INSTITUTIONAL BIOSAFETY COMMITTEE UNIVERSITY of WASHINGTON

Meeting Minutes

Date:	Wednesday, June 15, 2016
Time:	10:00 AM – 12:00 PM

Location: Foege N-130A

Present:

Members 1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)

- 2. Lesley Colby, Comparative Medicine (Animal Containment Expert)
 - 3. Richard Grant, Washington National Primate Research Center
 - 4. Garry Hamilton, (Community Member)
 - 5. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 - 6. Scott Meschke, Environmental & Occupational Health Sciences
 - 7. Jason Smith, Microbiology
 - 8. Eric Stefansson, Environmental Health & Safety (Biosafety Officer)
 - 9. Paul Swenson, Seattle-King Co. Dept. of Public Health (Community Member)

Commonly Used Abbreviations IBC: Institutional Biosafety Committee BSO: Biological Safety Officer BUA: Biological Use Authorization BSL: biosafety level PI: Principal Investigator IACUC: Institutional Animal Care and Use Committee NIH: National Institutes of Health DURC: Dual Use Research of Concern SOP: standard operating procedure

- **1. CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:04 am. 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. CRISPR PRESENTATION

• Dr. Karin Bornfeldt was introduced to the committee, and gave a presentation about CRISPR technology. CRISPR-Cas9 is a genetic editing technology that enables geneticists and medical researchers to edit parts of the genome by cutting out, replacing or adding parts to the DNA sequence.

4. APPROVAL OF MINUTES:

- The IBC Chair sought a motion to approve the minutes from the May 18, 2016 meeting.
- A member made a motion to approve the May 18, 2016 minutes. Another member seconded the motion.
- The committee voted unanimously, with three abstentions, to approve the May 18, 2016 meeting minutes.
- BIOSAFETY OFFICER (BSO) REPORT: The Biosafety Officer Report includes (1) projects involving recombinant or synthetic nucleic acids covered under section III-E and III-F of the *NIH Guidelines*, (2) proposals involving non-recombinant biohazardous agents requiring BSL-1 and BSL-2 containment, and (3) administrative updates, such as room additions.
 - a. Biosafety Officer Report
 - Several BUA letters were updated to list recombinant Risk Group 1 microorganisms at ABSL-2. Dr. Van Voorhis, Dr. Pun, Dr. Singh, Dr. Giacani, Dr. Catterall, Dr. West, Dr. Pepper, and Dr. Oberst each received an updated BUA letter. Dr. Murphy, Dr. Buckner, and Dr. Mougous will also have their BUA letters corrected.
 - Dr. Koelle added a new room and a new non-recombinant herpes virus strain to his BUA letter.
 - Dr. Queitsch renewed a BUA involving disarmed strains of *Agrobacterium tumefaciens*, and transgenic *Arabidopsis thaliana*.
 - Dr. Eaton renowned a BUA involving human source material.
 - Dr. Liu and Dr. Wang each received a new BUA approval for human source material.
 - Dr. Chu received a new BUA for human source material, non-recombinant respiratory syncytial virus, and non-recombinant metapneumovirus.
 - Dr. Villen renewed a BUA involving various Risk Group 1 species of yeast.
 - Dr. Brenowitz and Dr. Werth each added a new room to their BUA letters.
 - Dr. Adams-Waldorf added the Immunology Cell Analysis facility to her BUA letter.
 - Dr. Fuller added non-recombinant strains of Dengue virus and Zika virus (for in vitro use) to her BUA letter.
 - Dr. Nance received a new BUA approval for non-recombinant Zika virus used in vitro, as well as human and non-human primate cells.
 - 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.

• <u>The Committee unanimously voted, with one abstention, to approve this month's</u> <u>Biosafety Officer Report.</u>

6. CATEGORY III-D AMENDMENTS

- 1. Kiem, Hans-Peter, new, Cell and Gene Therapy for HIV Cure
 - The biosafety officer presented the project.
 - Dr. Kiem has submitted a new BUA application. He has already received approval for all of the agents listed on this BUA application on other BUA letters.
 - The assigned IBC member endorsed the biosafety officer's review.
 - The draft BUA letter was shown.
 - The assigned IBC member made a motion to approve the draft BUA for Dr. Kiem. A second is not needed since he endorsed the review.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kiem.

