INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, September 20, 2017
Time: 10:00 AM – 12:00 PM

Location: T-269

Members Present:
1. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
2. Richard Grant, Washington National Primate Research Center
3. Garry Hamilton (*Community Member*)
4. Kevin Hybiske, Allergy and Infectious Diseases
5. Stephen Libby, Laboratory Medicine (*IBC Chair*)
6. Scott Meschke, Environmental & Occupational Health Sciences
7. David Scarsella, Pacific Northwest Diabetes Research Institute (*Community Member*)
8. Jason Smith, Microbiology (*IBC Vice Chair*)
9. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
10. 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 10:01 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. **APPROVAL OF MINUTES:**
   - The IBC Chair sought a motion to approve the minutes from the August 16, 2017 meeting.
   - A member made a motion to approve the August 16, 2017 minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the August 16, 2017 meeting minutes.

4. **OLD BUSINESS:**
   - At the April meeting, Dr. Hybiske's BUA was approved pending receipt of NIH approval for Chlamydia strains falling under section III-A of the NIH guidelines. The NIH approval was received. Dr. Hybiske needs to submit some SOPs and confirm that he has set up additional practices as required by the NIH.
   - At the July IBC meeting, Dr. Kwon's BUA was approved contingent upon RCV testing results, revising the BUA application to list the BSL-1 room, and biosafety officer review of the IACUC protocol. The RCV testing results were submitted and the BUA application lists the correct BSL-1 room. The biosafety officer reviewed the IACUC protocol and the BUA letter was sent.
   - At the July IBC meeting, the IBC voted to send Dr. Gale a formal memo explaining the restrictions and options for research involving Junin virus. Dr. Gale will not be proceeding with this research.
   - At the August IBC meeting, Dr. Valdmanis's project was approved pending the biosafety officer's review of the IACUC protocol. The biosafety officer reviewed the IACUC protocol and the BUA letter was sent.
   - At the August IBC meeting, Dr. Blevins' project was approved pending the biosafety officer's review of the VA IACUC protocol. The biosafety officer reviewed the IACUC protocol and the BUA letter was sent.
   - At the August IBC meeting, Dr. Davis's project was approved pending the biosafety officer's review of the IACUC amendment. The IACUC amendment has not yet been submitted.
   - At the August IBC meeting, Dr. Hyde's project was approved pending the completion of the medical management plan, vaccine recommendations, and an occupational health consultation. This is still pending.

5. **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. Werth added Neisseria gonorrhoeae, used in vitro, to his approval.
      - Dr. Dey received a new BUA approval for various Risk Group 1 gut bacteria used in a mouse model.
      - Dr. Yeung renewed a BUA involving human cells, blood, and tissue.

- Dr. Bumgarner, Dr. Brockerhoff, and Dr. Ratner each added new rooms to their respective approvals.
- Dr. Xu received a new BUA involving human cells.
- Dr. Catterall and Dr. Dichek each added new vivarium spaces to their respective approvals.
- Dr. Jayadev added the stem cell core facility to her approval.
- Dr. Barria renewed a BUA involving human cells.
- Dr. Bomsztyk received a new BUA involving human 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.
- The Committee unanimously voted to approve this month's Biosafety Officer Report.

6. DURC REPORT

- The DURC IRE (Dual Use Research of Concern Institutional Review Entity) did not meet this month. They will be meeting next month to review a proposal involving *Francisella tularensis*.

7. TRAINING PRESENTATION

- The IBC heard a presentation from Barbara Benson, Records Management Services. She discussed the Washington Public Records Act and best practices for managing electronic records.

8. INDIVIDUAL PROJECT REVIEWS

1. Campbell, Lee Ann, renewal, *Chlamydia pneumoniae antigens of biological significance*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal application. The investigator studies the mechanisms of Chlamydia pathogenesis. Cell culture and murine infection models are used.
- Non-recombinant strains of *C. muridarum, C. pneumoniae*, and *C. trachomatis* are used. These strains are used in a transgenic animal model, so the research falls under section III-D of the NIH Guidelines.
- The lab was inspected and no deficiencies were found. 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. Campbell.
- The Committee voted unanimously to approve the draft BUA for Dr. Campbell.

