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April 21, 2014

Joanna Shisler, Ph.D.
IBC Chair
Department of Microbiology
University of Illinois Urbana-Champaign
B103 CLSL
601 S. Goodwin Avenue
Urbana, IL 61801

Dear Dr. Shisler:

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 or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), which had been approved by the Institutional Biosafety Committee (IBC) at Biosafety Level 2, was conducted in an Animal Biosafety Level (ABL) 1 room.

From your report, we understand that a graduate student performed intramuscular injections of recombinant lentivirus and adenovirus in an ABL-1 room. The mice were then housed individually in ventilated cages in the same room. Bedding for the first seven days was also changed and disposed of under ABL-1 conditions.

In response to this incident, the graduate student was trained by the principal investigator on procedures for inoculating animals with viruses and housing such animals. In addition, the IBC has recommended that an animal audit be performed to review ABL-2 procedures with investigators and students.

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: Carol Maddox, Ph.D., Professor, University of Illinois Urbana-Champaign
Tina Michelle McGill, Senior Project Specialist, University of Illinois Urbana-Champaign
Linda Marie Arseneau, Biosafety Officer, University of Illinois Urbana-Champaign
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 21, 2014

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

Dear Ms. Elsaesser:

Thank you for your March 28, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident at Cincinnati Children's Hospital Medical Center (CCHMC) in which a research assistant was splashed in the eye with human primary cells transduced with a lentiviral vector.

From your report, we understand the research assistant was sonicating the cells on the laboratory bench top, when she felt a mist-like vapor on her face and eyes. The volume in the tube that she was sonicating was much less than was originally placed in the tube. She immediately used the eyewash to clean her eyes and face and called the CCHMC incident reporting line. Because it was not known whether the cells were contaminated with HIV or Hepatitis B or C virus, the infectious disease physician treated the incident as a possible bloodborne pathogens exposure, and blood was drawn for testing. After testing the cells, the physician concluded that there was minimal risk from the exposure to both the primary cells and the replication incompetent lentiviral vector.

We also understand that the Institutional Biosafety Committee had approved the protocol for the sonication of human materials using Biosafety Level (BL) 2 practices and a Biological Safety Cabinet (BSC). Furthermore, protective eyewear and hearing protection were not being used during the procedure.

The sonicator is located on the laboratory bench top due to the size constraints of the BSC. The operator is required to move the sonicator into the BSC when sonicating materials. In response to this incident, a sign has been placed on the sonicator indicating that human derived and infectious materials must not be sonicated outside the BSC. At a Divisional meeting of all laboratory faculty and staff, the Principal Investigator and Division Director stressed the importance of following proper laboratory containment procedures and wearing appropriate personal protective equipment.

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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April 23, 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 March 25, 2014, and April 11, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a March 24, 2014, incident in which a research fellow was bitten on the finger by a knockout mouse while attempting to administer an intraperitoneal injection. According to your report, the mouse had been administered a recombinant strain of Lymphocytic Choriomeningitis Virus (LCMV) four days prior to this incident. Immediately following this incident, the research fellow placed the mouse back into its cage, removed his glove, and sprayed the wound site with 70-percent ethanol. He then washed his hand with soap and water and applied antibacterial ointment. The research fellow then reported the incident to the Cincinnati Children's Hospital Medical Center (CCHMC) occupational health provider. After reviewing the details of the exposure, the occupational health provider instructed the research fellow to self-monitor and report back if he exhibited any symptoms of LCMV infection. To date, no illness has developed, and the wound site has healed.

According to your report, a factor contributing to this incident was that the research fellow was using gloves that were thinner than the gloves normally worn for animal handling procedures. The gloves usually used, neoprene with an extended gauntlet, were not available when the research fellow donned his personal protective equipment, so he chose to use nitrile gloves with an interior coating of aloe. The nitrile gloves proved to be more slippery than the neoprene gloves and the research fellow had difficulty gripping the mouse.

The CCHMC biological safety officer is currently investigating the reason why the neoprene gloves were not available to the research fellow and will work to see that the appropriate gloves are available in the future for researchers to use.

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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April 23, 2014

Ryan Schlimgen, Ph.D.
Biosafety Manager
Tufts University
200 Westboro Road
North Grafton, MA 01536

Dear Dr. Schlimgen:

Thank you for your April 14, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an April 10, 2014, incident in which a Tufts University research technician stuck herself with a pin from a colony picker that previously had been used to separate colonies of a recombinant strain of *Vibrio cholerae*. According to your report, the colony picker began to malfunction, and the research technician noticed that one of the pins was damaged. The research technician attempted to repair the machine by removing the pin with a pair of pliers. During this attempt, her hand slipped and her thumb was stuck by the pin. Immediately after the exposure, the research technician washed out the wound and applied an antibiotic ointment and bandage to cover the wound. She then alerted the laboratory principal investigator about the incident. The following day, a Friday, the research technician saw her personal physician, who examined the wound site. On Monday, the research technician was instructed to see the Tufts University occupational health provider. To date, no symptoms of infection have been observed by the research technician.

After reviewing the details of this incident, the biosafety manager determined that the incident was caused, in part, by the research technician attempting to repair a machine before it was appropriately decontaminated. Consequently, all members of the laboratory staff were instructed not to attempt to repair any laboratory equipment unless it has been decontaminated. In addition, all laboratory staff were retrained by the biosafety manager on the appropriate timeframe in which to report incidents to the biosafety office.

While the above actions appear appropriate, we would also recommend that the laboratory staff be reminded that exposures need to be reported immediately to the occupational health provider. We would have expected the research technician to report the exposure immediately to the Tufts University occupational health provider, rather than wait to see her personal physician the following day.

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: Diane Souvaine, Ph.D., Vice Provost for Research, Tufts University
Celeste Thorpe, M.D., Chair, Tufts University IBC
Stephan Larson, M.S., CSP, CIH, RBO, Director, Environmental Health and Safety, Tufts University
Wai-Leung Ng, Ph.D., Assistant Professor, Tufts University
Robert H. Hall, 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 L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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April 29, 2014

Edward David, M.P.H.
Biosafety Officer
Cedars-Sinai Medical Center
Environmental Health and Safety
8701 W. 3rd Street, Suite 190
Los Angeles, CA 90048

Dear Mr. David:

Thank you for your April 8, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident of non-compliance at Cedars-Sinai Medical Center (CSMC) involving multiple protocol deviations on a phase III human gene transfer trial – *OBA Protocol 1013 Study of Chemotherapy and Chemoradiotherapy with or without Hyperacute Pancreas (algenpancutel-L) Immunotherapy in Subjects with Surgically Resected Pancreatic Cancer*.

From your report, we understand that the principal investigator and his research team reported several protocol deviations to the CSMC Institutional Review Board (IRB) in January and February of 2014. The deviation included:

- Multiple instances in which subjects were not reconsented with updated consent forms in a timely manner;
- Instances where the immunotherapy injections were begun, but not completely administered within the protocol-specified thaw time of 30 minutes. The administration delays of several minutes occurred due to subjects discomfort associated with the injections;
- Laboratory tests and assessments that were missed or done outsides of the protocol-specified window, including failure to collect vitals after study-agent administration in the time frame specified in the protocol and failure or delay in blood draws, CT scans, T cells, IgE, CA19-9, immunoglobulin, and a-gal antibody tests; and
- Modifications to dosing of a commonly used standard of care drug (gemcitabine) not done per protocol.

We also understand that the IRB noted that subjects experienced no clinical sequelae, and were not harmed by these deviations; however, the deviation pertaining to drug dosing posed a risk of potential harm to subjects. The IRB has determined that the investigator acted in good faith and without any intention wrongdoing, but the fact there were multiple deviations, their nature, and the delay in

reporting them, constituted a case of serious and continuing non-compliance and thus a report was made to the Food and Drug Administration and to NIH OBA.

In response to this incident, the investigator has fully cooperated with the IRB and has implemented a corrective action plan which includes re-education of study staff. The IRB will be conducting an audit to ensure the corrective action measures are working as intended.

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: Daniel Takefman, Ph.D., Chief, Gene Therapy Branch, Center for Biologics Evaluation and Research, Food and Drug Administration
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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May 13, 2014

Joseph Kanabrocki, Ph.D., CBSP
Associate Vice President for Research Safety
Associate Professor of Microbiology
University of Chicago
947 E. 58th Street
Abbott Hall 120
Chicago, IL 60637

Dear Dr. Kanabrocki:

Thank you for your May 9, 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-3 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) was conducted without submission of a protocol registration for review and approval by the Institutional Biosafety Committee (IBC).

From your report, we understand that the failure to obtain IBC approval was discovered during review of a paper published by the investigator that described the transduction of *Toxoplasma gondii* cells with a replication defective lentivirus. The investigator had an active IBC protocol approved at Biosafety Level (BL) 2 for the use of *T. gondii*, but did not have approval for the use of lentivirus.

In response to this incident, the investigator has submitted a protocol modification detailing the work with the lentivirus to the IBC. The protocol is currently undergoing preliminary review and is scheduled to be reviewed at the next IBC meeting on June 6, 2014. In addition, all personnel working on the project have been required to take viral vector training required for lentivirus research. Laboratory staff had previously completed training on the *NIH Guidelines*, including working with recombinant DNA at BL2. The University of Chicago IBC will be performing routine monitoring of the laboratory, which will include unscheduled informal laboratory visits as well as scheduled and unscheduled laboratory inspections.

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: Gopal Thinakaran, Ph.D., IBC Chair, University of Chicago
William Pugh, Director, Regulatory Compliance for Laboratory Programs, University of Chicago
Conrad Gilliam, Ph.D., Dean for Research and Graduate Education, University of Chicago
Kenneth Polonsky, M.D., Executive Vice President for Medical Affairs, University of Chicago
Allen Helm, Ph.D., Assistant Biosafety Officer at University of Chicago
Lauriane Quenee, Assistant Biological Safety Officer, University of Chicago
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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May 27, 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 April 4, 2014, and May 12, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an April 3, 2014, incident in which a graduate student at the Medical College of Wisconsin cut his palm with a scalpel that had previously been used to dissect a mouse that had been infected with a recombinant form of *Borrelia burgdorferi.*

According to your report, the incident occurred as the student attempted to reach for a bottle of 70-percent ethanol. Immediately following the exposure, the student removed his gloves, washed his hands with soap and water, and exited the ABSL2 facility. The student then went to the principal investigator's (PI) office to report the incident. The PI then escorted the student to the Medical College of Wisconsin occupational health provider for follow-up care. The student was evaluated by the occupational health physician, and as a precaution, given a prescription for doxycycline. The injury itself was only a minor laceration and did not require any further medical intervention.

