INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, June 18, 2014
Time: 10:00 AM – 12:00 PM

Location: Health Sciences Building T-269

Members Present:
1. Michael Agy, Washington National Primate Research Center
2. H.D. "Toby" Bradshaw, Biology
3. Lesley Colby, Comparative Medicine
4. Elizabeth Corwin, Community Member
5. Stephen Libby, Laboratory Medicine
6. Jeanot Muster, Pharmacology
7. Mei Y. Speer, Bioengineering
8. Eric Stefansson, Environmental Health & Safety
9. Paul Swenson, Community Member, Seattle-King Co. Dept of Public Health
10. Valerie Yerkes, Community Member

Members Absent:
11. Thea Brabb, Comparative Medicine
12. Jean Haulman, UW Travel Clinic
13. Scott Meschke, Environmental & Occupational Health Sciences
14. Matthew R. Parsek, Associate Professor, Microbiology

Guests Present:
1. Linda Arnesen, Biosafety Officer, EH&S Research & Occupational Safety
2. Andrea Badger, IBC/Research Coordinator, EH&S Research & Occupational Safety
3. Jacqui Bales, Biosafety Officer, EH&S Research & Occupational Safety
4. Tony Han, Biosafety Officer, EH&S Research & Occupational Safety
5. Katia Harb, Assistant Director, EH&S Research & Occupational Safety
6. Laury Istvan, Assistant Director, Office of Animal Welfare
7. Lesley Leggett, Biosafety Officer, EH&S Research & Occupational Safety
8. Glenn McLean, Biosafety Officer, EH&S Research & Occupational Safety
9. Karuna Patil, Comparative Medicine
10. Ronald Lee Quick, Public
11. Jude Van Buren, Director, EH&S

1. **CALL TO ORDER:** Steve Libby called the meeting to order at 10:03. A quorum was present.

2. **REMINDER:** Steve Libby reminded attendees that any notes that they retain are subject to public disclosure. A statement was also made about conflict of interest and voting on research proposals as described in the IBC Charter. This includes sharing a grant or a familial relationship.

3. **APPROVAL OF MINUTES:**
   - Steve Libby sought a motion to approve the minutes from the May 21, 2014 minutes meeting.
   - Eric Stefansson made a motion to approve the May 21, 2014 minutes. Jeanot Muster seconded the motion.
   - The committee voted unanimously to approve the May 21, 2014 meeting minutes.

4. **BIOSAFETY OFFICER (BSO) REPORTS***:* The BSO reports are for project reviews involving infectious agents and for projects falling under Section III-E and III-F of the *NIH Guidelines*.

   a. Biosafety Officer Reports
      - Each biosafety officer presented their own report and gave a summary of each project.
      - Steve Libby sought a motion to approve this month's Biosafety Officer Report.
      - A question was raised about the Kyra Becker project. She is moving her animals from ABSL2 back to ABSL1 after they are treated with antibiotics. A subcommittee was formed and extensive research was done about this issue three years ago.
      - Jeanot Muster made a motion to approve this month's Biosafety Officer Report. Lesley Colby seconded the motion.
      - The Committee unanimously voted to approve this month's Biosafety Officer Report.

5. **INDIVIDUAL PROJECT REVIEWS** *(IBC member Primary Reviewer Reports and Biological Use Authorization (BUA) letters available as separate documents)*

   1. Frevert, Charles, change, *Gene-targeted mouse models to study versican*
      - Steve Libby served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. Steve Libby presented the Primary Reviewer Report.
      - The investigator studies the role that large proteoglycans and associated glycosaminoglycan play in the innate immune response to infection.
      - This is a change in which they are requesting to use lentiviral vectors and recombinant DNA in human, canine, and deer cell lines.
      - The draft BUA letter was shown.
      - A discussion occurred regarding the deer cell lines that are being requested.
      - Steve Libby made a motion to approve the draft BUA for Dr. Frevert. A second is not needed since he is the Primary Reviewer.
      - The Committee voted unanimously to approve the draft BUA for Dr. Frevert.

   2. Gallagher, Evan, renewal, *Molecular and Biochemical Effects of Pollutants in Fish and Human Cells*
      - Toby Bradshaw served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. Toby Bradshaw presented the Primary Reviewer Report.

