INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, December 17, 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. Thea Brabb, Comparative Medicine *(Animal Containment Expert)*
3. H.D. "Toby" Bradshaw, Biology *(Plant Expert)*
4. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
5. Elizabeth Corwin, Community Member (*Human Gene Transfer Expert; IBC Vice Chair*)
6. David Koelle, Allergy and Infectious Diseases
7. Stephen Libby, Laboratory Medicine (*IBC Chair*)
8. Scott Meschke, Environmental & Occupational Health Sciences
9. Jeanot Muster, Pharmacology
10. Angela Rasmussen, Microbiology
11. Mei Y. Speer, Bioengineering
12. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)
13. Paul Swenson, Community Member, Seattle-King Co. Dept of Public Health

1. **CALL TO ORDER:** The IBC Chair called the meeting to order at 10:04 a.m. A quorum was present.

2. **REMINDER:** The IBC Chair 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. **SPECIAL PRESENTATION:**
   - The IBC heard a presentation about the construction plans and design of a new animal facility planned to be built on UW campus. The building will be called Animal Research and Care Facility (ARCF).
   - The ARCF building will be about 90,000 square feet. It is designed to provide state-of-the-art animal housing and research space to support research enterprise.
   - The project was approved by the UW Board of Regents and construction is scheduled to begin around February 2015.
   - The building will be underground. The presenter described the many complexities that went into forming the construction plans. For example, there are tentative plans for future above-ground construction nearby, and so the ARCF building will be constructed in a way that allows for that.
   - The ARCF building will have two floors. One floor will be designated for rodents and other small animals. The other floor will be used for larger animals and non-human primates.
   - The building will be secured and access will be restricted at many points. For example, vendors who are delivering animal food can access storage rooms but cannot enter into spaces where the animals are actually kept.
   - The rooms are designed to be flexible. They can be used as either ABSL-1 or ABSL-2, and the air pressure and other room mechanics can be easily controlled and switched to fit the current needs of a room.
   - The presenter showed the committee the construction plans and described the planned use of the spaces. There will be cage washing facilities, housing rooms, procedure rooms, surgery suites, and imaging facilities.
   - The facility is expected to open around 2017.

4. **APPROVAL OF MINUTES:**
   - The IBC Coordinator described the changes that were made to the IBC agenda and IBC minutes template. IBC agendas will be posted on the EH&S website at least 24 hours in advance of the IBC meeting, per new Washington state law requirements for public meetings.
   - The November 19, 2014 IBC minutes were shown to the committee. The IBC Chair sought a motion to approve the minutes from the November 19, 2014 meeting.
   - A member made a motion to approve the November 19, 2014 minutes. A member seconded the motion.
   - <u>The committee voted unanimously, with one abstention, to approve the November 19, 2014 meeting minutes.</u>

5. **SUBCOMMITTEE REPORTS:**
   - WaNPRC Waste Management Modernization
     - Two guests from the primate center were introduced.
     - The chair of the subcommittee described the background and the issues that the subcommittee discussed. The IBC has traditionally been involved in the regulation of waste from the animal facilities, particularly facilities requiring

ABSL-2 or greater containment. This subcommittee looked into the handling of waste excreted from non-human primates (e.g., feces and urine).