In response to this incident, the Medical College of Wisconsin Institutional Biosafety Committee (IBC) designated a subgroup to witness a live experiment conducted by the individual who was injured. This subgroup consisted of the IBC co-chair and the Medical College of Wisconsin biological safety officer. The observation session took place on April 28, 2014. The subgroup noticed a deficiency during the procedure when the student placed a scalpel on a piece of gauze within the biosafety cabinet after having completed a dissection. The practice of not immediately discarding the scalpel after using it was determined to be the root cause of the student's injury.

In response to these findings, the entire laboratory staff was reminded that scalpels are to be disposed of in the appropriate sharps container immediately after use. This requirement has also been added into the procedures manual of the laboratory.

It appears from the information that you have provided that the Medical College of Wisconsin response to this incident was appropriate. 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: 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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May 29, 2014

Stephen M. Lanier, Ph.D.
Associate Provost for Research
Medical University of South Carolina
Colcock Hall
179 Ashley Avenue
MSC 002
Charleston, SC 29425-0002

Dear Dr. Lanier:

Thank you for your May 7, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident at the Medical University of South Carolina (MUSC) in which a postdoctoral fellow was bitten by a mouse while administering an intra-peritoneal injection of anesthetic.

From your report, we understand that the mouse had been infected ten days prior to the incident with replication defective AAV and a recombinant, highly attenuated strain of rabies virus. The mouse had not exhibited any unusual or aggressive behavior prior to being picked up. Following the incident, the postdoctoral fellow washed the wound with soap and water, alcohol, and iodine and reported the bite the following day to the MUSC Biosafety Officer, who immediately directed the individual to MUSC Employee Health Services. MUSC Employee Health Services consulted with physicians in the Division of Infectious Disease, as well as a pediatric infectious disease specialist because the postdoctoral fellow was breastfeeding. The infectious disease physicians indicated that the risk of developing rabies was extremely low, but that post-exposure prophylaxis should be offered. The fellow received rabies immune globulin and will receive a total of 4 doses of the rabies vaccine. Employee Health Services will monitor the fellow over the course of the vaccination schedule.

As you are undoubtedly aware, it is extremely important that a medical evaluation be conducted as soon as possible after an exposure of this nature. We note that the postdoctoral fellow did not report to Employee Health until the day following the incident. In your report, you state that the laboratory Standard Operating Procedure will be modified to explicitly state that incidents involving an exposure require injured individuals to report immediately to Health Services. Information about this requirement will be distributed in an informational flyer and through email as a reminder to all personnel handling animals at MUSC.

The institutional 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: John Woodward, Ph.D., Principal Investigator, MUSC
Michael G. Schmidt, Ph.D., IBC Chair, MUSC
Yashmin Karten, Ph.D., IBC Program Administrator, MUSC
Daniel Eisenman, Ph.D., Biosafety Officer, MUSC
Wayne L. Brannan, Director, Risk Management, MUSC
Kathryn Magruder, Ph.D., Director, Office of Research Integrity, MUSC
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
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May 29, 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 May 20, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident involving a potential exposure to *Mycobacterium tuberculosis* when an individual entered a Biosafety Level 3 (BL3) suite possibly wearing the wrong make and model of N95 respiratory protection.

From your report, we understand that no work was taking place at the time the individual entered the BL3 suite, however the suite was active and recombinant strains of *M. tuberculosis* are stored and worked with in the location. The individual who entered the suite was fit tested and approved to wear the 9211 model of N95 respirator, but instead may have donned the 9210 model, which he had been fit tested to wear a year earlier. The individual later realized he was carrying his fit testing card from the incorrect year at the time he entered the suite.

Since the individual was unsure whether he wore the correct respirator, he was sent for serological testing as a precaution. In addition, he was also fit tested with the model of respirator he may have mistakenly worn, and passed that fit test. The root cause analysis of the incident pointed to the infrequency with which the individual is required to enter the laboratory when it is active. The individual has been re-trained on wearing only the respiratory protection he is currently fit tested for, and in the future, the individual will be given the opportunity to regularly enter the lab in order to ensure familiarity with the proper respirator make and model.

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
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May 30, 2014

Marcia Finucane
Biosafety Officer
University of Colorado Denver
Anschutz Medical Campus
1784 Racine Street
Aurora, CO 80045

Dear Ms. Finucane:

Thank you for your April 17, 2014, initial report and May 13, 2014, follow up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a graduate student received exposure from a needle that had been used to prepare cell suspensions of Ewing Sarcoma cells that were stably transduced with a replication-incompetent retroviral construct.

From your report, we understand that the student was loading the cell suspensions into a syringe, in preparation for injection into animals. The student was recapping the syringe needles using two hands prior to transport to the vivarium. While the student was recapping a needle, the needle stuck her thumb through her glove. Immediately after the exposure the student washed the area and expressed blood for several minutes. She then went to the University of Colorado Infectious Disease Clinic, as per institutional accidental exposure guidelines. Blood was drawn for baseline tests for HIV, and Hepatitis B and C, and anti-viral post-exposure prophylactic therapy was started. Additional follow-up tests will be conducted in the next few months.

In response to this incident, the Institutional Biosafety Committee (IBC) has discussed the current institutional policy for recapping needles. The IBC will remind investigators that safety devices should be used to assist with safer recapping techniques. The laboratory has established a protocol in which forceps will be used to recap needles and the investigator has instructed the student on safer techniques.

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: Denise A. Donnelly, CHMM, Assistant Biosafety Officer, 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
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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June 2, 2014

Amy Wilkerson, M.A.
Associate Vice President, Research Support
Rockefeller University
1230 York Avenue
New York, NY 10021-6399

Dear Ms. Wilkerson:

Thank you for your April 30, 2014, and May 8, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an April 29, 2014, incident in which a graduate student at the Rockefeller University stuck herself with a syringe containing a genetically modified, non-infectious strain of *Trypanosoma brucei.* Immediately following the incident, the student reported the incident to the laboratory principal investigator (PI) and sought treatment at Rockefeller University Occupational Health Services (OHS).

The graduate student was instructed by the OHS staff to self-monitor for signs of infection for eight weeks post-exposure. To date, the graduate student has not reported any symptoms of illness. Examination of the *T. brucei* that was contained in the syringe showed that the organisms had lysed. Additionally, mice injected with the *T. brucei* did not develop an infection. This information has led the OHS staff to conclude that the risk of infection resulting from this exposure is remote.

In response to this incident, the biological safety officer met with the student and the PI to review sharps procedures and work practices. The PI then revised the laboratory standard operating procedures to include information regarding after-hours incident reporting and information about prophylactic treatment.

It appears from the information that you have provided that the Rockefeller University response to this incident was appropriate. 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: Timothy P. O'Connor, Ph.D., Vice President for University Strategy and Research Operations, Rockefeller University
Harriet S. Rabb, J.D., Vice President and General Counsel, Rockefeller University
Nina Papavasiliou, Ph.D., Laboratory Head, Rockefeller University
Frank Schaefer, Director, Laboratory Safety & Environmental Health, Rockefeller 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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June 6, 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 June 2, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing May 13, 2014, incident in which a Duke University researcher dropped an open tube containing a recombinant HIV pseudovirus, resulting in a spill of approximately 100 microliters of virus culture supernatant on the laboratory floor. According to your report, the incident occurred as the researcher was attempting to dispose of some solid waste in the biohazardous waste container. Some of the trash being disposed caught the edge of the tube and knocked it out of the biosafety cabinet and onto the floor. A small amount of virus culture supernatant landed on the researcher's ankle. The researcher immediately applied 70-percent ethanol to the exposed area. The researcher then cleaned up the spilled material from the floor. A physician from Duke University Employee Health Services reviewed the incident and determined that this event did not constitute a concerning exposure since the researcher's skin was intact. No further follow-up was recommended.

In response to this incident, researchers in the laboratory were reminded to take more care when working around open samples. Setting up the biosafety cabinet to have a "clean to dirty" work flow was also reiterated a means to avoid cross contamination and potential accidents. Currently, the laboratory group is conducting an audit to observe the work practices of the researchers. At the conclusion of that audit, other corrective actions may be recommended and implemented.

While it appears that the Duke University response to this incident was appropriate, the incident should have been treated as an overt exposure under Appendix G-II-B-2 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,* and this event should have been reported to OBA immediately. We view this event as an overt exposure due to the fact that the virus culture supernatant made contact with the researcher's ankle. Please amend your reporting policies and procedures accordingly.

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
Carol Epling, M.D., Assistant Professor of Community and Family Medicine, 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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June 6, 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 May 13, 2014, and June 2, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing May 13, 2014, incident in which a Duke University researcher was stuck by a needle containing a recombinant lentiviral vector. According to your report, the exposure involved a replication-deficient, integrase-defective, VSV-G psuedotyped lentiviral vector expressing HIV Env. The vector is being developed as a potential candidate HIV vaccine. The vector does have the potential to induce an immune response to HIV Env creating the potential for a false-positive HIV test result. However, due to the low exposure dose involved in this incident, the risk of infection is considered low.

The Duke University Employee Health Services evaluated the exposure and recommended that the researcher receive an HIV ELISA test at 0, 3, and 6 months post-exposure. If seroconversion does occur, additional testing would be performed to distinguish whether the seroconversion was a result of an immune response to the viral vector or a true HIV infection. The researcher was also retrained on the proper handling of sharps from the safety team in the researcher's laboratory group.

It appears from the information you have provided that the Duke University response to this incident was 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: Wayne Thomann, Dr.P.H., Co-Chair, Institutional Biosafety Committee, Duke University
Debra Hunt, Dr.P.H., Director of Biological Safety, Duke University
Carol Epling, M.D., Assistant Professor of Community and Family Medicine, 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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June 6, 2014

Sonia Rosenberger, D.V.M., M.S.O.H.
Biosafety Officer
University of Rochester
685 Mt. Hope Ave
RC Box 278878
Rochester, NY 14620

Dear Dr. Rosenberger:

Thank you for your May 28, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a violation of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) in which an investigator at the University of Rochester performed research subject to Section III-E without first notifying the Institutional Biosafety Committee (IBC).

According to your report, the biological safety officer (BSO) converted the information from the principal investigator's (PI's) IBC protocol to a new form recently adopted by the IBC. When this information was sent back to the PI, a laboratory technician informed the BSO that several transfection experiments that the laboratory had conducted were not listed on the form. The details of the experiments were then provided to the BSO and IBC Chair. The experiments were determined to be subject to Section III-E of the *NIH Guidelines* and were approved at the IBC's subsequent meeting on April 30, 2014.