- The investigator studies the metabolism and health effects of environmental pollutants on fish (zebrafish, coho, Chinook salmon, and sculpin).
- The draft BUA letter was shown.
- The investigator should list fecal/oral as potential modes of transmission, and humans and animals as potential susceptible species (questions 25 and 26).
- Toby Bradshaw made a motion to approve the draft BUA for Dr. Gallagher. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Gallagher, contingent upon correctly answering questions 25 and 26 on the BUA application.

3. Greenberg, Philip, change, *Mechanisms of Murine Tumor Eradication*

- Eric Stefansson served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. Eric Stefansson presented the Primary Reviewer Report.
- The change requests the use of mouse cells transfected with recombinant DNA/RNA and mouse cells transduced with amphotropic gammaretroviral vectors.
- The draft BUA letter was shown.
- Eric Stefansson made a motion to approve the draft BUA for Dr. Greenberg. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Greenberg.

4. Hurley, James, renewal, *Determinants of Rod and Cone Response Characteristics*

- Jeanot Muster served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. Jeanot Muster presented the Primary Reviewer Report.
- The investigator is breeding and using transgenic zebrafish.
- The draft BUA letter was shown.
- A discussion occurred about the IACUC protocol. IBC applications and IACUC applications are reviewed concurrently by the two offices, for the most part.
- Jeanot Muster made a motion to approve the draft BUA for Dr. Hurley. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Hurley.

5. Klatt, Nichole, change, *Mucosal Immune Dysfunction After SIV Infection*

- Elizabeth Corwin served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. Elizabeth Corwin presented the Primary Reviewer Report.
- The investigator is requesting to use plasmid DNA and VSV (vesicular stomatitis virus) vectors as an HIV vaccine (given to macaques).
- A discussion regarding whether or not this agent requires an APHIS permit. EH&S will follow up on this. Both the investigator and supplier will be asked to show evidence that this does not require a permit.
- The draft BUA letter was shown.
- Elizabeth Corwin made a motion to approve the draft BUA for Dr. Klatt. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Klatt, contingent upon EH&S investigation of the aforementioned APHIS permit question.

6. Perkel, David, new, *Neural circuits for auditory and vocal processing*

- Michael Agy served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. Michael Agy presented the Primary Reviewer Report.
- This is a new project involving use of viral vectors in zebra finches (birds).
- A discussion of biosafety levels occurred. The lab is not currently set up to conduct work at biosafety level 2, and so they will perform RCV (replication-competent virus) testing in order to conduct the work at biosafety level 1.
- The investigator has not yet performed RCV testing. A discussion occurred regarding whether the committee would vote to approve the project today, pending completion of RCV testing, or whether the project should be moved to the next meeting. The committee decided to vote today on the contingent approval.
- The investigator must conduct RCV testing on the lentiviral vectors.
- The draft BUA letter was shown.
- Michael Agy made a motion to approve the draft BUA for Dr. Perkel. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Perkel, contingent upon completion of RCV testing.</u>

7. Rathod, Pradipsinh, renewal, *Genomic Tools to Characterize Hypermutating Plasmodium falciparum*

- Matt Parsek served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. On behalf of Matt Parsek, Jacqui Bales presented the Primary Reviewer Report.
- The project involves culturing malarial plasmids using human red blood cells and plasma. Malarial parasites are not capable of causing an infection when no vector (mosquito) is present.
- A discussion regarding the resistance markers occurred. The PI uses plasmids to transfect the parasites conferring antibacterial selection markers. The plasmids do not carry any sort of anti-malarial markers.
- The draft BUA letter was shown.
- Dr. Rathod must complete biosafety training. Other members of the lab have completed all necessary training.
- The autoclave procedures for the lab are being updated and revised.
- Eric Stefansson made a motion to approve the draft BUA for Dr. Rathod. Toby Bradshaw seconded the motion.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Rathod, contingent upon completion of biosafety training.</u>

8. Sewell, Toddy, new, *Sorting 22Rv1/GFP prostate cancer cells*

- Lesley Colby served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. Lesley Colby presented the Primary Reviewer Report.
- This project involves an investigator from another company who is requesting to use UW facilities (the SLU flow cytometry room). The agents she will be using are human cells infected with xenotropic murine leukemia virus-related virus and human cells transduced with lentiviral vectors.
- A discussion of the XMRV occurred. This is a mouse pathogen, but Dr. Sewell is not going to any animal housing facilities, or anywhere near them.
- The draft BUA letter was shown.

