleic acid molecules.

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

Sincerely,

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

Cc: Ashlee V. Moses, Ph.D., IBC Chair, Oregon Health and Science University
Eric Gouaux, Ph.D., Oregon Health and Science University
Richard Goodman, M.D., Ph.D., Director, Vollum Institute, Oregon Health and Science University
Daniel Dorsa, Ph.D., Vice President for Research, Oregon Health and Science University
Debra Brickey, Biosafety Officer, Oregon Health and Science University
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
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February 3, 2014

Lydia L. Sohn, Ph.D.
CLEB Chair
Associate Professor
Department of Mechanical Engineering
University of California, Berkeley
Berkeley, CA 94720-1740

Dear Dr. Sohn:

Thank you for your December 11, 2013, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a graduate student sustained a small cut from a broken glass pipette that had been used to aspirate media from HEK293 cells that had been genetically modified with a second generation lentiviral vector.

From your report, we understand that the injury occurred while the graduate student was cleaning up the broken pipette. Immediately following the injury, the individual washed the wound with soap and water. The incident was immediately reported to the supervisor but was not reported to the biological safety officer until the following day, at which time medical attention was sought.

In response to this incident, double gloves will be used for cleaning up broken glass in the future, and an attempt will be made to find an appropriate plastic alternative to the glass aspirator pipettes.

No further information is required at this time. However, in spite of the low risk of exposure, in the event of an injury, medical advice should usually be sought immediately rather than waiting until the following day.

If you have any questions or require further information, please contact OBA staff by email at oba@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Robert Hashimoto, Biological Safety officer, University of California, Berkeley
Brandon Defrancisci, Associate Director for Health and Safety, University of California, Berkeley
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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February 3, 2014

Kathleen Gallagher, B.S., M.S.
Biosafety Officer
IBC – COMS/Harvard
Schepens Eye Research Institute
20 Staniford Street
Boston, MA 02114

Dear Ms. Gallagher:

Thank you for your December 27, 2013, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a research associate sustained a scratch from a needle that had been used to inject a mouse that had previously been administered an AAV vector containing a CMV-GFP insert.

From your report, we understand that the mouse had been administered the AAV vector three weeks earlier, and that the scratch did not draw blood. At the time of the incident, the individual was wearing appropriate personal protective equipment, including gloves, gown, face, and a surgical mask.

Following the injury, the individual washed her hands thoroughly with soap and water, and contacted the occupational health office by telephone. The physician on call determined that the incident was minor and that follow up would only be needed if the tissue became inflamed, which it did not.

The research associate was inexperienced in performing injections and likely did not have a good grip on the mouse. She was also using the same needle repeatedly to perform the peritoneal injections. In response to this incident, an experienced animal handler will now be designated to work with new or less experienced employees until they are cleared by veterinary staff to work on their own. In addition, all staff have been retrained in the requirement that needles not be reused.

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

Sincerely,

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

Cc: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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February 3, 2014

Marshall V. Williams Jr., Ph.D.
Chairperson, Institutional Biosafety Committee
Ohio State University
300 Research Administration
1960 Kenny Road
Columbus, OH 43210-1063

Dear Dr. Williams:

Thank you for your December 3, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an incident in which a principal investigator (PI) failed to obtain Institutional Biosafety Committee approval prior to initiating an experiment subject to Section III-D of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*).

According to your report, the PI submitted an IBC application in October 2013, which was tabled by the IBC due to insufficient information about the use of a lentiviral vector. The IBC asked the PI to provide additional information on the vector. During a laboratory inspection, it was determined that some of the PI's staff were already using the lentiviral vector. When this information was communicated back to the Ohio State University IBC, it ordered that the research be halted. Once again, the PI was required to submit additional information on the lentiviral vector for the IBC to review at its next meeting.

In response to this incident, the IBC Chair met with the PI to reiterate the review requirements of the *NIH Guidelines*. Additionally, an article will be published in a future research newsletter to draw attention to the necessity to register research subject to the *NIH Guidelines*. Finally, Ohio State University Environmental Health and Safety staff will bring a copy of a PI's IBC registration with them to each laboratory inspection. If any discrepancies are found, they will immediately be reported to the IBC.

The Ohio State University response to this incident appears appropriate. We require no additional information 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc Jan Weisenberger, Ph.D., Senior Associate Vice President for Research, Ohio State University
Karen Hale, M.P.H., Director, Office of Responsible Research Practices, Ohio State University
Tina Bogac, M.A., RBP, Institutional Biosafety Officer, Ohio State University
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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February 4, 2014

James Klenner, M.Sc., M.P.H., CBSP, RBP
Biological Safety Officer
Richard Roudebush Veterans Affairs Medical Center
980 Indiana Avenue, Room 4228
Indianapolis, IN 46202

Dear Mr. Klenner:

Thank you for your January 10, 2013, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an incident in which a principal investigator (PI) failed to obtain IBC approval before he initiated an experiment subject to Section III-D of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*).

According to your report, the PI was utilizing plasmid expression vectors subcloned with murine or human serum to transfect kidney cells that were then transplanted back into rats. The research involving animals was performed in a laboratory on the Indiana University-Purdue University Indianapolis (IUPUI) campus, while the *in vitro* work was performed in a laboratory at the Richard Roudebush Veterans Affairs Medical Center (VAMC). The PI never received IBC approval for the *in vitro* portion of the research. The lack of IBC approval was discovered when the VAMC performed a routine audit of laboratory activities. The biological safety officer then informed the PI that the research involving the transfection of kidney cells was subject to the *NIH Guidelines*. The PI was instructed to cease all research with the cell lines until IBC approval was obtained.

In response to this incident, the PI was retrained in his responsibilities under the *NIH Guidelines*. The PI has since received IBC approval from the VAMC IBC for this research. The VAMC response to this incident appears appropriate. We require no additional information 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc Susan Harper, D.V.M., Associate Director, Research Safety& Animal Welfare Program, Department of Veterans Affairs
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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February 13, 2014

Rhonda O'Keefe
Director of Environmental Health and Safety
Broad Institute
7 Cambridge Center, Room7031
Cambridge, MA 02142

Dear Ms. O'Keefe:

Thank you for your January 22, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a December 30, 2013, incident in which a Broad Institute researcher was splashed in the eye with a small amount of protein solution while pipetting. According to your report, the protein lysate had been isolated from a human lung adenocarcinoma cell line. Your report states that any recombinant DNA in the solution would have been in trace amounts. Immediately following this incident, the researcher washed her eye in the eyewash station. She was offered the opportunity to seek medical attention from the occupational health provider, but declined. The Broad Institute biosafety officer confirmed with the occupational health provider that the exposure posed no serious risks.

According to your report, the researcher was not wearing safety goggles when this incident occurred. As a result of this incident, the researcher was retrained on the appropriate procedures regarding personal protective equipment. Goggles will now be worn during all pipetting procedures.

The Broad Institute response to this incident appears appropriate. However, we noted in your report that this incident occurred on December 30, 2013, but was not reported to OBA until January 22, 2014. Please be aware that Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* requires that institutions immediately report to OBA any overt exposure to organisms containing recombinant DNA molecules when research is performed under BL2 conditions.