In response to this incident, the BSO sent a memo to PIs instructing them to review their IBC approvals to ensure that all aspects of their laboratory research have been appropriately registered with the IBC.

It appears from the information that you have provided that the University of Rochester response to this incident was appropriate. 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: Martin Pavelka, Ph.D., IBC Chair, University of Rochester
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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June 16, 2014

Despina Felis, M.S., RBP
Biosafety Officer
Boston Children's Hospital
1 Blackfan Circle, Karp 01011
Boston, MA 02115

Dear Ms. Felis:

Thank you for your May 30, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident involving an exposure to a 3rd generation replication deficient lentiviral vector containing an erythropoietin gene insert.

From your report, we understand that the exposure occurred while the research staff member was aspirating solution from a culture plate with a syringe and needle. The employee was wearing all appropriate personal protective equipment, including gloves at the time of the incident. After the needlestick, he removed his gloves, washed his hands with soap and water, and then immediately reported to Occupational Health Services.

The incident was discussed at the Laboratory Support Group meeting for laboratory managers and safety representatives to educate staff. The incident will also be reviewed by the IBC on June 18, 2014.

Your report did not include any information on the root cause of the event, or any description of corrective measures being taken to prevent a reoccurrence. As a general matter, it is helpful if incident reports to NIH OBA contain information on what actions are taken by the institution to minimize the risk of similar incidents occurring in the future, for example employing alternative procedures, using safety equipment, or retraining, if warranted. Please update us if, based on its evaluation of this incident, the IBC determines that any additional action needs to be taken. 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: William Lorenzen, M.S., Radiation Safety Officer, Boston Children's Hospital
Simon Dove, Ph.D., Immune Disease Institute, 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
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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June 18, 2014

Lawrence I. Karsh, M.D., FACS, CPI
Director of Research
The Urology Center of Colorado
2777 Mile High Stadium Circle
Denver, CO 80211

Dear Dr. Karsh:

Thank you for your June 5, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to Section III-C of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) did not receive IBC approval prior to initiation of the trial.

From your report, we understand that the study, AGS-003-007, "An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma," sponsored by Argos Therapeutics, opened for enrollment without submission of a protocol registration for review and approval by The Urology Center of Colorado (TUCC) Institutional Biosafety Committee (IBC).

In your report you state that the TUCC IBC is in the process of initiating retrospective IBC review, and has conducted internal education to ensure future research subject to the *NIH Guidelines* undergoes IBC review as required.

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: Chris Jenkins, Ph.D., IBC Chair, The Urology Center of Colorado
Robin L. Dorsey, B.A., CCRC, Regulatory Director, The Urology Center of Colorado
Maria Oyaski, Regulatory Affairs Manager, Argos Therapeutics
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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June 18, 2014

Rennie Twigg, CCRP, CRA
Clinical Research Associate
The Sandra and Malcolm Berman Cancer Institute
Greater Baltimore Medical Center
6569 North Charles Street, PPW Suite 210
Baltimore, MD 21204

Dear Ms. Twigg:

Thank you for your June 9, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to Section III-C of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) did not receive IBC approval prior to initiation of the trial.

From your report, we understand that the study, AGS-003-007, "An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma," sponsored by Argos Therapeutics, opened for enrollment without submission of a protocol registration for review and approval by the Greater Baltimore Medical Center (GBMC) Institutional Biosafety Committee (IBC).

In your report you state that the GBMC IBC is in the process of initiating retrospective IBC review, and has conducted internal education to ensure future research subject to the *NIH Guidelines* undergoes IBC review as required.

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: Chris Jenkins, Ph.D., IBC Chair, Greater Baltimore Medical Center
Dana Hack, Pharm D., Lead Pharmacist, Greater Baltimore Medical Center
Maria Oyaski, Regulatory Affairs Manager, Argos Therapeutics
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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June 18, 2014

Gustavo Wendichansky, COO, CFO
Lady Davis Institute for Medical Research
Sir Mortimer B. Davis Jewish General Hospital, Suite F-6
McGill University
3755, chemin de la Côte-Sainte-Catherine
Montreal, Québec H3T 1E2
Canada

Dear Mr. Wendichansky:

Thank you for your June 9, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which research subject to Section III-C of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) did not receive IBC approval prior to initiation of the trial.

From your report, we understand that the study, AGS-003-007, "An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma" (ADAPT), sponsored by Argos Therapeutics, opened for enrollment without submission of a protocol registration for review and approval by the Sir Mortimer B. Davis Jewish General Hospital Institutional Biosafety Committee (IBC).

In your report you state that no research participants have yet been enrolled at your site. You also state that the sponsor of the study (Argos) informed you that the trial does not fall under a category of research that requires IBC review. Please note that this is not correct. This study is subject to Section III-C of the *NIH Guidelines*, and as Argos is a recipient of NIH funding, all studies sponsored by Argos that involve recombinant or synthetic nucleic acid molecules are subject to the *NIH Guidelines* must undergo IBC review. In light of this, no research participants should be enrolled in this trial before IBC review and approval is obtained.

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: Chris Jenkins, Ph.D., IBC Chair, Sir Mortimer B. Davis Jewish General Hospital
Franca Cantini, Chief REC, Sir Mortimer B. Davis Jewish General Hospital
Maria Oyaski, Regulatory Affairs Manager, Argos Therapeutics
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
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June 20, 2014

Alyse DiStefano
IBC Administrator
Office of Environment, Health and Safety
University of California Los Angeles
501 Westwood Plaza, 4th Floor
Los Angeles, CA 90095-1605

Dear Ms. DiStefano:

Thank you for your May 13, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a rat's nest was discovered in a medical waste accumulation site at the University of California Los Angeles.

From your report, we understand that the nest consisted of shredded biohazard bags and that the nest contained materials such as disposable pipette tips, gloves, and plastic tubes. Adjacent to the site are dumpsters used to dispose of non-biohazardous waste, and it is possible the materials were taken from those dumpsters and used to make the nests. However, it is possible that the waste used in the nests was generated from one of the building's BSL2 or BSL2+ laboratories. All biohazard waste bags that are stored in the waste accumulation site are tied shut and stored in barrels with locking lids, but there has been a report of a rat being observed climbing out of one of the storage barrels, which was subsequently discovered to have a broken latch on its lid.

In response to this incident, traps were set in the vicinity of the nest and 14 rats were caught. The nest was removed and the area decontaminated. An investigation into the integrity of the locking mechanisms of the storage barrel lids revealed that at least 30 percent of the locks were broken. All broken lids were removed and replacements obtained. UCLA is working with the waste vendor to address the issue of the lid integrity, and storage barrels will be routinely inspected to ensure that the lids are properly locked.

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.
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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June 20, 2014

James Henry, Jr., M.B.A.
Biological Safety Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place
Mail Stop 730
Memphis, TN 38105

Dear Mr. Henry:

Thank you for your May 15, 2014, and June 11, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a May 12, 2014, incident in which a technician cut her hand on the door of a cage housing ferrets that had been previously administered H7N9 avian influenza virus created through reverse genetics. The H7N9 virus was created to be the same as the wild type viral sequence and no mutations were introduced. The ferrets had been inoculated seven days prior, and showed no signs of infection.

According to your report, the technician noticed that five ferrets had escaped from their cage within a flexible film isolator; however the animals did not breach the primary containment of the flexible film isolator. The technician then proceeded to corral the ferrets back into the cage. While performing this task, the technician noticed a tear on the right index finger of her glove. The technician exited the flexible film isolator and removed her glove to reveal a small laceration. The technician initiated first-aid measures, which included washing the affected area with soap and water. She then showered out of the biocontainment suite and notified her supervisor of the event. She immediately sought follow-up care with the St Jude Children's Research Hospital occupational health provider.

Based on a detailed review of the incident, the occupational health provider concluded that the risks associated with the technician's exposure were low. However, given the technician's proximity to the infected ferrets and their cage, the occupational health physician gave the technician the option of taking a five-day post-exposure chemoprophylaxis course of oseltamivir. The technician was also instructed to self-monitor her health for the next ten days, and report any signs of a respiratory infection. Additionally, the technician had a baseline and a three-week post-exposure serology sample taken to look for H7N9 specific antibodies. The technician has since completed the course of oseltamivir, and at twenty days post-exposure is asymptomatic.

After reviewing the details of this incident, it was determined that the technician had not deviated from the laboratory standard operating procedures. In response to this incident, the St. Jude Children's Research Hospital Institutional Biosafety Committee (IBC) will discuss whether an additional locking mechanism should be utilized as a secondary measure to secure ferret cage doors. The results of this discussion will be communicated to the Institutional Animal Care and Use Committee and to the Biocontainment Facility Manager for final resolution.

It appears from the information that you have provided that the St. Jude Children's Research Hospital response to this incident was appropriate. 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.
Director
Office of Biotechnology Activities

cc: Richard Webby, Ph.D., IBC Chair, St. Jude Children's Research Hospital
Philip M. Potter, Ph.D., Associate Member, St. Jude Children's Research Hospital
James Gout, Ph.D., Director, Environmental Health and Safety, St. Jude Children's Research Hospital
Aditaya Gaur, M.D., Medical Director, Occupational Health, St. Jude Children's Research 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
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June 20, 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 May 28, 2014, and June 4, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a May 28, 2014, incident in which a mouse that had been previously administered a recombinant strain of California/04/09 H1N1 influenza virus 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. 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, was 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 provide additional animal handling training that is specific to this strain of mouse. A checklist has also been developed by UNC to assist in the training. The checklist details the aspects of animal handling with which laboratory staff will need to be familiar before being permitted to handle live 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.
Director
Office of Biotechnology Activities

cc: Doug Cyr, Ph.D., IBC Chairperson, University of North Carolina
Mary Beth Koza, Director of Environmental Health and Safety, University of North Carolina
Nick Chaplinksi, M.S., Interim Biosafety 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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June 26, 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 June 20, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 19, 2014, incident in which a post-doctoral fellow was bitten by a mouse that had previously been infected with the La Reunion strain of Chikungunya virus. According to your report, the bite occurred as the fellow was attempting to remove the mouse from its cage. Immediately following the bite, the fellow removed her gloves and washed the affected area with soap and water. She then reported the incident to the laboratory principal investigator.

The fellow did not seek medical care for the bite, since it was not very deep. The mouse that bit the fellow was not viremic, as determined by an infectious virus assay. Currently, there is no prophylactic treatment for Chikungunya virus. The fellow has not exhibited any signs or symptoms of infection, and the wound site has healed without complication.