- The primate center has received a grant to buy new cages, which would facilitate modernizing the way non-human primate waste is handled.
  - Currently, animal technicians manually remove bedding and waste from cage pans, and the waste is then double-bagged and autoclaved prior to disposal in the solid waste stream.
  - The primate center would like to buy new cages that can be washed out. The waste would be directed to a trough system that dispenses to the sanitary sewer. The new cages would not contain pans.
- A member pointed out that most primate centers throughout the country dispense non-human primate waste into the sanitary sewer.
- The sanitary sewering process is designed to decontaminate fecal bacteria. A member pointed out that waste from uninfected non-human primates is quite similar to human waste.
- The WaNPRC Waste Management Subcommittee and the IBC have been asked to consider only whether direct sewering of waste is appropriate for uninfected non-human primates that have never been experimentally exposed to biological agents.
- Animals that have been experimentally exposed to biological agents may be considered at a later time. Waste from these animals will continue to be autoclaved prior to disposal in the solid waste stream. NIH OBA and the Seattle Public Utilities will be consulted before any changes to waste handling procedures for biohazardous animals are made.
- The guests who attended the meeting provided some insight and background about their reasoning for requesting this change.
- The committee discussed these issues and the appropriate wording of the motion to be made.
- A member made a motion to allow direct sewering of the waste of non-human primates who have never been experimentally exposed to any sort of biohazardous agent, including recombinant DNA. Another member seconded the motion.
- <u>The Committee voted unanimously to approve the motion and allow direct sanitary sewering of primate waste only from animals that have never been experimentally exposed to any sort of biohazardous agent, including recombinant DNA.</u>

6. **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 Report
      - Dr. Thompson renewed a project involving the use of human source material.
      - Dr. Nehilla received approval for a new project involving the use of human source material.
      - Dr. Maggio-Price added the use of human feces to be administered mice to her project.
      - Dr. Jayadev moved her laboratory and received approval for several new rooms.
      - Dr. Meschke received approval for a new project involving the use of several wild-type Risk Group 2 agents.

- Dr. Buckner added a new Risk Group 2 organism to be used in mice.
- Dr. Koelle received approval to use human cells from human subjects known to be HIV positive.
- The IBC Chair sought a motion to approve this month's Biosafety Officer Report.
- A member made a motion to approve this month's Biosafety Officer Report. Another member seconded the motion.
- The Committee voted unanimously, with three abstentions, to approve this month's Biosafety Officer Report.

7. INDIVIDUAL PROJECT REVIEWS

1. Abkowitz, Janis, renewal, *The role of FLVCR in hematopoiesis and iron homeostasis*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of the project is to understand the role of FLVCR (a heme exporter) in differentiation of blood cells, maintenance of iron concentration, and to develop model systems for studying normal and abnormal blood cell development.
- Agents used on this project include gammaretroviral vectors, lentiviral vectors, and human cell lines.
- The investigator needs to complete questions 22 and 23 on the BUA application. She also needs to sign the application and complete her biosafety training.
- The draft BUA letter was shown.
- A discussion occurred about the wording on the BUA application. The wording 'murine cells transduced with lentiviral vectors' should be added to her BUA letter for clarity.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Abkowitz. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Abkowitz, contingent upon completing questions 22 and 23 on the BUA application, signing the BUA application, retaking biosafety training, and adding the language above to the BUA letter.

2. Fuller, Deborah, change, *Immunogenicity and Efficacy of DNA Vaccines and Therapies Against Influenza*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is studying a novel antiviral drug and they are requesting to use two strains of influenza that are reassortants of avian influenza strains and the mouse-adapted strain PR8.
- The lab is requesting to use the viruses both in-vitro and in-vivo. The requested procedures include serial passaging of the viruses in mice.
- Although it is more likely that the process of passing will make the virus less virulent, there is potentially a small chance that the investigator could possibly make the virus more virulent to humans. The IBC Primary Reviewer and other committee members explained that there is a chance that this work could be characterized as GOF (gain-of-function) research and fall under federal restrictions and policies.
- A discussion occurred regarding whether or not this would be considered a gain-of-function study. More information and research is needed.
- The IBC Primary Reviewer explained that NIH OBA (National Institutes of Health Office of Biotechnology Activities) has influenza experts available for questions like

this. The committee agreed that EH&S should contact OBA and ask them about this study.