No further information regarding this incident is requested at this time. If you have any questions or require further information, please contact OBA staff by email at oba@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

cc: David Root, Ph.D., Chair, Broad Institute IBC
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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February 14, 2014

Leslie Hofherr, M.P.H., M.S., CBSP
Director, Partners Institutional Biosafety Committee
1620 Tremont Street, BC3-012.12
One Brigham Circle Building, 3rd Floor
Boston, MA 02120

Dear Ms. Hofherr:

Thank you for your February 3, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing the laboratory acquired infection of a postdoctoral researcher at Massachusetts General Hospital. According to your report, the researcher works with both wild type and genetically modified forms of *Shigella flexneri.* The researcher informed the principal investigator (PI) on January 17, 2014, that she was ill with a high temperature, headache, and loose stools. She then sought medical attention and provided a stool sample for analysis. On January 27, 2014, the stool sample was positively identified as containing an attenuated laboratory strain of *Shigella flexneri* 2457T.

According to your report, the researcher was symptomatic for only two days. By the time the stool sample was identified as containing *Shigella flexneri,* the researcher was no longer experiencing any symptoms. Though asymptomatic, she was treated with a short course of antibiotics given the possibility that she still may have been shedding the bacteria. In consultation with the Massachusetts General Hospital Infection Control and Occupational Health Departments, it was decided that the researcher should not return to work until 72 hours after beginning antibiotic treatment.

At present time, a definitive route of exposure to the attenuated strain of *Shigella flexneri* has not been identified. One potential route of exposure could have been the keyboard the researcher kept on the bench top. It is possible that the researcher touched the keyboard with contaminated gloves and then used the keyboard after removing the gloves. The keyboard has since been removed from the bench top and will not be replaced.

Because there was only one illness in the laboratory, despite the low infectious dose of *Shigella flexneri*, self-inoculation via hand to mouth exposure is suspected. The biosafety officer and the PI reviewed hand hygiene and other preventive measures with the researcher and the other

members of the laboratory. The laboratory workspace, including bench tops and equipment, have been decontaminated. This incident has been reported to the Cambridge Public Health Department, and Massachusetts General Hospital will work with them on any actions they request. The Institutional Biosafety Committee will also be discussing this event at its next meeting.

The Massachusetts General Hospital response to this incident appears appropriate. No further information is required at this time, however, please inform us of any additional actions requested by the Cambridge Public Health Department. If you have any questions, 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: Cammie Lesser, M.D., Ph.D., Principal Investigator, Massachusetts General Hospital
Anne Sallee, RBP, Biosafety Manager, Massachusetts General Hospital,
Jessica Healey, M.S., RBP, Biosafety Officer, Massachusetts General Hospital
Melody Mills, Ph.D., Program Officer, National Institute of Allergy and Infectious Diseases, NIH
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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February 19, 2014

Susan H. Cook, Ph.D., CBSP
Biological Safety Officer
Washington University
Campus Box 8229
660 South Euclid Avenue
St. Louis, MO 63110

Dear Dr. Cook:

Thank you for your February 14, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a February 12, 2014, incident in which a researcher was splashed in the eye with a polymerase chain reaction (PCR) solution containing a recombinant form of *Streptococcus pyogenes*. According to your report, the incident occurred as the researcher was preparing a colony PCR assay. Immediately following the incident, the researcher flushed his eye with water and reported to the Washington University occupational health provider. The researcher received treatment and, to date, there are no signs of infection.

In response to this incident, the principal investigator of the laboratory will retrain the researcher on the appropriate personal protection equipment required for this type of research. The importance of wearing goggles will be emphasized.

The Washington University response to this incident appears appropriate. We require no additional information 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
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February 19, 2014

David D. Gutterman, M.D.
Senior Dean for Research
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226-0509

L. William Cashdollar, Ph.D.
Biosafety Officer
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226-0509

Dear Drs. Gutterman and Cashdollar:

Thank you for your February 4, 2014, response to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) January 16, 2014, letter requesting additional information about an incident involving an exposure to *Borrelia burgdorferi.*

In our letter, we requested information as to how the Medical College of Wisconsin would ensure that all researchers working under BL2 containment conditions wear appropriate personal protective equipment (PPE), specifically gloves. In your response, you provided an excerpt from the Medical College of Wisconsin BL2 manual that states "Gloves are worn when hands may contact potentially infectious or toxic materials, contaminated surfaces, or equipment." In addition, your letter points out that the Medical College of Wisconsin BL2 training module describes the required PPE as including lab coats, gloves, and facial protection.

In response to our letter, the Medical College of Wisconsin is implementing a plan to help ensure that researchers working under BL2 containment conditions wear gloves. As part of this plan, a message will be sent to principal investigators (PI) and their staff emphasizing that research involving recombinant or synthetic nucleic acid molecules must be performed in full compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*). The message will also remind PIs and their staff of the requirements of the Medical College of Wisconsin BL2 research policy. This policy states that gloves are required to be worn when performing BL2 research.

In addition to the above message, the Medical College of Wisconsin will instruct the IBC not to grant approval for a protocol unless the protocol application clearly states that gloves will be worn.

The report you have provided satisfies our request for additional information. No further information about this incident is requested at this time. If you have any questions, 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: Rebecca Seevers, CIH, Director, Environmental Health and Safety, Medical College of Wisconsin
Dara Frank, Ph.D., Professor of Microbiology, Medical College of Wisconsin
David Wilcox, Ph.D., IBC Chair, Medical College of Wisconsin
Jenifer Coburn, Ph.D., Professor of Medicine, Medical College of Wisconsin
Joseph Breen, Ph.D., Program Officer, NIAID, NIH
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
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February 21, 2013

Kalpana Rengarajan, Ph.D., M.P.H., RBP
Biosafety Officer
Emory University
1762 Clifton Road NE, Suite 1200
Mailstop 0940-001-1AB
Atlanta, GA 30322

Dear Dr. Rengarajan:

Thank you for your January 15, 2014, and February 14, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a January 14, 2014, incident in which an Emory University researcher was bitten by a rat that had previously been administered an adenoviral vector in October 2013.

According to your report, the researcher was performing a behavioral test on the rat at the time of the incident. The test called for the rat to be held by the neck while its paw was dragged across a machine to test grip strength. During the test, the rat turned its head and bit the researcher on the hand. The researcher immediately placed the rat back into its cage and washed the wound site for 15 minutes with water, alcohol and betadine. The researcher chose not to seek additional medical attention from the Emory University occupational health provider.

In response to this incident, the Emory University Health and Safety Office (EHSO) ensured that the researcher was current on all Emory University mandated training. The EHSO also recommended that laboratory personnel wear bite resistant gloves, rather than only nitrile gloves, when handling rats. It was also recommended that the laboratory obtain multiple samples of bite resistant gloves to find the brand that works best.

The Emory University response to this incident appears appropriate. No further information is requested 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

Cc: Kris West, J.D., M.S., Associate Vice President, Office of Research Compliance, Emory University
Gary Miller, Ph.D., Chair, Institutional Biosafety Committee, Emory University
Nicholas Boulis, M.D., Ph.D., Associate Professor, Neurosurgery, Emory University
Patricia Olinger, RBP, Director, Environmental Health and Safety, Emory University
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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February 28, 2014

Louis V. Kirchhoff, M.D., M.P.H.
Chair, Institutional Biosafety Committee
Professor of Internal Medicine and Epidemiology
University of Iowa – SW54 GH
Iowa City, Iowa 52242

Dear Dr. Kirchhoff:

Thank you for your February 3, 2014, and February 17, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an incident in which a University of Iowa principal investigator (PI) performed research with a recombinant strain of MERS-CoV without first obtaining Institutional Biosafety Committee (IBC) approval.