2. Childers, Martin, change, *Gene Therapy in Canine Myotubular Myopathy*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change request to add human cells used in a dog model.
- The cells have been tested and are negative for bloodborne pathogens including HIV, herpes simplex virus, hepatitis B & C, and lymphocytic choriomeningitis virus.
- The administration of the human cells will be conducted at ABSL-2, and the dogs will then be housed at ABSL-1.

- A lab inspection was not required because all of the rooms on this protocol are vivarium spaces. 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. Childers.
- The Committee voted unanimously to approve the draft BUA for Dr. Childers.

3. Fields, Stanley, renewal, *Genetic interaction profiling of p53 mutations in transcription and blood cancer; Functional analysis of mutant versions of human genes*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab researches technology development. They seek to better understand biological processes, especially disease, through leveraging large-scale functional assays and next-generation sequencing.
- Human cells and a third generation lentiviral vector will be used on the project. No oncogenic inserts will be used.
- The draft BUA letter was shown.
- The lab was inspected and all deficiencies were minor and have been corrected. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Fields.
- The Committee voted unanimously to approve the draft BUA for Dr. Fields.

4. Gale, Michael, renewal, *Gene Expression Analysis of Virus Infection*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. In this protocol, the Gale lab will analyze non-human primate and cell culture samples infected by lentiviruses (HIV, SIV, or SHIV) using transcriptomic and proteomic methods. There is no work with live animals on this project, only tissue samples.
- The draft BUA letter was shown.
- The lab was inspected and no deficiencies were found. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gale.
- The Committee voted unanimously to approve the draft BUA for Dr. Gale.

5. Gire, David, renewal, *Neural circuit mechanisms of odor localization*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The lab researches how the brain processes natural sensory signals to guide complex and adaptive behaviors.
- Mice and rats will be injected with AAV and CAV (canine adenovirus) viral vectors that have fluorescent inserts and other reporters.
- The draft BUA letter was shown.
- The lab was inspected and no deficiencies were found. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gire.
- The Committee voted unanimously to approve the draft BUA for Dr. Gire.

6. Goverman, Joan, renewal, *Animal Models of Autoimmunity*

- The assigned IBC Primary Reviewer presented the Primary Review.

- The overall goal of the research is to use and develop mouse models of multiple sclerosis in order to understand the pathogenesis of this disease and to identify potential points of therapeutic intervention.
- Vaccinia virus and adenoviral vectors will be administered to mice. Pertussis toxin will also be used. SOPs are in place.
- The draft BUA letter was shown.
- The lab was inspected and no deficiencies were found. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Goverman.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Goverman.</u>

7. Kiem, Hans-Peter, renewal, *Targeted Modification of Host and Proviral DNA to Treat Latent HIV Infection*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The research involves using gene therapy as a treatment modality for lentivirus infections.
- On this protocol, macaques are experimentally infected with SHIV, and then receive engineered autologous stem cells. An adenoviral vector is used on the project.
- The draft BUA letter was shown.
- A lab inspection was not required because all of the rooms listed on this project are vivarium spaces. Dr. Kiem's in vitro work occurs at Fred Hutch. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kiem.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Kiem.</u>

8. Neal-Perry, Genevieve, new, *Neuropeptide Genes Governing Reproduction*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of the research is to develop a murine model that recapitulates the thermoregulatory dysfunction observed in humans after withdrawal of sex steroids. The long-term goal is to develop safer, novel treatments for human hot flashes.
- Adeno-associated viral vectors are used in mice.
- A discussion occurred regarding P-33, a radioactive isotope. Dr. Neal-Perry does not have immediate plans to use this agent, so it will be removed from the BUA application.
- The draft BUA letter was shown.
- The lab was inspected and no deficiencies were found. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Neal-Perry.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Neal-Perry, pending the correction to remove P-33 from the BUA application.</u>

9. Reniere, Michelle, change, *Redox regulation and virulence in bacterial pathogens*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of this change is to add lentiviral vectors and human cell lines. CRISPR-Cas9 technology will be used. No animal work will involve lentiviral vectors.
- The draft BUA letter was shown.