- Lesley Colby made a motion to approve the draft BUA for Dr. Sewell. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Sewell.

9. Skerrett, Shawn, change, *Host Defense Against Bacterial Pneumonia*

- Paul Swenson served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. Paul Swenson presented the Primary Reviewer Report.
- The investigator wants to add recombinant strains of *Francisella novicida* and *Legionella pneumophilia* for use in tissue culture experiments.
- The draft BUA letter was shown.
- A discussion regarding *Francisella novicida* occurred. This is not a select agent. It is used as a proxy to study *Francisella tularensis*, which is a more hazardous species.
- Paul Swenson made a motion to approve the draft BUA for Dr. Skerrett. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Skerrett.

10. Stamatoyannopoulos, John, renewal, *Regulatory Genomics*

- Scott Meschke served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. On behalf of Scott Meschke, Steve Libby presented the Primary Reviewer Report.
- The draft BUA letter was shown.
- The investigator needs to take biosafety training, and there are some minor lab inspection concerns yet to be resolved.
- A discussion of documentation and whether or not the PI has provided sufficient documentation regarding lowering containment with third generation lentiviral vectors with oncogenic inserts occurred. The committee decided that the PI has provided enough documentation.
- Steve Libby made a motion to approve the draft BUA for Dr. Stamatoyannopoulos. A second is not needed since he endorsed the primary review.
- The Committee voted unanimously to approve the draft BUA for Dr. Stamatoyannopoulos, contingent upon completion of training and resolution of the lab inspection issues.

11. Yang, Xiaoming, change, *MR Imaging of Stem Cell Gene Therapy of Atherosclerosis*

- Valerie Yerkes served as the Primary Reviewer and Linda Arnesen served as the Biosafety Officer Reviewer. Valerie Yerkes presented the Primary Reviewer Report.
- The investigator is requesting to add rat cells transduced with lentiviral vectors and use of rats for in-vivo work.
- Dr. Yang needs to take both biosafety training and bloodborne pathogen training.
- The draft BUA letter was shown.
- Valerie Yerkes made a motion to approve the draft BUA for Dr. Yang. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Yang, contingent upon completion of the necessary training.

12. Zhang, Feng, change, *Radiofrequency Heat(RFH)-Enhanced Gene Therapy for Liver tumor*

- Mei Speer served as the Primary Reviewer and Linda Arnesen served as the Biosafety Officer Reviewer. Mei Speer presented the Primary Reviewer Report.

- The change adds two new species (mice and rats) and also human and rat cells transduced with lentiviral vectors, and mice and rat cells transfected with HSV-TK plasmid DNA.
- The draft BUA letter was shown.
- Mei Speer made a motion to approve the draft BUA for Dr. Zhang. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Zhang.

FOR YOUR INFORMATION:

- NIH Reportable Event:
  - The PI involved was Dr. Steiner. The incident involves a mouse bite to an animal technician. One month prior to the bite, the mouse had been injected with AAV (replication deficient and adenovirus-free).
  - The individual properly washed the bite and contacted Employee Health. The person was provided with a tetanus booster.
  - The committee discussed the potential risks to the individual. The risk to the individual regarding the AAV is very low, and probably identical to the risks associated with receiving a bite from a naïve mouse.
- Serious Adverse Event:
  - The patient was enrolled in the Maloney clinical trial. She received the study treatment per the clinical protocol on May 20, 2014, and six hours later, became ill. She appears to have suffered what is termed a 'cytokine storm' – a potentially fatal immune reaction. She died on May 23, 2014. As a precaution, the investigator has lowered the dose of the study treatment. The patient who had the adverse reaction was receiving the highest level of the dose described in the protocol. The investigator will no longer administer that dose to patients.
  - We have requested the autopsy reports and Elizabeth Corwin, medical oncologist, will review them.