On February 3, 2014, the University of Iowa biosafety officer discovered a principal investigator had been conducting experiments with MERS-CoV since September 2013 without IBC approval. At that time, the biosafety officer ordered the PI to halt all research with recombinant MERS-CoV. According to your report, the PI received a bacterial artificial chromosome (BAC) clone from a collaborator in Spain on September 14, 2013. Several days after receiving the BAC, two postdoctoral researchers in the laboratory transformed bacterial cells with the MERS-CoV BAC clone. In November 2013, the postdoctoral researchers constructed MERS-CoV BAC clones into which green and red fluorescent proteins had been inserted. All work with the recombinant MERS-CoV up to this point was conducted in a BL2 laboratory. Concurrent with the publication of the November 2013 *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, which classified MERS-CoV as a risk group 3 agent, the research was transferred to a BL3 laboratory. Research continued in the BL3 laboratory until the biosafety officer contacted the PI on February 3, 2014, with an order to halt the research.

After reviewing the details of this incident, the University of Iowa IBC determined that the PI did not effectively communicate to his staff the importance of first obtaining IBC approval before initiating research. The PI also did not sufficiently review the relevant standard operating procedures with his staff prior to members of the staff using the BL3 facility. In response to this incident, the PI will receive additional monitoring by the IBC during a probationary period. Under the terms of the probation, the PI and his subordinate staff members who work with recombinant DNA, will meet on a monthly basis with the biosafety officer, a member of the

University of Iowa Environmental Health and Safety (EHS) program, and a virologist from the IBC. At these meetings, the PI and his staff will present details about current and proposed recombinant DNA research. The information obtained will then be used to ensure the PI and his staff are performing all recombinant DNA research in accordance with the approval granted by the IBC. The effectiveness of this probationary period will be assessed by EHS staff, and the results will be communicated to the IBC. The IBC will then decide whether the probationary period should continue.

The University of Iowa response to this incident appears appropriate. No further information is requested 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

cc: James C. Walker, Ph.D., Associate Vice President for Research, University of Iowa
Carol A. McGhan, M.P.H., CBSP, Director, Environmental Health and Safety Office, University of Iowa
Stanley Perlman, M.D., Ph.D., Professor of Microbiology, University of Iowa
Haley Sinn, Ph.D., CBSP Biological Safety Officer, University of Iowa
Erik Stemmy, Ph.D., Program Officer, National Institute of Allergy and Infectious Diseases, NIH
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
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February 28, 2014

Nancy Hoe, Ph.D., CBSP
Biosafety Officer
Rocky Mountain Laboratories
903 S. 4th Street
Hamilton, MT 59840

Dear Dr. Hoe:

Thank you for your February 19, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a February 14, 2014, incident in which a Rocky Mountain Laboratories (RML) researcher was bitten by a mouse that had previously been co-infected with a wild type and a recombinant strain of *Borrelia burgdorferi*.

According to your report, the researcher was in the process of transferring a mouse from its cage to a bell jar when the mouse curled up and bit her on the right hand. Immediately following this incident, the researcher placed the mouse back in its cage, removed her gloves, and washed the wound site with soap and water. The researcher then reported this incident to the laboratory principal investigator and sought medical attention at the RML Occupational Medical Services (OMS). After evaluation, the OMS staff provided a topical antibiotic cream to the researcher. Oral antibiotics were not deemed necessary based on the fact that there is no evidence *Borrelia burgdorferi* is secreted through mouse saliva. To date, the researcher has not shown any symptoms of infection.

In response to this incident, the researcher will be retrained on appropriate animal handling techniques. The RML response to this incident appears appropriate. No further information is requested 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, J.D., M.D.
Acting Director
Office of Biotechnology Activities

Cc: Marshall Bloom, M.D., Associate Director for Science Management, RML
Sue Priola, Ph.D., IBC Chair, RML
RADM Deborah Wilson, Dr. P.H., Director, Division of Occupational Health and Safety, NIH
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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March 7, 2014

Bianca Trollinger
Biological Safety Specialist
University of North Carolina
1120 Estes Drive Extension
Campus Box 1659
Chapel Hill, NC 27599-1659

Dear Ms. Trollinger:

Thank you for your February 18, 2014, and February 20, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a February 18, 2014, incident in which a mouse that had been previously administered a recombinant strain of California/04/09 H1N1 escaped from the biosafety cabinet. The incident occurred as a researcher was attempting to weigh the mouse. The mouse was immediately captured by the researcher and euthanized. The personal protective equipment that came into contact with the mouse when it jumped from the biosafety cabinet, as well as the floor of the laboratory, were disinfected with a chlorine dioxide solution. The occupational health provider was notified of the escape and instructed the researcher to self-monitor for flu-like symptoms.

In response to this incident, the principal investigator (PI) will implement a stricter BL2 policy that limits access to research animals to those with sufficient animal handling experience. Researchers will need to exhibit proficiency in a number of different animal handling techniques prior to gaining access to the research animals. After the researchers have mastered the appropriate animal handling techniques, the PI will then give a final approval on whether the researchers can handle animals.

It appears that the University of North Carolina response to this incident was appropriate. No further information is requested at this time. Please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

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

cc: Amy Sims, Ph.D., IBC Chairperson, University of North Carolina
Mary Beth Koza, Director of Environmental Health and Safety, University of North Carolina
Deborah Howard, M.P.H., Biological Safety Officer, University of North Carolina
Mark Heise, Ph.D., Associate Professor, University of North Carolina
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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March 11, 2014

Dorothy Elsaesser, M.S.
Biosafety Officer
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
MLC 7040
Cincinnati, OH 45229-3039

Dear Ms. Elsaesser:

Thank you for your February 10, 2014, and February 24, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a February 6, 2014, incident in which a surgical resident was bitten on the finger by a knockout mouse while attempting to administer an anesthetic. According to your report, the resident was holding the mouse by the tail with one hand, and the scruff of the neck with the other, when the mouse turned and bit her left index finger. Immediately following this incident, the resident washed the wound site with soap and water and applied an alcohol wipe. The resident then reported the injury to the Cincinnati Children's Hospital Medical Center (CCHMC) employee injury hotline. She was told to keep the area clean and watch for any signs of infection.

According to your report, the resident was new to the laboratory and had received animal handling training less than a month prior to this incident occurring. The resident had limited experience working with mice and did not properly secure the mouse by the scruff of its neck. Instead, she secured the mouse's shoulders which allowed the mouse to turn its head and bite her.

CCHMC is taking several steps to ensure these types of incidents do not reoccur. First, the biosafety staff has notified all animal researchers that training on animal handling must be performed with wild type animals in order to reduce the likelihood of an exposure to genetically modified organisms. Second, to assist novice animal handlers, a special restraining device will be made available that will help temporarily immobilize the animal while the injection is being performed. Finally, the CCHMC Office of Research Compliance and Regulatory Affairs has arranged for an animal vivarium to be available for additional bi-weekly, hands-on animal training, when needed.

It appears that the Cincinnati Children's Hospital Medical Center response to this incident was appropriate. No further information is requested at this time. Please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

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

cc: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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March 11, 2014

Sylvia Blondelle, Ph.D.
IBC Chairperson
Sanford-Burnham Medical Research Institute
10901 N. Torrey Pines Road
La Jolla, CA 92037

Dear Dr. Blondelle:

Thank you for your February 25, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a February 21, 2014, incident in which a researcher was splashed in the arm with media from a culture flask containing packaging cells that had been transduced with a lentiviral vector. The spill occurred while the researcher was attempting to collect the viral vector media. The amount of spilled material was estimated to be approximately 10 mL, half of which landed on the researcher's forearm. Since the researcher thought the procedure would be brief, she was not wearing the required laboratory coat and cover sleeves. Immediately following this incident, the researcher removed the clothing that the came into contact with the media and washed the affected area of skin with soap and water for twenty minutes. The researcher then contacted the biosafety officer to report the incident and discuss how to proceed. After consulting with the occupational health provider, it was determined that this was a low risk exposure due to the low chance of skin penetration and the fact that the media contained a virus which targets mouse genes. No additional follow-up care was deemed necessary.