In response to this incident, the principal investigator of the laboratory will retrain the researcher on appropriate animal handling techniques. 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-osp@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Jacqueline Corrigan-Curay, J.D., M.D.
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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http://osp.od.nih.gov/

June 26, 2014

Brenda Petrella, Ph.D.
Biological Safety Officer
Dartmouth College
37 Dewey Field Road
Suite 6217
Hanover, NH 03755

Dear Dr. Petrella:

Thank you for your June 25, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 6, 2014, incident in which a Dartmouth College graduate student cut himself on a glass pipette that had been used to aspirate breast carcinoma cells transduced with an adenoviral vector. After the first aspiration step, prior to any washes, the student's gloved hand came in contact with the tip of the pipette. The student immediately stopped work, removed his glove, and squeezed the cut to forcibly bleed the wound site. He then applied soap and water and cleaned the wound site with an alcohol wipe. The student then reported the incident to the laboratory principal investigator and sought medical care at the Dartmouth College infirmary. The medical staff at the infirmary once again cleaned the wound and ensured that there was no glass remaining in the student's finger. The student was given a tetanus shot and instructed to self-monitor for any signs of flu-like symptoms. To date, the student has not reported any symptoms of illness.

In response to this incident, the laboratory revised the standard operating procedures to state that plastic serological pipettes filled with a plastic pipette tip are to be used instead of glass pipettes for procedures involving aspiration. Dartmouth College believes that the switch from glass to plastic should eliminate the risk of a sharps injury during the aspiration process. Additionally, a message has been sent to each Dartmouth College investigator recommending that plastic pipette tips be used when working with agents that must be worked with at BL2 or higher.

While it appears from the information you have provided that the Dartmouth College response to this incident was appropriate, we noted that this incident occurred on June 6, 2014, but was not reported to OBA until June 25, 2014. Please be aware that Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) requires that institutions immediately report to OBA any overt exposure to organisms containing recombinant or synthetic nucleic acid 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-osp@od.nih.gov or by telephone at (301) 496-9838.

Sincerely,

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

cc: James DiRenzo, Ph.D., Associate Professor of Pharmacology, Dartmouth 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 L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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July 8, 2014

Mark Robbins, M.T.
Biosafety Officer
University of South Carolina
306 Benson School
Columbia, SC 29208

Dear Mr. Robbins:

Thank you for your July 3, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 24, 2014, incident in which a University of South Carolina researcher was stuck by a needle containing 3T3 cells that had been transduced with an HIV-based lentivirus.

According to your report, the researcher was preparing the cells for loading onto the Western blot by passing the cell lysate through a needle to further break up the cells. After expelling all of the cellular contents, the researcher attempted to put the needle back in the tube to pull up the sample and stuck himself in the finger. Immediately following this event, the researcher washed the wound site with soap and water for approximately ten minutes. He then reported to the University of South Carolina occupational health provider. The researcher was given a one day supply of anti-HIV medication. The next day, the researcher returned for further evaluation and the occupational health physician determined that no further HIV medication was necessary. No further follow-up was requested by the physician and the risk of infection from this exposure was deemed low.

After reviewing the details of the incident, the biological safety officer determined that the risk of exposure could have been minimized if the tube had been placed in a tube holder rather than being held in the researcher's hand. Additionally, needles will no longer be used to solubilize cellular material since safer alternatives exist. The laboratory standard operating procedures will be amended to reflect the requirement to use a tube holder and prohibit the use of sharps when solubilizing cellular material.

While it appears from the information you have provided that the University of South Carolina response to this incident was appropriate, we noted that this incident occurred on June 24, 2014, but was not reported to OBA until July 3, 2014. Please be aware that Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) requires that institutions immediately report to OBA any overt exposure to organisms containing recombinant or synthetic nucleic acid molecules when research is performed under BL2 conditions.

No further information regarding this incident 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.

Sincerely,

Jacqueline Corrigan-Curay, J.D., M.D.
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
Lydia Matesic, Ph.D., Professor of Biology, University of South Carolina
Susan Wood, Ph.D., Assistant Professor of Pharmacology, Physiology, and Neuroscience 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 L. Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Office of Biotechnology Activities, NIH

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July 10, 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 June 4, 2014, initial notification and July 8, 2014, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a laboratory worker was bitten by a mouse that had previously been administered adeno-associated virus (AAV).

From your report, we understand that the employee was performing an injection when the mouse bit her. The mouse had received an intracranial injection of replication deficient and adenovirus-free AAV one month prior to this incident. Immediately following the injury, the individual scrubbed the wound with soap and water for 15 minutes. The employee then consulted with the Employee Health Center who administered a tetanus booster. Based on the agent involved no further treatment was deemed necessary. In response to this incident, all personnel have been reminded of proper animal handling procedures and will ensure that animals are not held longer than necessary when performing injections.

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.
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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July 10, 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 June 18, 2014, initial notification and July 8, 2014, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a laboratory worker was bitten by a mouse that had previously been infected with *Bacillus anthracis* (Sterne strain).

From your report, we understand that the employee was preparing to euthanize the mouse when the mouse bit her. The employee was wearing all necessary personnel protective equipment at the time of the incident. The employee was evaluated by a medical provider the day after the incident, and it was determined that the wound was superficial and there were no signs of infection, so no treatment was prescribed. The root cause of the incident appears to be improper restraint of the animal during the procedure, despite the fact that the employee has a number of years of animal handling experience. The Institutional Animal Care and Use Committee has also reviewed the incident and has not recommended additional animal handling training. However, the attending veterinarian will meet with the individual and observe her technique. If the veterinarian feels additional training is needed, it will be provided at that time.

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.
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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July 10, 2014

Cynthia McGill, CIP
Assistant Director
Human Research Protection Program
University of Minnesota
D528 Mayo Memorial Building
420 Delaware Street SE
Minneapolis, MN 55455-0392

Dear Ms. McGill:

Thank you for your June 24, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an incident in which a University of Minnesota principal investigator (PI) continued to perform research after his Institutional Biosafety Committee (IBC) registration had expired. According to your report, the PI was notified 60 and 30 days prior to the expiration of his registration with the IBC. However, the PI did not submit a renewal application to the IBC until three days after the protocol had expired. As a result, the University of Minnesota IBC decided to halt the PI's research until a *de novo* review of the protocol can occur.

In response to this event, a copy of the IBC's decision to halt the research was submitted to the PI's department head, as well as the Institutional Animal Care and Use Committee (IACUC) director. The PI acknowledged that he would halt his research until the protocol was reviewed at the next IBC meeting (July 21, 2014). Additionally, the PI stated that in the future, he will pay stricter attention to the IBC's deadlines for protocol renewal.

The University of Minnesota 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.
Director
Office of Biotechnology Activities

cc: Brian Herman, Ph.D., Vice President for Research, University of Minnesota
David Brown, Ph.D., IBC Chair, University of Minnesota
Tracy Rouse, Research Compliance Supervisor, University of Minnesota
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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July 10, 2014

Michael T. Elliott
Biosafety Officer
Office of Environmental Health and Safety
Virginia Commonwealth University
1101 East Marshall Street
P.O. Box 980112
Richmond, VA 23298-0012

Dear Mr. Elliott:

Thank you for your July 3, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a graduate student at Virginia Commonwealth University (VCU) was stuck while recapping a needle after injecting a mouse.

From your report, we understand that the mouse had been injected with mouse melanoma cells that had been transformed with a non-replicating Moloney Murine Leukemia Virus (MMLV) vector. At the time of the incident, the student was wearing the appropriate personal protective equipment.

In response to this incident, the student immediately washed the puncture site with soap and water and then reported to the VCU Student Health Services. The principal investigator (PI) assessed there was minimal likelihood of any MMLV being present in the transformed cells, and no further actions were deemed necessary by Student Health Services. The PI has counseled the student on VCU's policy that recapping of needles is prohibited unless a specific recapping waiver is issued.

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.
Director
Office of Biotechnology Activities

Michael T. Elliott
July 10, 2014

Cc: Dean W. Broga, Ph.D., Director, Environmental Health and Safety, VCU
Dennis E. Ohman, Ph.D., IBC Chair, VCU
Roma Maraj-Owen, Assistant Director, Environmental Health and Safety, VCU
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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July 31, 2014

Gaylen Howell, M.A., M.B.A.
Manager
Office of Research Administration
M.D. Anderson Cancer Center
1515 Holcombe Blvd.
Unit 1436
Houston, TX 77030

Dear Mr. Howell:

Thank you for your July 9, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 20, 2014, lentivirus spill that occurred in an M.D. Anderson Cancer Center laboratory.

According to your report, an M.D. Anderson Cancer Center postdoctoral fellow was processing lentivirus, using an ultracentrifuge with which she was unfamiliar. The ultracentrifuge in her laboratory was out of service, and she asked if she could use one in another building. The fellow was provided a basic overview of the ultracentrifuge's operation by a member of the laboratory staff. A special feature of the ultracentrifuge being used in this incident was it had a fixed-angle rotor, and the centrifuge the fellow was accustomed to working with had a swinging bucket rotor. The fellow failed to cap the centrifuge tubes and instead relied on the rotor cap cover to contain the lentivirus being processed.

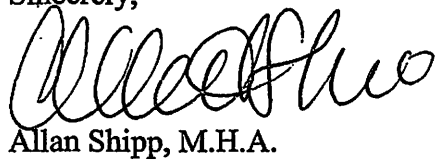
At approximately 5:00 p.m., an error code appeared on the ultracentrifuge. When the spin cycle was complete and the ultracentrifuge was opened, it was apparent that a spill had occurred. The fellow had on all the appropriate personal protective equipment (PPE) and began to decontaminate the ultracentrifuge with ethanol. The fellow requested that a colleague in the laboratory assist her in the cleanup. The colleague instead reported the incident to the Environmental Health and Safety (EHS) department who instructed everyone to leave the laboratory in order to give any potential aerosols a chance to settle. After 40 minutes, a cleanup team reentered the laboratory and decontaminated the spill area in accordance with M.D. Anderson Cancer Center practices.

In response to this incident, the laboratory principal investigator (PI) and laboratory manager met with the EHS department to discuss the incident. As a result, the PI was asked to retrain the laboratory staff to always cap tubes containing viral materials that are to be centrifuged and that any loading or unloading of infectious material needs to be performed in a biosafety cabinet. Additionally, the PI was instructed to retrain laboratory personnel on the appropriate decontamination procedures.