ADMINISTRATIVE UPDATES:

- The secondary reviewer policy will begin next month.
- Agents that fall under section III-F of the *NIH Guidelines* will no longer appear on BUA letters.
- The revised BUA application is almost complete.
- The human cells subcommittee is underway. The committee will be looking into the issue of whether it is necessary to house animals at ABSL2 for their entire lives after they have been administered human cells.
- Pat Azeltine is no longer with UW.

MEETING ADJOURNED AT APPROXIMATELY 11:58.

Documents sent to OBA

Andrea Badger

From: Eric D. Stefansson
Sent: Monday, July 07, 2014 4:21 PM
To: 'OBA-OSP@od.nih.gov'
Cc: Stephen J. Libby; Jude Van Buren; Katia Harb (kharb@uw.edu)
Subject: Incident Report
Attachments: Mouse Lab Handout 6-27-14 JL.pdf; NIH-OBA_Steiner.doc

Dear OBA,

Please see the attached incident report involving an employee that received bite to her finger from a mouse that was previously administered Adeno-associated virus. This was originally reported to you via email on June 4th, 2014 .

Please let me know if there any questions.

Thank you,

Eric

ENVIRONMENTAL HEALTH & SAFETY
UNIVERSITY of WASHINGTON

Eric Stefansson, MS
Biosafety Programs Manager
(206) 543-4969 desk/voicemail
(206) 543-6713 fax
estefans@uw.edu

Template for Reporting Incidents Related to Research Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids* to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA)

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

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. This template is also available on the NIH OBA Web pages as a Word document (http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting) in which the fields will expand according to the amount of text entered. Use of this template is not required and other formats for submitting reports may be acceptable.

A separate template for reporting Human Gene Transfer Adverse Events is available at:
http://osp.od.nih.gov/sites/default/files/resources/Adverse_Event_Template_.docx

Please note that submitting this completed template to NIH OBA does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

Attention: Incident Reports
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(For all non-USPS deliveries use Zip Code 20817)
Telephone 301-496-9838

Fax 301-496-9839
E-mail: oba-osp@od.nih.gov

NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://osp.od.nih.gov/sites/default/files/resources/Adverse_Event_Template_.docx

Does this incident involve research subject to the *NIH Guidelines*?	YES
Institution name:	University of Washington
Date of report:	Email notification: 6/04/2014 Formal report: 7/3/2014
Reporter name and position:	Eric Stefansson, Biosafety Programs Manager
Reporter telephone:	(206) 543-4969
Reporter email:	estefans@uw.edu
Reporter mailing address:	University of Washington Environmental Health and Safety Department Research and Occupational Safety Section 1705 NE Pacific St Box 357165 Seattle, WA 98195-7165
Date of incident:	5/06/2014
Name of principal investigator:	Robert A. Steiner Ph.D.
Is this an NIH funded project?	YES
If yes, please provide:	NIH grant or contract number: R01 HD049651
	NIH funding institute or center: NICHD
	NIH program officer contact information (name, email etc): Charisee Lamar: Charisee.Lamar@nih.hhs.gov
What was the **nature** of incident?	A research scientist received a bite to the tip of her finger while scruffing a mouse to administer an IP injection of a low dose of clozapine-N-oxide (CNO). One month prior to this procedure, the animal had received an intracranial stereotaxic injection of

	an adeno-associated viral vector (AAV; replication deficient and adenovirus-free).

Did the Institutional Biosafety Committee (IBC) approve this research	YES If yes, on what date? 9/21/2011
If yes, please provide:	Approval date: 9/21/2011
	Approved biosafety level(s) for the research: BSL-1 / ABSL-1
	Additional approval requirements: None
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-4-a
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	Other – please describe: The incident has been recorded in the Institution's OSHA 300 Log
Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc. as relevant.)	An adeno-associated viral vector (AAV; replication deficient and adenovirus-free) containing the gene for a stimulatory DREADD receptor into the arcuate nucleus of the hypothalamus (one month prior to the bite). The vector designation is: AAV-hSyn-DIO-hM3D(Gq)-mCherry. The mouse was a male KissCre heterozygote, with Cre being expressed only in Kiss1-expressing cells. He had been the product of a KissCre homozygotic male and a wild-type C57BL/6J female mating pair.