In response to this incident, the employee will attend a one-on-one training on handling viral vectors. This training will be taught by the biosafety officer. In addition, the laboratory principal investigator (PI) has been asked to be more rigorous in the enforcement of the proper personal protective equipment (PPE). Additionally, the PI was reminded that two people should be in the laboratory when high concentrations of viral vectors are being used. The biosafety staff sent a reminder notice to the entire laboratory staff reminding them of the PPE requirements and the requirement of having more than one individual in the laboratory when working with high concentrations vectors.

The Sanford-Burnham Medical Research Institute response to this incident appears appropriate. We require no additional information at this time. Please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

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

cc: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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March 12, 2014

Despina Felis, M.S., RBP
Biosafety Officer
Boston Children's Hospital
300 Longwood Avenue
Boston, MA 02115

Dear Ms. Felis:

Thank you for your February 20, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a February 15, 2014, incident in which a Boston Children's Hospital researcher cut his hand while trying to remove a flask containing *E. coli* Rosetta Strain BL21 from an incubator. The researcher washed the wound site with soap and water, but the bleeding did not stop, so he went to the nearest hospital for treatment. The researcher was treated and put on an antibiotic regimen.

According to your report, the research being conducted at the time of the incident was not reviewed and approved by the Institutional Biosafety Committee (IBC). The researcher was approved to perform research with *E. coli* K-12 and the pET expression system, but not *E. coli* Rosetta strain BL21.

In response to this incident, the researcher was instructed to amend his current registration to include the *E. coli* B strain. The researcher will also be required to retake a training course which includes details on the requirements of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) and the Boston Children's Hospital IBC. Safety training will also be provided to all members of the laboratory staff. This training will reinforce emergency response procedures, personal protective equipment requirements, and the *NIH Guidelines*.

The Boston Children's Hospital response to this incident appears appropriate. No further information about this incident is requested at this time. Please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

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

cc: William Lorenzen, Radiation Safety Officer, Boston Children's Hospital
Simon Dove, Ph.D., Professor of Pediatrics, Boston Children's Hospital
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
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March 14, 2014

Christine T. McFarland, Ph.D.
Biosafety Officer
Office of Research Compliance and Biosafety
Texas A&M University
750 Agronomy Road, Suite 3501
1186 TAMU
College Station, TX 77843-1186

Dear Dr. McFarland:

Thank you for your February 21, 2014, notification and February 28, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a researcher at Texas A&M University was nicked by a needle while injecting a mouse previously infected with *Borrelia burgdorferi.*

From your report, we understand that the researcher was wearing appropriate personal protective equipment at the time of the incident, but as he was injecting the mouse with D-luciferin used for imaging studies, the needle scratched the palm of his hand. It was not clear whether the skin was compromised and the Biological Safety Officer determined that the risk of exposure to anything recombinant was very low. However, as a precaution, the researcher was referred to the Occupational Health Provider who provided Tdap vaccination and post exposure prophylaxis. The researcher is scheduled for a follow-up appointment with the Occupational Health Provider in one month.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Garry Adams, D.V.M., Ph.D., Professor, TAMU
Joe Kornegay, Ph.D., Professor, TAMU
Evelyn Castiglioni, Ph.D., Professor, TAMU
Glen Laine, Ph.D., Professor, TAMU
Bhanu Chowdhary, Ph.D., Professor, TAMU
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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March 14, 2014

Susan Cook, Ph.D., CBSP
Biological and Chemical Safety Officer
Environmental Health and Safety
Washington University in St. Louis
Campus Box 8229
660 South Euclid Avenue
St. Louis, MO 63110

Dear Dr. Cook:

Thank you for your February 13, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a postdoctoral fellow reviewed an eye splash while cleaning apparatus used to filter *Toxoplasma gondii* parasites.

From your report, we understand that the splash occurred while rinsing the equipment. Because the apparatus had been soaking in water for 20 minutes prior to rinsing, the concentration of parasites in the rinse water was likely very low.

In response to this incident, the individual was immediately seen by medical professionals in Occupation Health for post-exposure treatment. Staff from the Environmental Health and Safety Officer will follow-up to re-train the individual on the importance of wearing proper safety equipment, including eye protection, at all times.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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March 14, 2014

Stephen C. Dahl, Ph.D., RBP
Director, Biological Safety
Health, Safety, and Environment
Johns Hopkins Institutions
2024 E. Monument Street, Room B-200
Baltimore, MD 21287

Dear Dr. Dahl:

Thank you for your January 22, 2013, notification and February 12, 2014, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a graduate student at Johns Hopkins University was stuck with a needle contaminated with a WR strain vaccina virus-based vector while attempting to perform a tail-vein injection on a mouse.

From your report, we understand that the incident occurred on December 13, 2013, but the student did not immediately report the incident because she had not depressed the plunger on the syringe and thus thought she had not been exposed. On January 17, 2014, the incident was brought to the attention of the Biological Safety Office after the student sought medical care for pustules that appeared at the injury site. The student has subsequently made a full recovery` from the infection.

In response to this incident, the student will receive additional training on the correct technique for mouse tail-vein injection, and has been retrained on the proper response to exposure incidents. In addition, the principal investigator of the laboratory has incorporated safety discussions into scheduled laboratory meetings. The Office of Health, Safety and Environment is planning to increase awareness throughout the campus by posting materials in laboratories about safe sharps handling and the proper procedures to follow in the event of a spill or exposure.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
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March 14, 2014

Lydia L. Sohn, Ph.D.
CLEB Chair
Associate Professor
Department of Mechanical Engineering
University of California, Berkeley
Berkeley, CA 94720-1740

Dear Dr. Sohn:

Thank you for your January 16, 2014, notification and March 6, 2014, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a postdoctoral researcher at the University of California, Berkeley was potentially exposed to *Mycobacterium marinum*.

From your report, we understand that the researcher pricked his gloved thumb while unsheathing a clean needle. Although the needle was clean, the researcher had been handling cultures of *M. marinum* for about an hour prior to the injury, so there was a possibility that the gloves were contaminated. The researcher immediately washed the injury with soap and water. A physician at the occupational health clinic later evaluated the injury.

No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Robert Hashimoto, Biological Safety Officer, University of California, Berkeley
Brandon Defrancisci, Associate Director for Health and Safety, University of California, Berkeley
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
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March 14, 2014

Beverly Harding, MSL
Director, IBC Office
University of Pittsburgh
Suite 202
3500 Fifth Avenue
Pittsburgh, PA 15213

Dear Ms. Harding:

Thank you for your December 5, 2013, notification and March 11, 2014, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a staff member at the University of Pittsburgh sustained a needle stick injury while performing minor surgery on a non-human primate that had previously been administered a synthetic clone of SIV (smmFtq).