7. INDIVIDUAL PROJECT REVIEWS

- 2. Altemeier, William, change, Inflammatory Response Modulation by Mechanical Ventilation
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - Dr. Altemeier wishes to add non-recombinant respiratory syncytial virus to transgenic mice in previously approved rooms.
 - The draft BUA letter was shown.
 - All of the required trainings have been completed. The biosafety officer inspected the lab last week and no issues were identified.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Altemeier. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Altemeier.
- 3. Banerjee, Ashis, renewal, Development of an Optomagnetic Platform for Engineered Tissues
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The investigator will be using various types of human cells to study how these cells can be assembled to form three-dimensional tissues. Lentiviral vectors will also be used on the protocol.
 - A discussion about ESCRO (Embryonic Stem Cell Research Oversight) occurred regarding this project. Research involving human embryonic stem cells or induced pluripotent stem cells must be reviewed and approved by the ESCRO committee at UW. The ESCRO contact receives a copy of all BUA letters involving stem cells. The committee expressed interest in learning more about the ESCRO committee. EH&S will contact their office and try to arrange for a representative to describe the process to the IBC.
 - An optical tweezer that employs a low power laser will be used for optical trapping of cells. This activity has been reviewed by the EH&S Radiation Safety office and no hazards to human health were noted.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Banerjee. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Banerjee.

- 4. Bermingham-McDonogh, Olivia, renewal, Sensory Cell Development in the Cochlea
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the project is to determine what signals are required to develop the sensory patches in the inner ear that are necessary for hearing and balance, and to examine if hair cells can be regenerated.
 - Plasmid DNA is used on the project. Tamoxifen and other hazardous chemicals are also used. The investigator has received Occupational Health Recommendations from the EH&S occupational health nurse.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Bermingham-McDonogh. A second is not needed since he is the Primary Reviewer.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Bermingham-McDonogh.</u>
- 5. Buckner, Frederick, renewal, *Buckner Antiparasitic Drugs*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The PI is interested in targeting enzymatic functions of various bacteria and parasites therapeutically. Potential therapeutics will be tested in vivo and in vitro to determine their effectiveness. Recombinant plasmids expressing genes of interest and/or reporter genes/antibiotic markers in *E. coli* and baculovirus. These plasmids will be used to transfect parasites. Transgenic parasites can then be used to heterologously express genes of interest. These parasites can then be grown in culture and used in murine (or in some cases rats) models of infection.
 - Various species of Risk Group 2 parasites and bacteria will be used on the project, including *Trypanosoma cruzi*, *Plasmodium berghei*, and *Staphylococcus aureus*.
 - The lab has been inspected and no issues were identified. The required trainings have been taken.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Buckner. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Buckner.
- 6. Chavkin, Charles, renewal, Chavkin: Mice
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Chavkin neuroscience lab uses a variety of molecular techniques to understand the effects of stress on motivated behavior, understand the molecular basis of addictive drug action, develop novel strategies to treat drug addiction, mood disorders, and pain.
 - Adeno-associated viral vectors and canine adenoviral vectors will be used in mice.
 - The lab has been inspected, and the required trainings have been taken.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chavkin. A second is not needed since he is the Primary Reviewer.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Chavkin.</u>
- 7. Giachelli, Cecilia, renewal, Inflammation and Ectopic Calcification
 - The assigned IBC Primary Reviewer presented the Primary Review.

- The Giachelli lab studies the mechanisms of calcification in soft tissue, for example, aortic valve disease. Plasmids and third generation lentiviral vectors will be used, as well as human cell lines.
- The lab inspection is scheduled for later this month.
- The required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Giachelli. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Giachelli,</u> <u>pending the lab inspection.</u>
- 8. Giachelli, Cecilia, renewal, Calcification and Cell Differentiation
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Giachelli lab studies the mechanisms of calcification in soft tissue, for example, aortic valve disease. Plasmids and third generation lentiviral vectors will be used, as well as human cell lines and amphotropic and ecotropic gammaretroviral vectors.
 - The IACUC protocol renewal has not yet been received. The biosafety officer will need to review the IACUC protocol before the BUA approval letter is sent out.
 - The lab inspection is scheduled for later this month.
 - The required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Giachelli. A second is not needed since he is the Primary Reviewer.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Giachelli,</u> pending the lab inspection, and completion of the IACUC protocol.
 - Post-Meeting Update: The investigator decided to remove the animal work from this BUA. All research involving gammaretroviral vectors and lentiviral vectors used in mice was removed.
- 9. Murphy, Sean, renewal, Immunity to malaria infection
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the project is to develop effective vaccines against malaria and other complex pathogens. The Murphy lab studies the immune response to malaria in an infected mouse model to learn about fundamental aspects of malaria immunology.
 - Recombinant strains of *Plasmodium falciparum*, *Plasmodium berghei*, and *Plasmodium yoelii* are used on the project. *Plasmodium berghei* and *Plasmodium yoelii* are mouse malaria strains that are not pathogenic to humans. Previously, the Murphy lab has worked with these strains at ABSL-1, but the NIH recently clarified that all experiments involving recombinant microorganisms used in a whole animal model must be conducted at a minimum of ABSL-2 containment. Dr. Murphy and another investigator, Dr. Pepper, have been working with EH&S to submit a petition to NIH requesting approval for ABSL-1 containment for several *Plasmodium* strains, including *P. berghei* and *P. yoelii*, which have not been shown to be pathogenic for humans.
 - The biosafety officer clarified that Herpes B virus is not used on the protocol.
 - The draft BUA letter was shown.