- The IBC Primary Reviewer recommended deferring the approval of this project so that a subcommittee can be formed and more information can be gathered before making a final decision.
- The IBC Primary Reviewer discussed some steps that the subcommittee could potentially take, such as increasing the containment level.
- The IBC discussed the next steps to be taken. EH&S will write to OBA, and to Dr. Fuller explaining why her project will not be approved at today's meeting. The IBC Chair and EH&S will form a subcommittee which will be scheduled to present at the January IBC meeting.
- The IBC Primary Reviewer made a motion to defer the approval of Dr. Fuller's draft BUA until a subcommittee could be formed and more information gathered.
- <u>The Committee voted unanimously to defer the approval of Dr. Fuller's draft BUA until a subcommittee can be formed and more information gathered.</u>

3. MacLellan, Robb, change, *Cardiac development and growth, and cardiac regeneration*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting to add the use of murine cells transduced with lentiviral vectors, to be used in mice.
- The lab inspection has been completed.
- The draft BUA letter was shown.
- An animal housing room needs to be added to the BUA letter.
- The Appendix A has a typo.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. MacLellan. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. MacLellan, contingent upon correction of the appendix A and adding the animal room to the BUA letter.</u>

4. Neitz, Jay, renewal, *Expression and Function of Cone Pigment Genes*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a project renewal. The lab investigates whether vision defects associated with cones can be helped by gene therapy. Agents used on this project include AAV (adeno-associated viral vectors) and human cells.
- The lab inspection is scheduled for later this week.
- Training records are in place.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Neitz. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Neitz, contingent upon successful completion of the lab inspection.</u>

5. Moon, Randall, change, *Wnt genes and signaling*

- One member declared a conflict of interest.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator wants to add a rabies viral vector, a Sindbis viral vector, and AAV.
- The requested rabies viral vector uses a vaccine strain backbone, designated SAD 819, and is used as a vaccine strain in wildlife studies primarily in Europe.

- The rabies viral vector can replicate - it kills the neuron it is in. But the vector will not transmit and cannot spread to any other cell. The virus should not be shed from the host. It is a viral vector with an attenuated form of the vaccine strain as its backbone, and so the pathogenicity should be low.
- This project will receive an occupational health review.
- A member exited the meeting at 11:30. Quorum was not lost.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Moon. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Moon.

6. Iritani, Brian, renewal, *Gene Function in Lymphopoiesis and Cancer*

- One member declared a conflict of interest.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the research is to understand the roles and mechanisms of specific genes in the development, function, and transformation of immune cells.
- Gammaretroviral vectors in-vitro and in mice are used on the project.
- The draft BUA letter was shown.
- Training records are in place and the lab inspection has been completed.
- The language "*Mouse cells transduced with gammaretroviral vectors*" will be added to the BUA letter.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Iritani. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Iritani, contingent upon adding the aforementioned agent to the BUA letter.

7. Kean, Leslie, change, *New Biologic Therapies for Graft Versus Host Disease (GVHD) Prevention and Treatment During Hematopoietic Cell Transplantation*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting the addition of SHIV. Third generation lentiviral vectors and foamy viral vectors will be used.
- The lab's goal is to model graft versus host disease in macaques.
- Training records are in place.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kean. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Kean.

8. Lee, Donghoon, new, *MR Methods for Small Animal Imaging*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The research project involves MR imaging of mice that have previously been infected with AAV.
- The draft BUA letter was shown.
- Training records are in place.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Lee. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Lee.

9. Liu, Alvin, renewal, *Prostate Cell Biology - Stromal Epithelial*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab studies cell-cell interaction between epithelial and stromal cells in prostate and bladder development and cancer.
- The investigator is using lentiviral vectors with oncogenes. This necessitates raised containment, BSL-2 with 3 practices, unless the investigator can show that the lentiviral vectors are third generation. Thus far, the information submitted by the investigator does not show proof of third generation vectors and actually suggests that the vectors are second generation.
- There is no BSL-2 with 3 practices room given on the BUA application.
- The committee discussed the issue. The IBC Primary Reviewer suggests tabling the approval until further clarification from the investigator can be provided.
- A memo will be drafted and sent to the PI explaining why his project was not approved at today's meeting and what information we need from him before approving the project.
- The IBC Primary Reviewer made a motion to table the approval for Dr. Liu until we receive more information about the lentiviral vectors and the proposed facilities.
- <u>The Committee voted unanimously to table the approval for Dr. Lee until this information is received.</u>
- A member exited the meeting. Quorum was not lost.