For your report, we understand that the employee was injured while performing a non-research related procedure related to the care of the animal. Immediately following the injury, she scrubbed the area for 15 minutes and then went to Employee Health Services. She was prescribed Truvada (200mg SID) and Valacyclovir (1 gram TID). We also understand that the virus clone that had been administered to the animal is highly susceptible to the antiretroviral drugs present in Truvada. The Institutional Biosafety Committee reviewed the incident and determined appropriate safety practices were in place and personal protective equipment was been worn at the time the event occurred.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Molly Stitt-Fischer, Ph.D., Biosafety Officer, University of Pittsburgh
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH

Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
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March 14, 2014

Colleen Driskill, RBP
Senior Biosafety Officer
Environmental Health and Safety
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

Dear Ms. Driskill:

Thank you for your February 1, 2014, notification and February 24, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a researcher at the University of Massachusetts Medical School (UMMS) sustained a needle stick injury while conducting research subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*).

From your report, we understand that needle had been used to disrupt cells of Ampicillin-resistant *E. coli* (Rosetta strain). The needle was used in deviation from normal procedure because the sonicator normally used for the procedure was not functioning properly. Immediately following the injury, the wound was washed with soap and water, iodine, and 70% alcohol. The finger began to swell overnight, and the swelling progressed to the knuckle the following day, at which time the researcher reported to the Emergency Department. An antibiotic known to have activity against the bacteria was prescribed, and the swelling resolved.

In response to this incident, biosafety safety staff informed the researcher of the importance of immediate reporting of injuries. The sonicator was repaired, and the Principal Investigator has instructed his laboratory staff to limit the use of needles.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Charleen Sotolongo, M.S.P.H., Director, Environmental Health and Safety, UMMS
Thomas Greenough, M.D., Associate Professor of Medicine, UMMS
Samuel Varghese, Ph.D., IBC Director, UMMS
Danielle Connolly, Safety Associate, UMMS
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
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March 16, 2014

Christine T. McFarland, Ph.D.
Biosafety Officer
Office of Research Compliance and Biosafety
Texas A&M University
750 Agronomy Road, Suite 3501
1186 TAMU
College Station, TX 77843-1186

Dear Dr. McFarland:

Thank you for your March 4, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a researcher at Texas A&M University was bitten by a mouse that had previously been infected with *Borrelia burgdorferi*.

From your report, we understand that the researcher was bitten as he attempted to restrain the animal. All appropriate personal protective equipment was being worn and there was no deviation from animal handling SOPs. We also understand that the individual who was bitten also recently sustained a needlestick injury while injecting a mouse infected with *B. burgdorferi*. That incident was reported to us on February 21, 2013, and we responded to that report in a separate letter dated March 14, 2014.

The individual involved in both incidents has experience working with animals, however given that two incidents occurred in a short time span, the researcher will complete a hands-on refresher training on rodent handling. The individual was again evaluated by the Occupational Medical Provider, but as the chance of infection from a bite is very small (*B. Burgdorferi* is not found in saliva), and the he was still completing antibiotic treatment from the previous exposure, no further treatment was recommended. The researcher was asked to return to the Occupational Medical Provider in two weeks for a final follow-up visit.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Garry Adams, D.V.M., Ph.D., Professor, TAMU
Joe Kornegay, Ph.D., Professor, TAMU
Evelyn Castiglioni, Ph.D., Professor, TAMU
Glen Laine, Ph.D., Professor, TAMU
Bhanu Chowdhary, Ph.D., Professor, TAMU
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
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March 19, 2014

Benjamin Fontes
Biosafety Officer
Environmental Health and Safety
Yale University
135 College Street, Suite 100
New Haven, CT 06510

Dear Mr. Fontes:

Thank you for your November 7, 2013, notification and March 3, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident at Yale University in which a primary centrifuge tube broke and released approximately 22 ml of solution containing a defective lentiviral vector inside the centrifuge rotor. The resultant leakage caused a slight imbalance during the two-hour centrifuge run at 40,000G.

From your report, we understand that upon discovering the breakage of the tube, laboratory staff immediately closed and shut off the centrifuge and the Environmental Health and Safety (EHS) staff were notified. EHS staff responded wearing appropriate personal protective equipment to clean up and decontaminate the equipment.

In response to this incident, the centrifuge rotor was returned to the manufacturer for a detailed evaluation. The investigation resulted in the following determinations:

- The failure of the primary centrifuge tube was likely due to it being weakened by repeated autoclaving and reuse. It has subsequently been determined that tubes should be retired after five to seven uses to minimize the chance of failure.
- There is a possibility that the leakage and imbalance of the rotor for 2 hours at 40,000G could have led to the release of contents from the sealer rotor. The rotor was tested for biocontainment by the Health Protection Agency of Porton Down in the UK, and an inspection of the rotor and O-ring seal determined they were in good visual shape.

The laboratory will now use the centrifuge tubes a maximum of five times in keeping with the manufacturer's recommendations. Yale University has arranged for the centrifuge manufacturer to hold a centrifuge maintenance and safety clinic for laboratory staff.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: W. Dean Rupp, Ph.D., IBC Chair, Yale University
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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March 19, 2014

Mark Robbins
Biological Safety Officer
University of South Carolina
715 Sumter Street
Coker Life Sciences 611
Columbia, SC 26208

Dear Mr. Robbins:

Thank you for your January 18, 2014, and February 24, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a January 16, 2014, incident in which a researcher stuck himself with a syringe containing a third generation lentiviral vector expressing microRNA. According to your report, the researcher was performing several microinjections of lentiviral vector solution into the brains of rats. After injecting two microliters of lentiviral vector solution into one of the rats, the researcher cleaned the syringe and needle with a saline solution in preparation for the next injection. When the researcher was ready to perform the next injection, he stuck himself in the finger with the previously cleaned syringe.

Immediately following the incident, the researcher washed the wound site with soap and water and squeezed blood from the injured finger for approximately four minutes. He then bandaged the wound and reported to the emergency department of the local hospital for evaluation. Based on the information the researcher provided to the healthcare providers, it was determined that no medical treatment was necessary.

In response to this incident, the standard operating procedures (SOP) for administering lentiviral vectors in animals was updated to include more detailed information regarding appropriate techniques for performing stereotactic injections. The laboratory SOP was also revised to provide additional information regarding sharps management and incident reporting. The Institutional Biosafety Committee (IBC) also suspended the principal investigator's authorization to perform stereotactic injections until an in-person consultation by the biological safety officer has been conducted to ensure the new SOPs are appropriate. Finally, the IBC has recruited a new member with experience in viral vector research who will be able to provide additional expertise to the committee.

The University of South Carolina response to this incident appears appropriate. We require no additional information at this time. Please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

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

cc: Thomas Syfert, CHMM, Associate Vice President, Environmental Health and Safety, University of South Carolina
Thomas Coggins, Director of Pre-Award Services, University of South Carolina
Jun Zhu, Ph.D., Assistant Professor of Pharmaceutical and Biomedical Sciences, University of South Carolina
Lydia Matesic, Ph.D., Associate Professor of Biological Sciences, University of South Carolina
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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March 27, 2014

Kara Manning Drolet, Ph.D.
Associate Director
Office of Research Integrity
Oregon Health and Science University
3181 SW Sam Jackson Park Rd
Mail Code L106RI
Portland, OR 97239

Dear Dr. Drolet:

Thank you for your March 12, 2014, response to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) February 20, 2014, request for more information regarding an incident in which a principal investigator (PI) at Oregon Health & Science University (OHSU) failed to obtain Institutional Biosafety Committee (IBC) and OBA approval prior to initiating an experiment involving a replication-defective adenoviral vector expressing a gene from *Variola major*, a restricted agent under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*)

In our letter, we requested that OHSU provide us with information as to how the OHSU IBC will ensure that future research with restricted agents will not be conducted prior to obtaining OBA approval. Additionally, we requested that the IBC be retrained on its responsibilities under Section III-D of the *NIH Guidelines.* Finally, we requested details on how the PI involved in this incident would be retrained with respect to his responsibilities under the *NIH Guidelines*.