- The lab has been inspected and no issues were noted. The required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Murphy. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Murphy.
- **10.** Murry, Charles, renewal, AAV Gene Therapy for Heart Failure in Pigs
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the project is to develop novel methods to treat heart disease, specifically heart failure and scar-triggered arrhythmias.
 - AAV and human embryonic stem cells are used on the project in a pig model. The human cells are tested for lymphocytic choriomeningitis virus and bloodborne pathogens including HIV and Hepatitis B. The pigs will be housed at ABSL-1 after administration of the human cells.
 - The draft BUA letter was shown.
 - The lab has been inspected and there were no issues. The investigator should complete the training section of the BUA application. The required trainings have been taken, but are not listed on the application.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Murry. A second is not needed since she is the Primary Reviewer.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Murry, pending</u> <u>completion of the BUA application.</u>

11. Plymate, Stephen, renewal, *Mechanisms of transition to castrate resistant prostate cancer*

- The assigned IBC Primary Reviewer presented the Primary Review.
- Plasmid DNA and lentiviral vectors are used on the project.
- The IBC coordinator clarified that the transgenic mice themselves are exempt, but research involving lentiviral vectors administered to transgenic mice falls under NIH Section III-D.
- The lab has been inspected and all required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Plymate. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Plymate.
- **12.** Wang, Edith, new, Regulation of gene expression in cell proliferation and differentiation
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - Human, hamster, mouse, and insect cell lines are used on the project. Amphotropic gammaretroviral vectors are also used.
 - The lab has been inspected. The primary review mentions that several times still need to be addressed, but these issues have all been resolved now. The required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Wang. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wang.
- **13.** Zweifel, Larry, renewal, Genetic Dissection of the Emotional Basis of Learning

- The assigned IBC Primary Reviewer presented the Primary Review.
- Adeno-associated viral vectors and canine adenoviral vectors are used on the project. Human cells are also used.
- A discussion occurred regarding transgenic mice. Breeding rodents from new strains (generating a new strain) is exempt from the NIH Guidelines provided that the rodent that results from the breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses, and also that neither parental rodent contains the following genetic modifications (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, or (ii) incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat. The transgenic mice used on the Zweifel project are exempt from the NIH guidelines.
- The inspection has been completed and all of the required trainings have also been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Zweifel. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Zweifel.

FOR YOUR INFORMATION:

- NIH Reportable Incident
 - A researcher sustained an injury while working with recombinant *Mycobacterium tuberculosis* in a lab. The researcher was using an ultra-fine point permanent marker to label tissue culture plates, which contained human cells infected with *M. tuberculosis*. As the researcher put the cap back on the pen, he punctured his gloves with the tip of the pen and tore the skin on his finger. He followed proper post-exposure steps and performed first aid, and reported the incident appropriately and sought medical assistance from the Employee Health Center. *M. tuberculosis* is not known to be transmitted percutaneously, but the researcher is nevertheless being monitored by Employee Health Center. The laboratory and facility replaced these markers with felt-tipped pens. This incident was reported to NIH OBA and we are awaiting their response.
- NIH Reportable Incident
 - An NIH report has been submitted in response to the clarification from the Office of Biotechnology Activities that experiments involving recombinant Risk Group 1 microorganisms used in whole animals must be conducted at a minimum of ABSL-2 containment. All approvals have now been reissued stating that ABSL-2 containment is required.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

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

MEETING ADJOURNED AT APPROXIMATELY 11:50 a.m.