While the M.D. Anderson Cancer Center response to this incident appears adequate, it seems that the root cause was the fellow was not being properly trained on how to use the ultracentrifuge. Your institution should consider ways to ensure that all employees are fully trained to use laboratory equipment before it is used. This could be accomplished by requiring employees to demonstrate a base level of competency with the equipment before allowing them to use infectious agents.

No further information is requested at this time. Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being coordinated through the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,



Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Zahid Siddik, Ph.D., Professor of Medicine, M.D. Anderson Cancer Center
Wesley Harrott, Executive Director of Research Administration, M.D. Anderson Cancer Center
Dean Tang, M.D., Ph.D., Professor, M.D. Anderson Cancer Center
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 13, 2014

Alyse DiStefano
IBC Manager
University of California, Los Angeles
1100 Kinross Avenue, Suite 260
Los Angeles, CA 90095-1694

Dear Ms. DiStefano:

Thank you for your June 13, 2014, and July 14, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a violation of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) that occurred at the University of California, Los Angeles (UCLA).

According to your report, a UCLA principal investigator (PI) had an approved IBC registration to work with recombinant Hepatitis C Virus (HCV) and human cell cultures under BL2+ containment conditions. The PI's approved registration listed two staff members. Recently, the UCLA biosafety and laboratory safety offices became aware that the laboratory's training records included nine undergraduate volunteers working in the laboratory. Of those nine volunteers, only two had completed all the training required by the IBC to work in a BL2+ laboratory. Upon further investigation by the biosafety office, it was discovered that none of the nine volunteers were documented as having received laboratory-specific or hazard communication training or offered the Hepatitis B vaccine. As of May 2014, the PI confirmed there are no longer any undergraduate volunteers working in this laboratory.

The UCLA Office of Research Administration (ORA) contacted several of the undergraduate volunteers who had been listed in the laboratory records. Of the four that were contacted, three indicated that while working in the laboratory they believed they were handling live HCV. These same three students also indicated they had worked with human cell lines.

On June 1, 2014, the biosafety officer, IBC chair, IBC manager, and the ORA Director met with the PI to discuss the allegations of non-compliance. During the meeting, the PI explained that his laboratory's policy prohibited undergraduate students from working with live HCV as well as HCV-infected cells. Undergraduates would be permitted to work with uninfected human cell lines, portions of the HCV genome, as well as detergent-inactivated HCV. The PI stated that

he has relied on his laboratory manager to communicate and enforce this and all other laboratory policies. As a result, the PI never met with the undergraduate students to explain these policies. The PI is not certain whether the undergraduates handled live HCV, and the laboratory manager cannot be asked as his employment at UCLA has been terminated. Also during the course of the meeting, the PI admitted to not being unaware that working with certain portions of the HCV genome in plasmids could potentially be covered under the *NIH Guidelines*. Additionally, the PI indicated he was not aware that the handling of human cells was considered biohazardous. Currently, no research is taking place in the laboratory, but there are plans to hire a new laboratory manager when operations resume.

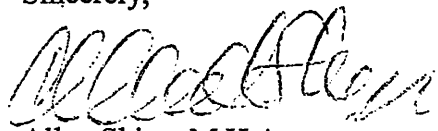
In response to this incident, UCLA is requiring several corrective actions on the part of the PI. These actions include:

- Having the PI retake all of the Environmental Health and Safety (EHS) biosafety training required for working in a BL2+ laboratory;
- Requiring the PI to develop a comprehensive orientation program for new laboratory members, which includes a checklist of the necessary training required before new researchers may begin work;
- Requiring the PI to review and update the laboratory standard operating procedures for any and all biohazardous experiments that might be conducted in his laboratory;
- Having the PI retake bloodborne pathogens training; and
- Reminding the PI that, even though some supervisory responsibilities can be delegated to a laboratory manager, the PI retains the ultimate responsibility for laboratory compliance.

The actions taken by UCLA in response to this incident appear appropriate. No further information is requested at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being coordinated through the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,



Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Jennifer Perkins, Assistant Director, Animal Research Committee, UCLA
Jerome Zack, Ph.D., IBC Chair, UCLA
Asim Dasgupta, Ph.D., Professor of Immunology, UCLA
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 13, 2014

Colleen O. Driskill, RBP
Senior Biosafety Officer
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

Dear Ms. Driskill:

Thank you for your June 23, 2014, and July 18, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 20, 2014, incident in which a volunteer student cut herself while preparing non-human primate (NHP) spinal cord tissue for a cryostat. The NHP had previously been administered a replication-defective adeno-associated virus vector expressing green fluorescent protein.

According to your report, the volunteer was attempting to remove the tissue from the specimen plate when the blade slipped and cut her left hand. The volunteer immediately removed her gloves, washed her hands with soap and water, and then soaked her hands in iodine for fifteen minutes. The volunteer then reported to University of Massachusetts Medical School (UMMS) Employee Health Services for evaluation. Since the species of NHP was unknown at the time of the incident, the standard operating procedures for potential Herpes B virus exposure were followed and prophylaxis was provided. The following day, it was determined that the tissue was derived from an African Green Monkey, which is not known to harbor Herpes B virus. As a result, the volunteer discontinued the use of the prophylaxis prescribed to her. No further follow-up care was deemed necessary.

In response to this incident, all members of the laboratory (including the volunteer) have been retrained in the appropriate methods for cutting cryostat samples. Additionally, all members of the laboratory will be retrained in the risks associated with Herpes B virus. Finally, the laboratory principal investigator will amend his IBC registration to include all types of NHP tissues being utilized in the laboratory.

It appears from the information you have provided that the UMMS response to this incident was appropriate. No further information is requested at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being coordinated through the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

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
Christian Mueller, Ph.D. Assistant Professor, UMMS
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 13, 2014

Delia Vieira-Cruz
Laboratory Safety Officer
Albert Einstein College of Medicine
1300 Morris Park Avenue
Room 800
Bronx, NY 10461

Dear Ms. Vieira-Cruz:

Thank you for your July 10, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 25, 2014, incident in which a graduate student was bitten by a transgenic mouse that had previously been administered HIV. According to your report, a graduate student was performing intraperitoneal injections on a transgenic mouse. When the injection was complete, and the mouse was being put back into its cage, it slipped from the student's grasp and bit her right hand. Immediately following this incident, the graduate student reported to the Albert Einstein Medical College occupational health provider, who took a baseline serology sample and provided post-exposure prophylaxis.

In response to this incident, the graduate student will be trained on sterile surgery techniques for rodents, as well as safe and humane handling of rodents.

While the Albert Einstein Medical College response to this incident appears adequate, we noted that this incident occurred on June 25, 2014, but was not reported to OBA until July 10, 2014. Please be aware that Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) requires that institutions immediately report to NIH any overt exposure to organisms containing recombinant or synthetic nucleic acid molecules when research is performed under BL2 conditions. No further information is requested at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being coordinated through the NIH Program for Biosecurity and Biosafety

Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Harris Goldstein, M.D., Associate Dean for Scientific Resources, Albert Einstein Medical College
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 14, 2014

Anne Sallee, RBP
Biosafety Manager
Massachusetts General Hospital
West End House – BA019
16 Blossom Street
Boston, MA 02114

Dear Ms. Sallee:

Thank you for your July 31, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a July 30, 2014, incident in which a Massachusetts General Hospital researcher cut herself with a glass pipette while loading a lentiviral vector onto a stereotaxic surgery apparatus. The lentiviral vector was constructed using a three-plasmid system with a gene insert that expresses optical channel properties. The insert is not known to be oncogenic.

Immediately following this incident, the researcher washed the wound site and sought treatment from the occupational health provider. After an evaluation by the occupational health provider, it was determined that exposure posed a low risk to the researcher due to the nature of the vector and gene insert.

In response to this incident, the principal investigator and all members of the laboratory staff will be provided refresher training on the appropriate and safe use of stereotaxic surgery equipment. In addition, the laboratory staff will also be retrained in general laboratory safety.

The Massachusetts General Hospital response to this incident appears appropriate. No further information about this incident is requested at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being conducted by the NIH Program for

Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Jatin Vyas, M.D., Ph.D., IBC Chair, Partners Healthcare
Leslie Hofherr, Director, Partners IBC
Julien Farland, S.M., Director of Biological Safety, Boston Public Health Commission
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 14, 2014

Gaylen Howell, M.A., M.B.A.
Manager
Office of Research Administration
M.D. Anderson Cancer Center
1515 Holcombe Blvd.
Unit 1436
Houston, TX 77030

Dear Mr. Howell:

Thank you for your July 9, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 19, 2014, loss of containment involving 70 microcentrifuge tubes that held a deubiquitizing enzyme open-reading frame cDNA library. According to your report, the laboratory had purchased the plasmids, and the cDNA was inserted into a pBABE backbone cloning retroviral vector. The plasmids were then propagated in DHS alpha bacteria. The cDNA clones were isolated and then stored in microfuge tubes inside of a freezer. A laboratory worker checked the freezer and found that the samples were missing. The individual who reported the tubes missing suspected that the cDNA library had been stolen by someone familiar with the research that took place in that laboratory. A report of the stolen materials was made to the University of Texas Police Department and the investigation is ongoing. To date, the cDNA library has not been recovered.

In response to this incident, M.D. Anderson Cancer Center has placed restrictions on who may access the freezer. In addition, a new lock has been placed on the freezer door.

No further information is requested at this time. However, if any new information regarding the missing samples is uncovered, please provide it to us.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the

NIH Office of Biotechnology Activities are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Zahid Siddik, Ph.D., Professor of Medicine, M.D. Anderson Cancer Center
Wesley Harrott, Executive Director of Research Administration, M.D. Anderson Cancer Center
Li Ma, Ph.D., Assistant Professor, M.D. Anderson Cancer Center
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 14, 2014

Matthew Philpott, Ph.D., RBP
Biological Safety Officer
Oregon State University
218 Oak Creek Building
3015 SW Western Blvd.
Corvallis, OR 97331

Dear Dr. Philpott:

Thank you for your August 8, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an August 7, 2014, incident in which an Oregon State University graduate student stuck himself with a syringe that contained modified human cancer cells expressing a luciferase gene. According to your report, the student had just finished performing an injection on a mouse when the animal moved, causing the student to stick himself.

Immediately following this incident, the student washed the wound site, reported the incident to the Oregon State University biological safety officer, and sought treatment at the occupational health provider. The occupational health provider treated the wound and counseled the student. The student will follow up with the occupational health provider for scheduled blood tests for HIV and Hepatitis B.

In response to this incident, the Oregon State University attending veterinarian will provide additional training to the student on the appropriate methods of performing animal injections. Since the root cause of the incident was determined to be improper handling of the mouse, additional animal handling training will be provided to the student as well.