According to your report, OHSU has made several revisions to its IBC registration form to help ensure that research with restricted agents is not initiated until OBA approval has been obtained. First, a new question was added to the registration form asking whether OBA approval for the proposed experiment was required. The section of the form asking about DNA inserts was also revised to include language that states that the use of restricted agents requires OBA approval. Both of the amended sections link to a newly developed fact sheet that describes the types of experiments that require OBA approval.

To retrain the OHSU IBC on its responsibilities, several changes were made to existing training documents. The sheet provided to IBC members that describes research subject to Section III-D of the *NIH Guidelines* has been expanded to give more specific information about research subject to Sections III-D-1 through III-D-7. The revised reviewer sheet will be used to retrain IBC members at an upcoming IBC meeting. These training documents will also be added to the new IBC member orientation packet and highlighted when a new member joins the committee.

The revised IBC registration form and the revised IBC review sheet will also be provided to the PI for retraining purposes. An email will be sent to all OHSU PIs with information on how to access the new training materials. The materials will also be posted on the IBC's webpage. Finally, an email will be sent to all PIs utilizing pox-related agents, which will describe what types of research involving restricted agents requires OBA approval. OHSU will require each investigator to respond to the email as confirmation that they have read and understood its contents.

The information you have provided satisfies OBA's request for information. No additional information is requested at this time. If you have any questions, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

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

cc Daniel Dorsa, Ph.D., Vice President for Research, OHSU
Ashlee V. Moses, Ph.D., Chair, Institutional Biosafety Committee, OHSU
Klaus Frueh, Ph.D., Principal Investigator, OHSU
Jay Nelson, Ph.D., Director, Vaccine and Gene Therapy Institute, OHSU
DEBRA Deborah Brickey, Ph.D., Biosafety Officer, OHSU
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
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March 27, 2014

Fred L. Homa, Ph.D.
IBC Chair
University of Pittsburgh
515 Bridgeside Point II
450 Technology Drive
Pittsburgh, PA 15219-3143

Molly Stitt-Fischer, Ph.D., CPH
Biosafety Officer
University of Pittsburgh
3412 Forbes Avenue
Pittsburgh, PA 15260

Beverley Harding, M.S.L.
Director, IBC Office
University of Pittsburgh
Heiber Building
Suite G1
3500 Fifth Avenue
Pittsburgh PA 15213

Dear Drs. Homa and Stitt-Fischer and Ms. Harding:

Thank you for your March 12, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an incident in which a principal investigator (PI) at the University of Pittsburgh performed research subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) without Institutional Biosafety Committee (IBC) approval.

According to your report, the PI previously had an IBC approved registration to operate a tissue culture core facility. However, the registration for that protocol had expired in 2012 without being renewed. When the University of Pittsburgh IBC learned that research with recombinant or synthetic acid molecules was occurring in the core, they contacted the PI and ordered that the research be halted. The PI stopped the research and explained to the IBC that the core does not directly manipulate organisms containing recombinant DNA, but rather grows existing recombinant cell lines or viruses containing transgenes.

In response to this incident, the University of Pittsburgh IBC required the PI to submit a new application for IBC review and approval prior to any research with recombinant or synthetic nucleic acid molecules resuming. Additionally, the IBC required the PI to submit a corrective action plan detailing how future non-compliance will be avoided. The IBC also requested that the PI provide the Committee documentation listing all of the recombinant viral stocks and vectors that were used in the laboratory since the protocol was terminated in 2012. Finally, the PI and his laboratory staff will take an IBC-mandated training course which will include information on PI responsibilities under the *NIH Guidelines* as well as information regarding which type of research requires IBC review and approval. No research involving recombinant or synthetic nucleic acid molecules will be allowed to take place in the laboratory until the IBC approval has been obtained, and all members of the laboratory have taken the IBC-mandated training.

The University of Pittsburgh response to this incident appears appropriate. No further information regarding this incident is requested at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

cc: James Funderburgh, Ph.D., Professor of Ophthalmology, University of Pittsburgh
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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March 27, 2014

Ellyn Segal, Ph.D.
Biosafety Manager
Stanford University
480 Oak Road
Stanford, CA 94305-8007

Dear Dr. Segal:

Thank you for your February 18, 2014, and March 11, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a February 15, 2014, incident in which a Stanford University researcher was stuck by a needle containing human foreskin fibroblasts that had been transduced with *Toxoplasma gondii*. According to your report, the exposure occurred when the researcher was using a syringe and blunt needle to collect and lyse the fibroblasts. Immediately following this incident, the researcher washed his hand and sought medical attention at the Stanford University Occupational Health Center.

The Stanford University biosafety office is working with the laboratory to find another type of safety needle to replace the blunt-ended needle. Puncture proof gloves are also being explored as an additional piece of personal protective equipment to be used when lysing cells.

The Stanford University response to this incident appears appropriate. No further information regarding this incident is requested at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

cc: Ann Arvin, M.D., Vice Provost and Dean of Research, Stanford University
Kathy McClelland, Director, Research Compliance, Stanford University
Harry Greenberg, M.D., Senior Associate Dean, Stanford University Medical School
David Relman, M.D., Administrative Panel on Biosafety Chair, Stanford University
Mark Holodniy, M.D., Administrative Panel on Biosafety Co-Chair, Stanford University
Peter Sarnow, Ph.D., Chair, Department of Microbiology and Immunology, Stanford University
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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March 27, 2014

Alyse DiStefano
IBC Manager
University of California Los Angeles
11000 Kinross Ave, Suite 211
Los Angeles, CA 90095

Dear Ms. DiStefano:

Thank you for your February 14, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an incident in which two principal investigators (PI) at the University of California Los Angeles (UCLA) performed research in a laboratory that had not yet been approved by the Institutional Biosafety Committee (IBC). According to your report, the PIs had relocated their laboratory operations from the Life Sciences Building to the Center for Health Sciences Building. Prior to any research beginning, the UCLA Environmental Health and Safety (EHS) staff performed initial inspections of both laboratory locations. In subsequent weeks, a follow-up inspection was performed on the one laboratory that was ready to begin operations (Laboratory F). The other laboratory (Laboratory C) was not inspected, as most of the laboratory equipment had yet to be installed.

On January 22, 2014, the EHS department received a notification that research was taking place in a laboratory without a biohazard card affixed to the door. This laboratory turned out to be Laboratory C. The PIs responsible for this laboratory were contacted and asked to provide details on what type of research was being conducted in the laboratory. Since Laboratory C had not received a final inspection from the EHS staff, the PIs were not permitted to perform any biohazardous research in the room. However, the PIs were conducting research requiring BL2+ containment in Laboratory C.

The PIs were informed that Laboratory C would need to be inspected before any further research could be performed. The EHS staff inspected Laboratory C, and the laboratory was found to be compliant with BL2+ standards. The PIs were required to amend their existing IBC protocols to include Laboratory C as the location of the research. The IBC reviewed the events surrounding this incident at its February 20, 2014, meeting and did not have any additional concerns, or place any additional corrective actions on the PIs.