- The lab was inspected and no deficiencies were found. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Reniere. The Committee voted unanimously to approve the draft BUA for Dr. Reniere.

10. Salipante, Stephen, renewal, *Next-generation sequencing for clinical translation*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab's research focuses on the clinical applications of next-generation DNA sequencing.
- The work involves growing human cell lines, work with clinical bacterial pathogens *P. aeruginosa* and *S. aureus*, cell culture infection models, and some genetic engineering in these cell types (mutagenesis and reporter assays).
- The draft BUA letter was shown.
- The lab was inspected and no deficiencies were found. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Salipante.
- The Committee voted unanimously to approve the draft BUA for Dr. Salipante.

11. Zalatan, Jesse, renewal, *Physical organizing principles of biological signaling protein networks*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab researches the molecular mechanisms that control decision points in cell signaling pathways and the role of scaffold proteins in cell signaling networks.
- Lentiviral vectors and human cells will be used on the project. Risk Group 1 bacteria and yeast will also be used.
- The draft BUA letter was shown.
- The lab was inspected and no deficiencies were found. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Zalatan.
- The Committee voted unanimously to approve the draft BUA for Dr. Zalatan.

SUBCOMMITTEE REPORTS:

12. Green, Damian, new, *A phase 1 study of adoptive immunotherapy for advanced B-cell maturation antigen (BCMA)+ multiple myeloma with autologous CD4+ and CD8+ T cells engineered to express a BCMA-specific chimeric antigen receptor*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The primary objective of this phase I clinical trial is to evaluate the safety of adoptive therapy with ex vivo expanded autologous CD8+ plus CD4+ T cells transduced to express a human BCMA-targeting CAR for patients with relapsed or treatment refractory multiple myeloma.
- Autologous T cells are transduced with a self-inactivating, VSV-G pseudotyped, HIV-1 based third generation lentivirus.
- The subcommittee also reviewed the consent forms and found them to sufficiently explain the biosafety risks involved with this protocol.
- All of the required trainings have been completed.
- The draft BUA letter was shown.

- A member made a motion to approve the draft BUA letter for Dr. Green. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Green.

FOR YOUR INFORMATION:

- An NIH Reportable Incident occurred a few weeks ago. A graduate student was bitten by a macaque that had been administered a recombinant adeno-associated viral vector in 2014. The graduate student cleaned his wound with a herpes B virus scrub kit and followed all instructions in the kit packet. This includes scrubbing the wound with disinfectant for 15 minutes. The student received medical attention and was put on antibiotics for the bite wound and acyclovir for potential herpes B virus exposure. The student was wearing the appropriate PPE for primate center animal areas. The incident was reported to NIH, and NIH's response is pending.
- We received an NIH response regarding a previously reported exposure. The incident occurred when a student was drawing blood from a mouse and accidentally stuck her own finger with the needle. Several weeks previously, the mouse had been infected with lymphocytic choriomeningitis virus (LCMV Armstrong 53b) and adeno-associated viral vector AAVDJ/8. The student was wearing appropriate PPE. The student followed proper post-exposure protocol by washing the injury for 15 minutes and reporting the incident. Employee Health Center followed up with the student. The student will be undergoing more hands-on training in mouse handling before starting to work with mice again. The NIH said that all actions taken by the UW were appropriate and no further information is required.
- We received an NIH response regarding a previously reported exposure. The exposure occurred when an employee was bitten by a mouse previously experimentally infected with recombinant *Cryptosporidium parvum*. The employee was wearing appropriate PPE. The employee followed proper post-exposure protocol by washing the injury for 15 minutes and reporting the incident to her supervisor and principal investigator. Employee Health Center followed up with the employee. The laboratory has obtained additional protective glove liners to try to prevent future bite injuries. The NIH said that all actions taken by UW were appropriate and no further information is required.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:
There were no issues from the floor, and no public comments.

MEETING ADJOURNED AT APPROXIMATELY 11:38 a.m.