



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, April 18, 2018

Time: 10:00 AM – 12:00 PM

Location: Foegen N-130A

- Members Present:**
1. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 2. Garry Hamilton (*Community Member*)
 3. Kevin Hybiske, Allergy and Infectious Diseases
 4. David Koelle, Allergy and Infectious Diseases
 5. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 6. Tina Rogers (*Community Member*)
 7. Jason Smith, Microbiology (*IBC Vice Chair*)
 8. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)

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 10:01 am. A quorum was present. A new IBC member was introduced.
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. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the March 21, 2018 meeting.
 - A member made a motion to approve the March 21, 2018 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the March 21, 2018 meeting minutes.
4. **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
 - Dr. Pun, Dr. Ferreria, and Dr. Han each added the cell sorting facility to their respective BUAs.
 - Dr. Eichler renewed a BUA involving human cells and blood.
 - Dr. Tang added human cells used in rats to her BUA letter.
 - Dr. Becker renewed a BUA involving human cells and blood.
 - Dr. Kim renewed a BUA involving human cells and blood.
 - Dr. Maier, Dr. Barria, Dr. Zalatan, Dr. Patton, and Dr. Frasch each added a room to their BUA letters.
 - Dr. Klevit renewed a BUA involving human cells and blood.
 - Dr. Rieke renewed a BUA involving human and non-human primate cells and blood.
 - Dr. O'Keefe received a new BUA approval for human blood.
 - 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 unanimously voted to approve this month's Biosafety Officer Report.

5. CATEGORY III-D AMENDMENTS

1. Colby, Lesley, renewal, *Comparative Medicine Animal Biosafety Level 2 Biocontainment Facilities*
 - The biosafety officer presented the project.
 - This is a core BUA that lists all of the ABSL-2 vivarium spaces (at Harborview, the 6th floor vivarium, the Animal Research & Care Facility, SLU Brotman, SLU 3.1, HSB K-wing, and Foegen). Researchers who are using these facilities are still required to have their own BUAs, but individual rooms are listed only on this core BUA.
 - The assigned IBC member endorsed the biosafety officer's review.
 - One member declared a conflict of interest and left the room.
 - The draft BUA letter was shown.

- The assigned IBC member made a motion to approve the draft BUA for Dr. Colby.
 - The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Colby.
2. Martins, Timothy, renewal, *High Throughput Screening*
- The biosafety officer presented the project.
 - This is a renewal of a core facility that provides high throughput screening services.
 - Each user of the facility must have their own BUA that is approved by the IBC.
 - The biosafety officer inspected the space and there are no deficiencies remaining. All of the required trainings have been completed.
 - 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. Martins.
 - The Committee voted unanimously to approve the draft BUA for Dr. Martins.

6. INDIVIDUAL PROJECT REVIEWS

3. Fang, Ferric, change, *Salmonella Pathogenesis and Immunity*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change to add a new Risk Group 2 pathogen, *Klebsiella oxytoca*. Initially wild type strains will be used to characterize the cytotoxin produced by this bacterium, with production of mutants being a future aim.
 - One member declared a conflict of interest and left the room.
 - The lab was recently inspected, so a new lab inspection was not required for this change. All of 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. Fang.
 - The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Fang.
4. Fink, Susan, change, *Host-Pathogen Interactions During Viral Infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This BUA change adds the use of yellow fever virus vaccine strain 17D, *Yersinia pseudotuberculosis*, and *Salmonella Typhimurium*. Additional BSL-2 lab space has also been added as well as additional ABSL-2 vivarium space.
 - The lab was inspected with no deficiencies remaining. All of the required trainings have been completed.
 - The committee discussed the yellow fever vaccine strain. Laboratory personnel who are working with this strain will receive information from Employee Health Center about the yellow fever vaccine. The IBC recommended adding the vaccine information to the face page of the BUA letter.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Fink.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fink, contingent upon adding information about the yellow fever vaccine to the BUA letter.
5. Hu, Shiu-Lok, new, *Probiotic Use as an Adjuvant in HIV Vaccine*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This research project was previously approved under the PI Nichole Klatt. She is leaving the university and so the project is being renewed under Shiu-Lok Hu.
- The overall goal of the project is to use a persistent probiotic therapy to stimulate immunogenicity and protection provided by a combined SHIV vaccine.
- A DNA vaccine and SHIV will be used in a macaque model.
- The lab was inspected with no deficiencies remaining. All of the required trainings have been completed.
- The IACUC protocol is still under Dr. Klatt. The biosafety officer will make sure it is transferred to Dr. Hu.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hu.
- The Committee voted unanimously to approve the draft BUA for Dr. Hu, pending the transfer of the IACUC protocol to Shiu-Lok Hu.

6. Kerr, Benjamin, renewal, *Plasmid Maintenance*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab studies bacterial hosts and their plasmids to determine if evolution of a host/plasmid pair reduces the metabolic and physiological costs of maintaining plasmids within each host. Naturally-occurring plasmids will be transferred into *Klebsiella pneumonia*, *Pseudomonas aeruginosa* and non-pathogenic *E. coli* K-12 strains.
- The lab was inspected with no deficiencies remaining. The PI needs to retake the biosafety training. All of the other 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. Kerr.
- The Committee voted unanimously to approve the draft BUA for Dr. Kerr, pending completion of the PI's biosafety training.