The Oregon State University response to this incident appears appropriate. No further information about this incident is requested at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 14, 2014

Leslie Hofherr
Director, Partners IBC
One Brigham Circle, 3rd floor
1620 Tremont Street, BC3-012.12
Boston, MA 02120

Dear Ms. Hofherr:

Thank you for your July 28, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 13, 2014, incident in which a Brigham and Women's Hospital researcher euthanized several mice that had been previously administered a recombinant strain of vaccinia on a laboratory benchtop, as opposed to inside a biosafety cabinet.

According to your report, an animal care staff employee observed the researcher remove the animal cage and place it on the benchtop. The researcher then proceeded to euthanize the mice. The animal care worker stopped the researcher and instructed her to move her equipment and the remaining mice into a biosafety cabinet to perform the remainder of the work. The mice had been administered a TK vaccinia virus strain expressing ovalbumin peptide two months prior. The researcher believed that the euthanization of the mice could be performed on the benchtop because she had seen literature that indicated the mice would only shed the vaccinia virus for a maximum period of two weeks post-inoculation.

As a result of this incident, the laboratory has hired an experienced animal technician who will be responsible for all animal care procedures that will take place in the laboratory. In addition, retraining on appropriate animal handling procedures was provided to the laboratory staff.

No further information about this incident is requested at this time. While the Brigham and Women's Hospital response to this incident appears appropriate, we noted that this incident took place on June 13, 2014, but was not reported to NIH until July 28, 2014. Please be aware that section IV-B-2-b-(7) of the *NIH Guidelines for Research Involving Recombinant or Synthetic*

Nucleic Acid Molecules (*NIH Guidelines*) requires institutions to report violations of the *NIH Guidelines* within 30 days of the date of the violation.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Jatin Vyas, M.D., Ph.D., IBC Chair, Partners Healthcare
Jessica Healey, Biological Safety Officer, Brigham and Women's Hospital
Thomas Kupper, M.D., Chairman, Department of Dermatology, Brigham and Women's Hospital
Halonna Kelly, Ph.D., Program Officer, NIAID, NIH
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 14, 2014

Kim Volarcik
Executive Director for Research Compliance
Case Western Reserve University
10900 Euclid Avenue
Sears Library 663
Cleveland, OH 44106-7230

Dear Ms. Volarcik:

Thank you for your July 30, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a May 28, 2014, incident in which a transgenic mouse escaped from containment at Case Western Reserve University.

According to your report, a researcher was preparing two PrP knockout mice for anesthesia and euthanasia in order to harvest brain tissue as a control for the analysis of PrP isoforms produced by the transgenic lines. During the preparation, the researcher lost control of one of the mice and it ran away from the researcher. The researcher immediately contacted the laboratory principal investigator (PI) who provided instructions for how to prepare and set a trap for the mouse. The next morning, the mouse was found in the trap and euthanized. A post-mortem of the mouse determined the mouse did not contain any prion protein. The incident did not result in any personnel exposure or pose any veterinary concerns.

In response to this incident, laboratory PI will provide additional training to the researcher regarding the safe and effective handling of laboratory mice. The researcher is currently up-to-date and all other required training modules.

While the Case Western Reserve University response to this incident appears adequate, we noted that this incident occurred on May 28, 2014, but was not reported to OBA until July 30, 2014. Please be aware that Section IV-B-2-b-(7) of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) requires institutions to report violations of the *NIH Guidelines* within 30 days of the date of the violation.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Suzanne Rivera, Ph.D., Associate Vice President for Research, Case Western Reserve University
David Samols, Ph.D., IBC chair, Case Western Reserve University
Heidi Page, Biological Safety Officer, Case Western Reserve University
Wen-quan Zou, M.D., Ph.D., Associate Professor, Case Western Reserve University
May Tze Wong, Ph.D., Program Officer, NINDS, NIH
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 14, 2014

Kim Volarcik
Executive Director for Research Compliance
Case Western Reserve University
10900 Euclid Avenue
Sears Library 663
Cleveland, OH 44106-7230

Dear Ms. Volarcik:

Thank you for your July 11, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a May 1, 2014, incident in which a research assistant stuck herself with a syringe containing genetically modified glioblastoma cells that were expressing green fluorescent protein.

According to your report, the research assistant had just finished injecting the tumor cells into the flank of a mouse when the incident occurred. Immediately following this incident, the research assistant contacted the Case Western Reserve University Safety Office and then reported to the occupational health provider for evaluation and treatment. The individual involved in this incident had many years of experience in this type of procedure and was up-to-date on all the required training.

In response to this incident, a senior researcher will retrain the individual involved in this incident. The research associate will practice her injection technique using buffers only. She will not be permitted to perform any injections with the glioblastoma cells until her training has been completed.

While the Case Western Reserve University response to this incident appears adequate, we noted that this incident occurred on May 1, 2014, but was not reported to NIH until June 27, 2014. Please be aware that Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) requires that institutions immediately report to NIH any overt exposure to organisms containing recombinant or synthetic nucleic acid molecules when research is performed under BL2 conditions. No further information is requested at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Suzanne Rivera, Ph.D., Associate Vice President for Research, Case Western Reserve University
David Samols, Ph.D., IBC chair, Case Western Reserve University
Heidi Page, Biological Safety Officer, Case Western Reserve University
Susann Brady-Kalnay, Ph.D., Professor, Case Western Reserve University
Keyvan Farahani, Ph.D., Program Officer, NCI, NIH
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
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August 14, 2014

Peili Zhu, M.D., Ph.D., RBP
Biological Safety Officer
University of California, San Francisco
50 Medical Center Way, Box 0942
San Francisco, CA 94143-0942

Dear Dr. Zhu:

Thank you for your July 11, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a June 26, 2014, incident in which an undergraduate student stuck himself with a syringe that contained modified *E. coli* BL21 cells.

According to your report, the student was passing the *E. coli* cells through a syringe in order to make the solution more homogenous. While doing this, the student struck his hand with the syringe. Immediately following this incident, the student removed his gloves and washed his hands with disinfecting soap and water for approximately five minutes. He then reported the exposure to his laboratory mentor and the University of California, San Francisco (UCSF) exposure hotline. The UCSF Occupational Health Services followed up with the student and advised him to bandage the wound site and monitor for any signs of infection. No prophylaxis was recommended. To date, the student has not experienced any symptoms of infection resulting from this exposure.

In response to this incident, the laboratory principal investigator will hold a meeting with the laboratory staff in order to discuss this incident. In addition, blunt needles will now be used to perform this type of procedure. Finally, all summer undergraduate students will receive additional laboratory training.

The UCSF response to this incident appears appropriate. No further information about this incident is requested at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Robert Eaton, Director, Office of Environmental Health and Safety, UCSF
Kendra Aiken, M.P.H., Safety Committees Coordinator, UCSF
Danica Galonic Fukimora, Ph.D., Assistant Professor of Pharmacology, UCSF
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 20, 2014

Tamara B. Rausch
Laboratory Safety Consultant
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue, MLC 7040
Cincinnati, OH 45229

Dear Ms. Rausch:

Thank you for your July 22, 2014, and August 1, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a July 21, 2014, incident in which an undergraduate summer student cut herself with a glass Pasteur pipette containing bone marrow cells obtained from a transgenic mouse.

According to your report, the student was in the process of changing media for mouse cells cultures when the incident occurred. The student rested the vacuum tubing with the Pasteur pipette inside the biosafety cabinet in order to retrieve another flask of culture. When she reached back for the pipette, her hand grazed the tip of the pipette. Immediately, the student removed her gloves and washed her hands with warm soap and water. She then wiped the wound site with an alcohol pad, applied an antibiotic cream, and placed a bandage on the wound. Lastly, the student reported the incident to the laboratory principal investigator (PI) and the Cincinnati Children's Hospital Medical Center injury hotline. The student was instructed to monitor the wound for any symptoms of infection. To date, the student has not reported any symptoms and the site of the wound has healed.

In response to this incident, the laboratory was encouraged to replace the glass Pasteur pipettes with plastic tipped pipettes for use in cell culture. As a result, the laboratory PI has decided to cease the use of glass pipettes for all work, and instead will rely on plastic tipped pipettes.

The Cincinnati Children's Hospital Medical Center response to this incident appears appropriate. No further information about this incident is requested at this time.

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Sincerely,

Allan Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Marc Rothenberg, M.D., Ph.D., Director, Division of Allergy and Immunology
Cincinnati Children's Hospital Medical Center
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 20, 2014

Benjamin Fontes, M.P.H., CBSP
Biological Safety Officer
Yale University
135 College Street, Suite 100
New Haven, CT 06510

Dear Mr. Fontes:

Thank you for your May 22, 2014, and July 17, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a May 21, 2014, incident in which a Yale University postdoctoral fellow stuck himself with a syringe while attempting to load inoculum containing a recombinant strain of *Listeria monoocytogenes*.

Immediately following this incident, the fellow washed the exposed area with soap and water for approximately 20 minutes. He then squeezed around the wound to encourage bleeding. Finally, the fellow washed the exposed area with 70-percent ethanol. After performing first-aid, the fellow reported to the Yale University employee health clinic and was provided with post-exposure prophylaxis and told to monitor for any signs of infection. To date, the fellow has not experienced any symptoms of illness associated with this exposure.

In response to this incident, staff from the Yale University Environmental Health and Safety (EHS) office met with the fellow to review the incident. The fellow admitted to being distracted while performing the procedure. As a result, the EHS office required that the loading procedure now be performed in a dedicated animal procedure room in order to reduce the distractions posed by other laboratory operations. Additionally, the loading of needles and syringes will take place inside the animal room's biosafety cabinet. The needles and syringes will then be placed in a 50-ml Falcon tube until they are needed for inoculations. As a final measure, the EHS staff reminded the fellow of the importance of concentrating on the procedures being performed in the laboratory.

The Yale University response to this incident appears appropriate. No further information about this incident is requested at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: W. Dean Rupp, Ph.D., IBC chair, Yale University
Stephanie Eisenbarth, M.D., Ph.D., Assistant Professor of Laboratory Medicine, Yale University
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 22, 2014

Henry James, Jr., M.B.A.
Biological Safety Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 730
Memphis, TN 38105

Dear Mr. James:

Thank you for your July 10, 2014, and August 6, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a July 3, 2014, incident in which a researcher splashed herself in the face with a phosphate buffered saline solution containing mouse bone marrow cells that had been transduced with a lentivirus.