Your report states that the PIs were under the impression that laboratories had received a final inspection approval and were free to begin research. While the actions taken in response to this incident appear appropriate, UCLA should consider ways to improve communications between PIs and the EHS department with respect to the status of laboratory inspections so that misunderstandings such as this do not reoccur.

No further information regarding this incident is requested at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

cc: James Gibson, Ph.D., Director, Office of Environmental Health and Safety, UCLA
David Campbell, Ph.D., Professor of Microbiology, UCLA
David Wong, D.M.D., Professor of Oral Biology, UCLA
Yong Kim, Ph.D., Adjunct Assistant Professor, UCLA
Stacey Kraemer, Ph.D., Biosafety Officer, UCLA
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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April 1, 2014

Richard Frothingham, M.D., FACP
IBC Co-Chair
Duke University
909 S. LaSalle Street, Room 1019
Durham, NC 27710

Dear Dr. Frothingham:

Thank you for your August 22, 2013, and March 21, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an August 20, 2013, incident in which a Duke University researcher was stuck by a needle containing a recombinant form of *Mycobacterium marinum.* According to your report, the exposure occurred when the researcher was attempting to inject the bacteria into the larvae of a zebrafish. The researcher sought treatment at the Duke Employee Occupational Health and Wellness (EOHW) clinic. After discussing the incident, the infectious disease physicians decided not to prescribe any antibiotic treatment, and choose instead to monitor the individual for symptoms. The researcher periodically returned to the EOHW for evaluation. The exposure site healed and there have not been any signs of infection.

In response to this incident, the biological safety officer met with the principal investigator (PI) and his laboratory staff to review the procedures that were used for injecting zebrafish. The PI and the biological safety officer also provided additional training for personnel working with the injection apparatus. This training included special attention to the procedure for securing the needle to the injection apparatus. Additionally, researchers were informed to change out the needle after every 50 injections to reduce the risk of clogging.

The Duke University response to this incident appears appropriate. However, the amount of time that Duke University took between reporting this incident to issuing the final report is excessive. OBA made requests to Duke University on September 26, 2013, February 3, 2014, and March 21, 2014, for the final report. We ask that in the future, Duke University be more responsive to such requests. In addition, the Duke University IBC should review its incident reporting policies and procedures and make any revisions necessary to ensure that incidents reports detailing corrective actions are provided to OBA in the appropriate timeframe.

No further information regarding this incident is requested at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

cc: Wayne Thomann, Dr.P.H., Co-Chair, Institutional Biosafety Committee, Duke University
Debra Hunt, Dr.P.H., Director of Biological Safety, Duke University
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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April 2, 2014

Denise Donnelly
Assistant Biosafety Manager
University of Colorado Denver
1784 Racine Street
Mailstop F484, Room 203
Denver, CO 80045

Dear Ms. Donnelly:

Thank you for your March 20, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a March 6, 2014, incident in which a University of Colorado Denver researcher was scratched by a needle containing acute myelogenous leukemia cells that had been transduced with a lentivirus. According to your report, the exposure occurred when the researcher was preparing to perform a tail vein injection. The researcher had set the syringe down to readjust the position of the mouse in her hand. When the researcher attempted to pick up the syringe, she lost her grip, and the syringe fell onto her lap. The needle bevel scratched the researcher's left thigh causing it to bleed a small amount. Immediately following this incident, the researcher walked to the locker room and washed the wound site with soap and water for five minutes. She then applied isopropyl alcohol to the area. The researcher then changed her scrub pants, and continued performing the tail vein injections. After the injections were finished, she contacted a representative from occupational health to report the exposure.

After reviewing the details of this incident, the University of Colorado Denver determined that the researcher was performing the tail vein injections too close to the front of the biosafety cabinet, thus allowing the syringe to fall onto her lap. The biosafety staff reviewed the laboratory practices and personal protective equipment requirements with the researcher to ensure that she utilizes safe work practices.

The University of Colorado Denver report provided to OBA does not adequately address two important aspects of this incident. The first aspect involves animal handling. Your report states that the researcher was holding the mouse with her hand at the time of the incident. We recommend that you review this procedure to see if an alternate means of animal restraint could be used so that the researcher has use of both hands. The second aspect involves the researcher

not immediately seeking medical care for her injury. Your report states that the researcher finished performing the tail vein injections before reporting this incident to the occupational health provider. It is our expectation that the researcher would have immediately sought medical care for her wound rather than waiting until after the injections were finished. We recommend you review your emergency response procedures to ensure that it is clear that individuals who suffer a needlestick exposure are expected to immediately report the incident to the principal investigator and the occupational health provider.

In addition to the above comments, we noted that this incident occurred on March 6, 2014, but was not reported to OBA until March 20, 2014. Please be aware that Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* requires that institutions immediately report to OBA any overt exposure to organisms containing recombinant DNA molecules when research is performed under BL2 conditions.

If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

cc: Marcia Finucane, M.S., Biological Safety Officer, University of Colorado Denver
Craig Jordan, Ph.D., Professor of Hematology, University of Colorado Denver
Jori Leszczynski, D.V.M., Director, Office of Laboratory Animal Resources, University of Colorado Denver
Ethan Carter, Ph.D., Assistant Professor of Medicine, University of Colorado Denver
Beth Strimpel, RN., Manager, Occupational Health Clinic, University of Colorado Denver
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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April 2, 2014

Carol Whetstone, Ph.D., CBSP
Biological Safety Officer
University of Louisville
1800 Arthur Street
Louisville, KY 40208-2729

Dear Dr. Whetstone:

Thank you for your February 17, 2014, and March 13, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a February 17, 2014, incident in which a University of Louisville researcher was stuck by a needle containing AAV tagged with a green fluorescent protein. According to your report, the exposure occurred when the researcher was cleaning up after performing a surgery that involved injecting AAV into the sub-retinal space of the eye of a pig. During the cleanup process, the researcher stuck himself with a syringe that had been previously used. Immediately following this incident, the researcher removed his glove, bled the wound, and applied an ethanol pad. It was determined by the director of Campus Health Services that the exposure posed minimal risk to the researcher.

In response to this incident, the biosafety staff reviewed the incident with all members of the laboratory. A special container will now be placed on the surgical tray so that used needles can be safely contained until they are finally disposed of in the hard-sided, biohazard labeled sharps container.

The University of Louisville response to this incident appears appropriate. No further information regarding this incident is requested at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

cc: Scott R. Whittemore, Ph.D., IBC Chair, University of Louisville
Cheri Hildreth, Director, Division of Environmental Health Services, University of Louisville
Karen Brinkley, M.S., Biological Safety Specialist, University of Louisville
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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April 17, 2014

Juan Sanchez, Ph.D.
Vice President for Research
FAC 29, Suite 426
P.O. Box 7996, G1400
The University of Texas at Austin
Austin, TX 78713-7996

Dear Dr. Sanchez:

Thank you for your February 17, 2014, initial notification and March 26, 2014, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a student employee was splashed in the eye with recombinant material.