7. Ladiges, Warren, renewal, *Xenograft Program*

- The assigned IBC Primary Reviewer presented the Primary Review.
- Mouse cells transfected with a third generation lentiviral vector will be used. Human cells are also administered to mice.
- The lab was inspected with no deficiencies remaining. All of 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. Ladiges.
- The Committee voted unanimously to approve the draft BUA for Dr. Ladiges.

8. Paik, Jisun, renewal, *Nutrition, Inflammation, and Obesity*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab studies developing new compounds that inhibit retinoic acid synthesis.
- Human cell lines and lentiviral vectors are used.
- The lab was inspected with no deficiencies remaining. All of 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. Paik.
- The Committee voted unanimously to approve the draft BUA for Dr. Paik.

9. Shechner, David, new, *Nuclear Architecture and the Noncoding Transcriptome*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a new BUA from a new investigator. The lab researches the role of noncoding RNAs in shaping nuclear substructures.
 - A third generation lentiviral vector and an AAV vector will be used on the project.
 - The biosafety officer inspected the lab, but the investigator is new to UW and is still unpacking and setting up the lab space. The biosafety officer will return for a final walk-through when everything is set up and all of the equipment has been ordered.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Shechner.
 - The Committee voted unanimously to approve the draft BUA for Dr. Shechner, pending a final lab inspection and pending a chemical review by the industrial hygienist.
10. Theriot, Julie, new, *Advances in cellular motility*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The Theriot lab studies the biophysics of how cells move and change shape. Several pathogens (*Listeria monocytogenes*, *Candida albicans*) will be used to alter the cells and observe effect on motility. Human cells and a lentiviral vector will also be used.
 - The lab has not yet been set up. The investigator will be arriving within the next few months. The biosafety officer will inspect the lab once the investigator arrives at UW and the lab is ready.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Theriot.
 - The Committee voted unanimously to approve the draft BUA for Dr. Theriot, pending a lab inspection once the space is ready.
11. Xin, Li, new, *Studies on prostate homeostasis and prostate-related diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - Third generation lentiviral vectors (with and without oncogenes), gammaretroviral vectors, and adenoviral vectors will be used in vitro and in mice.
 - Human cells and uropathogenic *E. coli* strains will also be used.
 - The lab has not yet been set up. The investigator will be arriving within the next few months. The biosafety officer will inspect the lab once the investigator arrives at UW and the lab is ready.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Xin.
 - The Committee voted unanimously to approve the draft BUA for Dr. Xin, pending the final lab inspection and the addition of third-generation lentiviral vectors with oncogenes to the BUA letter.

SUBCOMMITTEE REPORTS:

12. Maloney, David, new, *A Multicenter, Open-Label, Expanded Access Study of Axicabtagene Ciloleucel for the Treatment of Subjects with Relapsed/Refractory Large B-Cell Lymphoma*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The product used on this clinical trial is a version of CAR-T cells that target the CD19 molecule on the surface of B cells. The product is FDA-approved for some indications including large B-cell lymphoma. The purpose of this trial is to provide access to the product for subjects whose commercially manufactured product did not meet commercial release specifications, for example if the transgene cell transduction percentage was slightly different than manufacturer guidelines.
- The subcommittee reviewers asked Dr. Maloney to provide documentation that states that all safety requirements such as sterility and lack of replication competent virus will be met.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Maloney. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Maloney, pending clarification that all safety specifications are met.

OTHER VOTING ITEMS:

- The Environmental Health & Safety Department, an IBC subcommittee, and the UW assistant attorney general's office worked together to write an updated PI definition. The definition will be incorporated into the IBC charter, the training, and the EH&S website. Two PI definitions were written. One definition was for general laboratory safety and one was specific to biosafety.
- The laboratory safety definition is as follows: *The Principal Investigator (PI) is an individual who is designated by a University department, school, or administrative unit to direct the research program or project. The PI has the scientific and technical direction for the research. The PI has the responsibility and authority to enforce regulations and policies related to research and worker safety. This includes ensuring that the facilities are appropriate for the research conducted and for training personnel who will be involved on the project.*
- The biosafety PI definition is as follows: *The Principal Investigator (PI) is an individual who is designated by a University department, school, or administrative unit to direct the research program or project. The PI has scientific and technical direction for the research. The PI has the responsibility and authority to enforce biosafety and biosecurity regulations and policies, including the NIH Guidelines. This includes ensuring that the facilities are appropriate for the research conducted and for training personnel who will be involved on the project. Any Biological Use Authorization Application with an assigned PI who does not fall within this definition will be considered on a case-by-case basis.*
- The committee discussed these definitions and suggested that "for training personnel" be changed to "ensuring personnel are trained" and that "involved on the project" be changed to "involved with the project."
- The Committee voted unanimously to approve the two PI definitions and to add the new PI definition for biosafety to the IBC Charter with the modifications mentioned above.

FOR YOUR INFORMATION:

- NIH Reportable Incident Response
 - The NIH responded to our report of the incident where an employee sustained a percutaneous needlestick injury that had been used in a procedure involving a non-human primate who had been previously vaccinated in November 2017 with a recombinant vesicular stomatitis virus vaccine. This incident was discussed at the March 21, 2018 IBC meeting. The NIH stated that our response to the incident was appropriate and no further action is required at this time.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

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

MEETING ADJOURNED AT APPROXIMATELY 11:39 a.m.