According to your report, the researcher was attempting to inject the transduced cells into the tail vein of a mouse but encountered resistance from one of the mouse's blood vessels. As a result, back pressure buildup occurred and dislodged the needle from the slip tip syringe, partially spraying its content. At the time of the event, the researcher was not wearing eye protection. Immediately following this incident, the researcher flushed the exposed eyelid with water for approximately 20 minutes. She then notified her supervisor and reported to the occupational health provider for medical evaluation. After considering the details of the researcher's exposure, the occupational health provider determined that the risks associated with this exposure were low. In addition, it was determined that post-exposure prophylaxis was not warranted. The researcher was instructed to monitor her eye for signs of infection and a baseline HIV serology was taken.

In response to this incident, the researcher will be retrained in the use of appropriate personal protective equipment. She will also undergo additional training relating to performing tail vein injections. Finally, the IBC will discuss at a future meeting whether the use of slip tip syringes should be continued or if an alternative should be found.

No further information about this incident is requested at this time. While the St. Jude Children's Research Hospital response to this incident appears appropriate, we noted that this incident occurred on July 3, 2014, but was not reported to NIH until July 10, 2014. Please be aware that Appendix G-II-B-2-k of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) requires that institutions immediately report to NIH any overt exposure to organisms containing recombinant or synthetic nucleic acid molecules when research is performed under BL2 conditions.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out through the NIH Office of Biotechnology Activities are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP). Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Richard Webby, Ph.D., IBC Chair, St. Jude Children's Research Hospital
Philip M. Potter, Ph.D., Associate Member, St. Jude Children's Research Hospital
James Gout, Ph.D., Director, Environmental Health and Safety, St. Jude Children's Research Hospital
Aditaya Gaur, M.D., Medical Director, Occupational Health, St. Jude Children's Research Hospital
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 25, 2014

Cheri Marcham, Ph.D., CIH, CSP, CHMM
University Environmental Health and Safety Officer
Environmental Health and Safety Office
The University of Oklahoma Health Sciences Center
P.O. Box 26901 ROB 301
Oklahoma City, OK 73126-0901

Dear Dr. Marcham:

Thank you for your July 11, 2014, report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident involving an exposure to *Toxoplasma gondii* at the University of Oklahoma Health Sciences Center.

From your report, we understand that a graduate student was lysing host cells containing *T. gondii* when he was stuck with the needle used in the procedure. The work was being conducted in a Biological Safety Cabinet (BSC) but the sash of the BSC was closed further than ideal, thus restricting the range of motion of the student. The student was wearing appropriate personal protective equipment at the time of the incident. The student immediately notified the Principal Investigator (PI), who instructed the student seek immediate medical attention at the emergency room. An infectious disease expert was called in to provide advice and the student was treated with a standard course of antibiotic therapy. Serology was drawn at the time of the incident and remains negative.

In response to this incident, the graduate student has been counselled to raise the sash of the BSC enough to allow safe movement within the hood but not to a level unsafe for personal protection. The actions taken in response to this incident appear appropriate. No further information is required at this time.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy (PBBP). The biosecurity and biosafety responsibilities formerly carried out through the NIH OBA are now being conducted by the NIH PBBP.

Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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Bethesda, Maryland 20892

Program on Biosecurity and Biosafety Policy
Office of the Director
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985
(301) 496-9838 (Phone)
(301) 496-9839 (Fax)

August 25, 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 June 3, 2014, initial correspondence and July 11, 2014, follow-up report to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident involving an spill of an attenuated strain of *Mycobacterium tuberculosis* outside of primary containment in a Biosafety Level (BL) 2 laboratory at Texas A&M University (TAMU).

From your report, we understand that a flask containing *M. tuberculosis* was stacked on top of other bottles in a roller bottle shaker inside an incubator. Subsequently, the bottle was discovered to have fallen and to have leaked some of its contents inside the incubator. When the spill was discovered, the roller apparatus was switched off, and the door to the incubator was kept closed for a sufficient period of time to allow potential aerosols to settle. The spill was then cleaned, and the bottle shaker and the interior of the incubator were decontaminated.

We also understand that the bacteria involved in the spill are severely attenuated and low numbers of the microorganism were present in the culture fluid, so the likelihood of illness resulting from any potential exposure is extremely low. Nonetheless, the four individuals involved in the clean-up were evaluated by the TAMU occupational medicine provider. Baseline Q Gold serology was recommended and three of the four individuals elected to have their titers drawn. All titers were negative. Repeat titers will be drawn in 10 weeks.

In response to this incident, additional roller units were placed inside the incubator so that stacking bottles will no longer be necessary. The actions taken in response to this incident appear appropriate. No further information is required at this time, however if any titers come back positive please update us.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy (PBBP). The biosecurity and biosafety responsibilities formerly carried out through the NIH OBA are now being conducted by the NIH PBBP. Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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August 25, 2014

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

Dear Dr. Rengarajan:

Thank you for your July 2, 2014, and August 11, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing a July 1, 2014, incident in which a research technician was cut with a pipette containing an AAV vector.

According to your report, the research technician was performing an animal procedure that required a special piece of equipment that contained a mechanical arm to hold the pipette. The arm then had to be moved before mounting and positioning the animal for injection. After getting the mouse into position, the research technician released the animal's head. After releasing the mouse's head, the researcher technician's hand scraped against the pipette, causing it to bleed. Immediately following the incident, the research technician washed the wound site with soap and water for 15 minutes then reported to the occupational health provider. The occupational health provider examined the research technician and provided him with a topical ointment. No additional medical care was required.

In response to this incident, the Emory University Environmental Health and Safety Office (EHSO) reviewed the incident and recommended rearranging the steps involved in this procedure. EHSO noted that the first step should be to restrain the animal. After the animal is restrained, the virus should be loaded into the pipette for the injection procedure.

While reviewing this incident, the EHSO noticed that this protocol was not listed on the principal investigator's (PI) IBC approval. EHSO contacted the PI, who informed EHSO that he believed this protocol was covered under another of his IBC registrations. The PI was notified to stop the

research that had not been previously approved by the IBC. He was then informed that an IBC registration application would have to be submitted. The PI has since submitted a registration for this work, and it is under review by the Emory IBC.

The Emory University response to this incident appears appropriate. No further information about this incident is requested at this time.

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Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

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
Patty Olinger, RBP, Director, Environmental Health and Safety Office, Emory University
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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August 25, 2014

Mike Kluzik
Biosafety Officer
Office of Research Assurances
Washington State University
P.O. Box 643005
Pullman, WA 99164-3005

Dear Mr. Kluzik:

Thank you for your August 4, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident involving an exposure to *Salmonella enteritidis* at Washington State University (WSU).

From your report, we understand that a graduate student was conducting a necropsy of a chicken at the time the exposure occurred. The student accidently stuck herself with a needle that was contaminated with salmonella infected chicken serum. The student immediately washed the infection site and applied 70% ethanol. The student's faculty advisor was notified, who instructed the student to contact a primary health care provider at the student wellness center of WSU. The student was advised by the attending nurse to visit the center the following day, at which point she received tetanus toxoid and was prescribed antibiotics. The student was wearing all appropriate personal protective equipment, including gloves at the time of the incident. In response to this incident, the laboratory principal investigator (PI) has advised the student to be especially careful while performing the procedure.

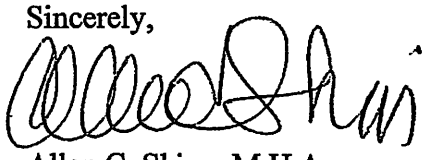
We note that the student did not contact a health care provider immediately at the time of the incident and did not receive treatment until the following day. We recommend that staff be reminded of the need to immediately consult a medical care provider after exposure incidents.

In addition, your report did not include any information on the root cause of the event, or any description of corrective measures being taken to prevent a reoccurrence beyond "taking extra care." As a general matter, it is helpful if incident reports to NIH contain information on what actions are taken by the institution to minimize the risk of similar incidents occurring in the future, for example employing alternative procedures, using safety equipment, or retraining, if warranted. Please provide a follow-up report indicating what additional measures will be taken,

for example retraining the student on sharps handling and the requirements for timely incident reporting.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy (PBBP). The biosecurity and biosafety responsibilities formerly carried out through the NIH OBA are now being coordinated through the NIH PBBP. Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,



Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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September 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 August 14, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding a violation of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) at Oregon Health and Science University (OHSU).

From your report, we understand that the OHSU Institutional Biosafety Committee (IBC) approved the lowering of containment from Biosafety Level (BL) 3 to BL2 for research with attenuated strains of *Mycobacterium tuberculosis* without seeking NIH approval as required under Section IV-C-1-b-(2)-(a) of the *NIH Guidelines*. Approval to conduct research with the strains was granted to two investigators in 2012. During subsequent review of the research, it was recognized that the containment lowering did, in fact, require NIH approval.

In your letter, you requested that NIH approve lowering the containment for the 5 strains of *Mycobacterium tuberculosis* (mc26030, mc26020, mc26230, mc27000, mc26206) from Biosafety Level 3 (BL3) to BL2. NIH has reviewed the request and granted approval on August 26, 2014.

In response to this incident, the IBC has conducted an audit of all registered protocols and has determined that there are no additional instances in which decreased containment requiring NIH approval was approved by the IBC alone. The IBC has also implemented a new administrative review checklist that involve verification of the specific *NIH Guidelines* section upon submission of each protocol, and confirmation that the project does not involve the use of a containment level different from that specified in the *NIH Guidelines*.

The actions taken in response to this incident appear appropriate. No further information is required at this time.

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Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Ashlee V. Moses, Ph.D., Chair, IBC, OHSU
Debra Brickey, Ph.D., Biological Safety Officer, OHSU
Jennifer Ruocco, Ph.D., Chief Integrity Officer, OHSU
Daniel Dorsa, Ph.D., Executive Vice President for Research, OHSU
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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September 4, 2014

Bianca Trollinger
Biological Safety Specialist
University of North Carolina
1120 Estes Drive Extension
Campus Box 1650
Chapel Hill, NC 27599-1650

Dear Ms. Trollinger:

Thank you for your August 13, 2014, and August 18, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) describing an August 13, 2014, incident in which a University of North Carolina researcher bumped into a cart holding used mouse cages, causing one of the cages to fall on the floor, spilling the bedding that was contained within it. The cages were used to house mice that had been previously administered an infectious clone of Chikungunya virus.

According to your report, the laboratory principal investigator (PI), who was present at the time, immediately contained the spill by pouring a concentrated disinfectant around the area and on the spilled bedding. The PI then ordered all of the researchers to leave the room for 30 minutes to allow any aerosols to settle. After waiting 30 minutes, the PI reentered the room, cleaned up the spill, and loaded the spilled bedding and cage into an autoclave for sterilization.