From your report, we understand that the student was filtering HEK cells when the incident occurred. The student immediately stopped work, rinsed the eye, and contacted the Occupational Health Program (OHP). OHP referred the student to an external clinic. In response to this incident, laboratory staff has been retrained on the use of appropriate personal protective equipment, including eye and face protection. Environmental Health and Safety has installed eye protection posters around campus and is in the process of providing sample eyewear to laboratories to promote the importance of eyewear usage.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Dennis Nolan, Biological Safety Officer, University of Texas at Austin
Alan Lloyd, Ph.D., Chair, Institutional Biosafety Committee, University of Texas at Austin
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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April 17, 2014

Bianca Trollinger
Biological Safety Specialist
University of North Carolina
1120 Estes Drive Extension
Campus Box 1659
Chapel Hill, NC 27599-1659

Dear Ms. Trollinger:

Thank you for your March 7, 2014, and March 14, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a March 7, 2014, incident in which a mouse that had been previously administered a recombinant strain of SARS-CoV escaped from the biosafety cabinet. The incident occurred as a researcher was attempting to restrain a mouse for harvesting. When the researcher reached inside the cage to grab the mouse, another mouse in the cage jumped out of the cage and then the biosafety cabinet. The mouse was immediately captured by the researcher and euthanized. The floor of the laboratory was then disinfected with a 70-percent ethanol solution.

In response to this incident, the University of North Carolina will explore strategies to reduce the likelihood of an animal escape, such as providing additional training on how to lightly anesthetize research animals and developing methods for hands-free animal handling.

The University of North Carolina response to this incident appears appropriate. No further information is requested at this time. Please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

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

cc: Amy Sims, Ph.D., IBC Chairperson, University of North Carolina
Mary Beth Koza, Director of Environmental Health and Safety, University of North Carolina
Deborah Howard, M.P.H., Biological Safety Officer, University of North Carolina
Ralph Baric, Ph.D., Professor, University of North Carolina
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor),
Office of Biotechnology Activities, NIH

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April 17, 2014

Philip C. Hanna, Ph.D.
Institutional Biosafety Committee Chair
Department of Microbiology and Immunology
University of Michigan
5740A Medical Science Building II
Ann Arbor, MI 48109-0620

Dear Dr. Hanna:

Thank you for your March 11, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to Sections III-D and III-E of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) was conducted without approval by the University of Michigan Institutional Biosafety Committee (IBC).

From your report, we understand that the IBC learned, through coordination with the IACUC, about a project to administer plasmid DNA to mice. The IBC sent a Letter of Violation to the Principal Investigator (PI), who then ceased work. The PI stated that when he transferred to the University of Michigan he had completed numerous forms for approval of different aspects of his work, and he mistakenly thought that the registration with the IBC was accomplished at that time.

In response to this incident, the investigator submitted a registration document to the IBC, which subsequently reviewed and approved the work. Your letter notes that although no approval had been in place at the time the work was initiated, all appropriate biosafety practices had been followed.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Janet Follo, Biological Safety Officer, University of Michigan
Raymond Hutchinson, M.D., Associate Dean for Regulatory Affairs, University of Michigan
James Ashton-Miller, Ph.D., Associate Vice President for Research, University of Michigan
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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April 17, 2014

Colleen Driskill, RBP
Senior Biosafety Officer
Environmental Health and Safety
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

Dear Ms. Driskill:

Thank you for your February 28, 2014, notification and March 25, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a postdoctoral fellow was bitten by a mouse that had been infected with *Mycobacterium tuberculosis*.

From your report, we understand that the researcher was holding a mouse by the scruff of the neck while attempting to clip the ear, when the mouse got loose and bit her thumb. The researcher was wearing appropriate Biosafety Level 3 personal protective equipment, including two pairs of gloves, at the time of the incident. The researcher completed her work, de-gowned, washed her hands for about one minute and exited the Biosafety Level 3 area. She then attended a meeting. Later that day, the Principal Investigator directed her to report immediately to Employee Health Services (EHS) where the wound was scrubbed, bandaged, and a baseline interferon gamma release assay (T-spot) for *M. tuberculosis* was completed. A second assay will be performed 10 to 12 weeks after the exposure.

In response to this incident, the researcher will be retrained on exposure and incident procedures. NIH OBA recommends that all staff be reminded of the need to immediately contact EHS after exposure incidents. For the ear clip procedure, the laboratory is investigating the use of a thin pair of cotton gloves to be worn under the nitrile gloves to provide increased protection from possible bites. The investigator is also looking into other mechanisms for restraining the animals.

The actions taken in response to this incident appear appropriate. No further information is required at this time, but please provide an update after the next T-spot test. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Charleen Sotolongo, M.S.P.H., Director, Environmental Health and Safety, UMMS
Thomas Greenough, M.D., Associate Professor of Medicine, UMMS
Samuel Varghese, Ph.D., IBC Director, UMMS
Danielle Connolly, Safety Associate, UMMS
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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April 17, 2014

Stephanie Buchholtz, M.S.
Director, Office of Research Compliance
TGen
445 N 5th Street, 6th Floor
Phoenix, AZ 85004

Dear Ms. Buchholtz:

Thank you for your March 20, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to Section III-D of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) was conducted without approval by the TGen Institutional Biosafety Committee (IBC).

From your report, we understand that the research involved the production of lentiviral particles. The failure to obtain approval was discovered while training investigators on a new compliance and safety resource. The investigator believed he had received IBC approval but a review of documentation by Environmental Health and Safety found that no approval was in place.

In response to this incident, the investigator submitted a registration document to the IBC, which subsequently reviewed and approved the work. Your letter notes that although no approval had been in place at the time the work was initiated, all appropriate biosafety practices had been followed.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Kathleen Kennedy, Manager, Environmental Health and Safety, TGen
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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April 17, 2014

Christine T. McFarland, Ph.D.
Biosafety Officer
Office of Research Compliance and Biosafety
Texas A&M University
750 Agronomy Road, Suite 3501
1186 TAMU
College Station, TX 77843-1186

Dear Dr. McFarland:

Thank you for your March 6, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident involving a spill of *Chlamydomonas reinhardtii* cells inside a centrifuge.

From your report, we understand that supernatant spilled inside the centrifuge when the centrifuge rotor cover screw sheared off and broke four plastic centrifuge tubes. The barrel of the centrifuge was marked, but there were no visible dents or damage to the spindle. The equipment was cleaned with bleach and ethanol and authorized service personnel will examine the equipment to ensure that it is safe to operate before it is used again. It is believed that the incident resulted from failure to properly close the rotor cover. There was no exposure and no injury.

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

Sincerely,

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

Cc: Garry Adams, D.V.M., Ph.D., Professor, TAMU
Glen Laine, Ph.D., Professor, TAMU
Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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April 17, 2014

Stephen C. Dahl, Ph.D., RBP
Director, Biological Safety
Health, Safety, and Environment
Johns Hopkins Institutions
2024 E. Monument Street, Room B-200
Baltimore, MD 21287

Dear Dr. Dahl:

Thank you for your March 19, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a research associate at Johns Hopkins University was stuck with a needle contaminated with a vaccina virus-based vector while attempting to recap a needle.

From your report, we understand that the incident occurred after performing a series of tail-vein injections on a mouse. The research associate noted there was no sharps container at the work station, and attempted to recap the needle to transport it for disposal.

In response to this incident, a sharps container will be stationed in the laboratory and the individual has received additional training on the proper disposal of sharps. As noted in a previous report (February 12, 2014), the Office of Health, Safety and Environment has been posting materials in laboratories to increase awareness about safe sharps handling and the proper procedures to follow in the event of a spill or exposure.

The actions taken in response to this incident appear appropriate. No further information is required at this time. If you have any questions or require further information, please contact OBA staff by email at oba-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

Cc: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH
Allan C. Shipp, Director of Outreach, Office of Biotechnology Activities, NIH
Kathryn L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH
Ryan Bayha, Senior Analyst for Science Policy Outreach, Office of Biotechnology Activities, NIH

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