10. Neitz, Maureen, change, *Genes and photopigments of red-green color vision: exploring circuitry with fMRI*

- The assigned IBC Primary Reviewer presented the Primary Review.
- Dr. Neitz has submitted a request to use eye tissue from non-human primates previously infected with primate lentiviruses. The committee also discussed this issue at last month's IBC meeting.
- Standard operating procedures still need to be submitted and then reviewed by EH&S before final approval can be granted.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Neitz. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Neitz, pending completion of standard operation procedures detailing how work with the eye tissue will be done.</u>

11. Nghiem, Paul, renewal, *Skin Cancer Studies in Mouse Models*

- One member declared a conflict of interest.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab studies skin cancer. The overall goal of the research is to develop methods of prevention and/or treatment for skin cell carcinomas.
- Agents used on this project include adenoviral vectors, lentiviral vectors, and human tissues.
- The draft BUA letter was shown.
- The lab inspection has been completed and trainings are up-to-date.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Nghiem. A second is not needed since she is the Primary Reviewer.
- <u>The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Nghiem.</u>

12. Oberst, Andrew, change, *Programmed Cell Death and Immunity*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting the addition of murine cytomegalovirus (MCMV) for in-vitro and in-vivo use, and the addition of mouse-adapted influenza strains for in-vivo use.
- MCMV falls under section III-D of the NIH guidelines when used in mice, and section III-E when used in-vitro. The Primary Reviewer will edit her review to reflect this.
- The draft BUA letter was shown.
- A discussion occurred regarding MCMV. Comp Med will assign the rooms and will likely also assign enhanced containment.
- Committee members discussed whether or not the PIs are truly aware of the footnotes listed on the BUA letter (particularly: "*Contact the vivarium supervisor for animal room assignments. Work with biohazardous agents in animals must be performed in the appropriate EH&S approved biohazard rooms. Refer to the tables in this letter for the specific biosafety containment and practices required for your biohazardous agents*." and "*The Biological Safety Level (BSL) listed above is the minimum required for human health. Additional Comparative Medicine requirements may apply for animal pathogens to protect the welfare of the animal colony. You must contact the Dept. of Comparative Medicine for housing assignment prior to commencing work with animal pathogens*.").
- The committee would prefer in this case that this information was listed on the front page of the BUA letter rather than in the footnote section.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Oberst. A second is not needed since she is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Oberst, contingent upon adding information from these two footnotes to the front page of the BUA letter.</u>

13. Soetedjo, Robijanto, renewal, *Neurophysiology of Saccade Adaptation*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator studies the neurological mechanisms of saccades (quick, simultaneous movements of both eyes) in non-human primates. Adeno-associated viral vectors will be used on the project.
- The training needs to be completed. The lab inspection has a couple of outstanding issues.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Soetedjo. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Soetedjo, contingent upon completion of training and resolving the outstanding lab inspection issues.</u>
- A member exited the meeting at 12:22. Quorum was not lost.

14. Woodward, Joshua, renewal, *Pathogenesis of Listeria monocytogenes and Staphylococcus aureus*

- The assigned IBC Primary Reviewer presented the Primary Review.

- The lab researches *Listeria monocytogenes* and *Staphylococcus aureus*, and the ways they are able to infect and replicate in the host. The lab also studies innate immune response to these pathogens.
- Biohazardous agents used on this project include *Listeria monocytogenes, Staphylococcus aureus*, lentiviral vectors, and human source material.
- The draft BUA letter was shown.
- The lab inspection has been completed and training records are in place.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Woodward. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Woodward.

8. There were no issues from the floor, and no public comments.

MEETING ADJOURNED AT APPROXIMATELY 12:25.