In reviewing this potential exposure, the University of North Carolina Environmental Health and Safety office noted that the spilled cage had been stacked on top of another cage on the cart. As a result, the PI and laboratory manager have prohibited laboratory members from stacking animal cages on top of each other.

The University of North Carolina response to this incident appears appropriate. No further information about this incident is requested at this time.

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Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Mark Heise, Ph.D., Assistant Professor of Genetics, University of North Carolina
Doug Cyr, Ph.D., IBC Chair, University of North Carolina
Nicholas Chaplinski, Interim Biological Safety Officer, University of North Carolina
Mary Beth Koza, Director of Environmental Health and Safety, UNC
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH

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September 4, 2014

Ron G. Wallace, Ph.D, CIH, RBP
Biological Safety Officer
Office of Research Safety
UConn Health
263 Farmington Avenue
Farmington, CT 06370-3930

Dear Dr. Wallace:

Thank you for your August 28, 2014, email to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding a violation of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) in which research subject to section III-D the *NIH Guidelines* was conducted without approval from the UConn Health (UCH) Institutional Biosafety Committee (IBC).

From your report, we understand the violation occurred in a laboratory that is being used by employees of The Jackson Laboratory (JAX), based in Bar Harbor, Maine. JAX has an agreement with UCH whereby UCH provides space for a number of JAX researchers while their own facilities are being constructed. Under this agreement, JAX researchers will comply with the same requirements that UCH researchers follow. During a UCH Institutional Animal Care and Use Committee (IACUC) post-approval monitoring activity, it was discovered that cells transduced with GFP had been transplanted into mice without the work being approved by the IBC.

In response to this incident, the investigator was instructed to suspend the work until a registration was submitted to and approved by the IBC. UCH training will now place more emphasis on compliance with the *NIH Guidelines*, and the wording related to the use of recombinant DNA in registration forms will be clarified and made more descriptive to avoid confusion as to what work is covered by the registration requirements.

The response to this incident appears appropriate. No further information is required at this time.

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Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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September 4, 2014

Alyse DiStefano
IBC Administrator
Office of Environment, Health and Safety
University of California Los Angeles
501 Westwood Plaza, 4th Floor
Los Angeles, CA 90095-1605

Dear Ms. DiStefano:

Thank you for your August 20, 2014, email to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding a violation of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) in which research involving the transplantation of human cells transduced with a lentiviral vector into mice and the subsequent housing of the mice was conducted in an unapproved location.

From your report, we understand that a postdoctoral fellow took mice to a laboratory that was not approved for the work, performed the transplant procedure, and then returned the mice to a room that was not an approved Biosafety Level (BL) 2 housing location. The investigator reported the incident to the University of California Los Angeles Institutional Biosafety Committee (IBC) and noted that it was an isolated event. The postdoctoral fellow did not realize the transplantation of the cells required BL2 housing.

In response to this incident, the investigator retrained the postdoctoral fellow on the laboratory's standard operating procedures (SOPs) and the approved IBC protocol containment requirements. Additionally, the investigator reminded all staff of the need to review the IBC protocol and SOPs before performing any procedures involving biohazardous materials or recombinant DNA.

The actions taken in response to this incident appear appropriate. No further information is required at this time.

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Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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September 4, 2014

Melissa Morland
Biosafety Officer
University of Maryland Baltimore
714 W. Lombard Street
Baltimore, MD 21201

Dear Ms. Morland:

Thank you for your August 19, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in research subject to Section III-D-1 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) was conducted without IBC approval, and a postdoctoral student sustained an eye splash while conducting work on the unapproved protocol.

From your report, we understand that the postdoctoral student was working with lentiviral pseudotyped particles encoding beta-lactamase and African green monkey kidney cells in a biological safety cabinet (BSC). She was wearing prescription eye glasses, but was seated in a manner so that her eyes were below the level of the sash of the BSC. She sustained a splash to the eye, but was unsure whether the splash was from disinfectant or the tissue culture material. She immediately flushed her eyes using the eyewash station, and then reported the incident to the Principal Investigator (PI). The PI called the Biological Safety Officer (BSO) who advised the postdoctoral student to report to the occupational health physician. Although the physician considered the exposure to be low risk, an antiviral medication was prescribed.

While following up with the PI on the incident, the BSO noted that the PI had an IBC approval for a different lentiviral construct and was not approved for the construct involved in the accident.

In response to this incident, the Biological Safety Officer instructed the PI cease all work with unapproved materials until the work has been submitted to and approved by the Institutional Biosafety Committee (IBC). As of the date of your report, the initial submission had been received by the IBC and was expected to be discussed at the next IBC meeting. In addition, the postdoctoral student has been retrained on how to correctly use a BSC, and specifically in how to position the sash. The PI has been retrained on the *NIH Guidelines* and the IBC review process.

The actions taken in response to this incident appear appropriate. No further information is required at this time.

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Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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September 4, 2014

Tim Muller, M.S., CBSP
University Biosafety Officer
University of New Mexico
1 University of New Mexico MSC08-4560
Albuquerque, NM 87131

Dear Mr. Muller:

Thank you for your August 27, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding an incident in which a student was potentially exposed to *Listeria monocytogenes*.

From your report, we understand that the student was working in a biological safety cabinet at the time of the exposure. She was displacing ambient air with nitrogen gas in a rubber-stoppered vial containing dried *L. monocytogenes* when she sustained a needlestick. The student was wearing appropriate personal protective equipment at the time of the injury, including gloves. Immediately after the injury, the student washed the wound with soap and water and reported the incident to the Principal Investigator (PI). The PI instructed the student to report immediately to Employee Occupational Health Services (EOHS). The EOHS clinician contacted the commercial supplier of the agent to determine antibiotic susceptibility and was given an appropriate prophylactic antibiotic (Bactrim DS). The student was reevaluated 15 days postexposure and surveillance will be continued for two months.

In response to this incident, the Biological Safety Officer worked with the PI to enhance the safety of the procedure to reduce the likelihood of another needlestick and the PI has implemented the additional safety measures in the laboratory.

The actions taken in response to this incident appear appropriate. No further information is required at this time.

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Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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September 4, 2014

Michael Jenson, M.D.
Ben Towne Center for Childhood Cancer Research
Seattle Children's Research Institute
P.O. Box 5371, Mailstop OL-1
Seattle, WA 98145-5005

Dear Dr. Jensen:

Thank you for your August 12, 2014, correspondence to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regarding a violation of the Appendix M reporting requirements of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*).

From your report, we understand that a serious adverse event (SAE) occurred on a human gene transfer trial CD19-CAR T cell protocol (NIH OBA protocol number 1306-1233) at Seattle Children's Research Institute. The SAE report was submitted to the Institutional Review Board and the Food and Drug Administration within the 15 day period required for reporting SAEs, but the report was not submitted to the Institutional Biosafety Committee (IBC) nor to NIH OBA within the 15-day period. When the omission in reporting to the IBC and NIH OBA was identified, a report was submitted to both the IBC and NIH OBA on July 15, 2014. In response to this incident, the institution has developed a new reporting checklist to ensure the timely submission of all required reports.

The actions taken in response to this incident appear appropriate. No further information is required at this time.

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Sincerely,

Allan C. Shipp, M.H.A.
Director of Outreach
Program on Biosecurity and Biosafety Policy

cc: Jaqueline Corrigan-Curay, Director, Office of Biotechnology Activities, NIH
Amy P. Patterson, M.D., Associate Director for Biosecurity and Biosafety Policy, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), PBBP, NIH
Ryan Bayha, Senior Analyst for Biosecurity and Biosafety Policy, PBBP, NIH

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September 8, 2014

Marissa M. Cardwell, Ph.D.
Biological Safety Officer
Massachusetts Institute of Technology
77 Massachusetts Avenue
Building N52-496
Cambridge, MA 02139-4307

Dear Dr. Cardwell:

Recently, when the Massachusetts Institute of Technology (MIT) was preparing for its May 15, 2014, site visit from the National Institutes of Health (NIH), it uncovered two incidents involving exposures to recombinant DNA-containing materials that had not been reported to NIH. Reports of those incidents were provided to NIH on July 11, 2014. Below is a summary of those incidents.

Incident involving a lentiviral vector

According to your report, on March 17, 2011, an MIT postdoctoral researcher was preparing to administer a lentiviral vector into the brain of a mouse via stereotaxic injection when he stuck himself with the pipette containing the vector. The researcher washed the wound site with soap and water for ten minutes and finished the experiment. The researcher reported the incident to the laboratory manager and sought medical care the next day. After reviewing the details of the incident, the occupational health provider determined that no follow-up care was required.

The incident was discussed at a meeting of the laboratory personnel, and it was determined that the incident did not represent a deviation from standard operating procedures.

Given the circumstances surrounding this incident, we would have expected the researcher to have been retrained, at a minimum, on stereotaxic injection procedures. Additionally, should such an event occur in the future, it is our expectation that the individual report immediately to the occupational health provider, as opposed to waiting until the next day.

Incident involving an AAV vector

According to your report, on April 3, 2014, an MIT postdoctoral researcher had finished injecting a small amount of AAV vector into a mouse's brain when he cut his wrist on the tip of the microinjection pipette. The researcher immediately washed the wound site with soap and water and then wiped his skin with an alcohol pad. After cleaning up his research area, the researcher then sought treatment at the MIT occupational health provider. No follow-up care was necessary.

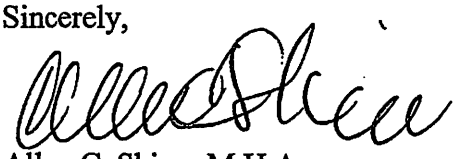
In response to this incident, the laboratory staff discussed the exposure and were reminded to take extra care when manipulating glass pipettes. We reiterate our comment above that stereotaxic injection retraining should be provided to the researcher involved in this incident in order to reduce the risk of these types of incidents from reoccurring.

Additionally, 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 NIH any overt exposure to organisms containing recombinant or synthetic nucleic acid molecules when research is performed under BL2 conditions.

Please note that you are receiving this communication from the NIH Program on Biosecurity and Biosafety Policy. The biosecurity and biosafety responsibilities formerly carried out by the NIH OBA are now being conducted by the NIH Program for Biosecurity and Biosafety Policy (PBBP).

Please contact PBBP staff by email at PBBP@od.nih.gov or by telephone at (301) 496-9838 if you have any questions.

Sincerely,



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Director of Outreach
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cc: Maria Zuber, Ph.D., Vice President for Research, MIT
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