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

A description of:

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

DESCRIPTION OF INCIDENT:

Timeline:

The bite occurred while a research assistant was scruffing the animal, prior to any injection. Following the bite, the individual placed the animal back in a cage and attended to her finger by washing with soap and water. Another member of the lab then successfully scruffed the animal and IP injected a low dose of clozapine-N-oxide (CNO) in saline into the animal without incident.

The mouse had received an intracranial stereotaxic injection of an adeno-associated viral vector (AAV; replication deficient and adenovirus-free) containing the gene for a stimulatory DREADD receptor into the arcuate nucleus of the hypothalamus. The vector designation is: AAV-hSyn-DIO-hM3D(Gq)-mCherry. This injection had been performed one month prior to the incident date (surgery performed 4/6/14; date of incident 5/6/14) to allow the gene to fully incorporate into the animal's genome and the receptor to be expressed.

The mouse was a male KissCre heterozygote, with Cre being expressed only in Kiss1-expressing cells. He had been the product of a KissCre homozygotic male and a wild-type C57BL/6J female mating pair.

- **The incident/violation location:** Magnuson Health Science Building room BB628. This is a standard BSL-1 laboratory that is approved for procedures on mice requiring ABSL-1 containment.

- **Who was involved in the incident/violation, including others present at the incident location?** A female research assistant. A graduate student that was supervising the area was also present.

- **Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.** The mouse was secured and the individual washed the bite. The individual then immediately consulted with the employee health clinic.

- **The training received by the individual(s) involved and the date(s) the training was conducted.** Biosafety Training (6/18/2012), Bloodborne Pathogens Training (7/05/2013), Mouse Hands-on Laboratory (4/04/2012), Surgery

Laboratory part 1 (8/23/2013 and Surgery Laboratory Part 2 (9/10/2013.

- **The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.** (see attached) Procedures were followed with no deviations.

- **Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.** No.

- **The personal protective equipment in use at the time of the incident/violation.** The individual was wearing standard PPE at the time of the incident, which includes nitrile gloves, a lab coat, face mask, hair bonnet, and shoe covers.

- **The occupational health requirements for laboratory personnel involved in the research.** Participation in the Animal Use Medical Screening program.

- **Any medical advice/treatment/surveillance provided or recommended after the incident.** She was seen by Employee Health clinic and the injury site was evaluated. The individual was provided a Tetanus booster. Based on the mouse specific agent, no further treatment was given. The clinic will follow up with the affected individual.

- **Any injury or illness associated with the incident.** Received a bite to the tip of her finger.

- **Medical surveillance results.** None.

- **Equipment failures.** N/A

Has the IBC reviewed this incident?	YES , the incident was presented at the June 18th IBC meeting. If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed. Final approval of the minutes is pending.
Has a root cause for this incident been identified?	YES If yes please describe: Scruffing of mice can lead to bites, though this rarely happens. The mouse was most likely a more aggressive male than is usually used for experiments and was further stressed by the experiment and was able to muscle its head out of her firm grip enough to bite the tip of her finger.

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

All personnel have been reminded of proper handling procedure. The employees will continue to ensure that she has the proper hold on the mice before giving an IP injection. They will also ensure that the animal is not held of disturbed any longer than absolutely necessary.

- **Please provide copies of any documents referenced in this report.**

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

OBA Response

Andrea Badger

From: Eric D. Stefansson
Sent: Wednesday, July 23, 2014 11:40 AM
To: Stephen J. Libby; Jude Van Buren; Katia Harb (kharb@uw.edu); 'Thea L. Brabb (thea@uw.edu)'
Subject: Final OBA response
Attachments: NIH_OBA_response_Steiner_2014.pdf; NIH-OBA_Steiner_incident_report_2014.pdf

Hi all,

I am attaching the final OBA response from the last incident report that I submitted last month. This was the incident involving a lab worker being bitten by a mouse that had been previously administered AAV. The PI was Dr. Steiner. I am also attaching the original report for your review.

Thanks,

Eric

ENVIRONMENTAL HEALTH & SAFETY
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(301) 496-9839 (Fax)
http://osp.od.nih.gov/

July 10, 2014

Eric Stefansson
Biosafety Programs Manager
Research and Occupational Safety
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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