



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, July 18, 2018

Time: 10:00 AM – 12:00 PM

Location: Foege N-130A

- Members Present:**
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. Kevin Hybiske, Allergy and Infectious Diseases
 6. Scott Meschke, Environmental & Occupational Health Sciences
 7. 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 10:15 a.m. A quorum was present.
2. **REMINDER:** The IBC Chair reminded attendees that any notes 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 June 20, 2018 meeting.
 - A member made a motion to approve the June 20, 2018 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the June 20, 2018 meeting minutes.
4. **OLD BUSINESS:**
 - At the April meeting, Dr. Hu's BUA was approved pending the transfer of the IACUC protocol from Dr. Klatt to Dr. Hu. The IACUC protocol is still undergoing triennial review under Dr. Klatt and the plan is to transfer the IACUC protocol to Dr. Hu once the triennial review is approved. The BUA letter was sent out.
 - At the April meeting, Dr. Schechner's BUA was approved pending a final lab inspection and pending a chemical review by the industrial hygienist. The PI is still getting things set up. The industrial hygienist will perform the chemical review during the final lab inspection at the end of July.
 - At the April meeting, Dr. Theriot's BUA was approved pending a lab inspection. The investigator has still not arrived at UW. The inspection will be conducted when the investigator arrives in July.
 - At the April meeting, Dr. Xin's BUA was approved pending a lab inspection and the addition of third-generation lentiviral vectors with oncogenes to the BUA letter. The agent was added to the BUA letter, but the PI hasn't yet arrived at the university, so the lab inspection is still pending.
 - At the May meeting, Dr. Starita's BUA was approved pending the completion of the final lab inspection and clarifying whether or not oncogenes will be used. These items are still pending until the investigator sets up the lab and is ready to start working.
 - At the May meeting, Dr. Shadman's BUA was approved pending completion of the PI's biosafety training. This is still pending.
 - At the June meeting, Dr. Seshadri's BUA was approved pending completion and subcommittee review of the verification study.
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. Murry received a change BUA adding human cells transfected with recombinant DNA
 - Dr. Kiem became the Principal Investigator of the projects "*Transplant Tolerance in Non-Human Primates*" and "*New Biologic Therapies for Graft Versus Host Disease (GVHD) Prevention and Treatment During Hematopoietic Cell Transplantations.*" The previous PI for both projects was Dr. Kean.

- Dr. Swanson renewed a BUA for the project *“Detailed functional analysis of gamete recognition protein interactions.”*
- Dr. Kublin received a change BUA adding non-recombinant bacteria in mice.
- Dr. Yazdan-Shahmorad received a change BUA adding in vitro work and in vivo work outside of the WaNPRC vivarium as well as a core facility.
- Dr. McGuire received a new BUA for the project *“Proof of Concept for an EBV Vaccine.”*
- Dr. Garden received a change BUA adding a core facility.
- Dr. Dey received a change BUA adding the administration of human feces to mice.
- Dr. Klavins added a new room to his BUA letter.
- Dr. Kennedy added a new room to his BUA letter.
- Dr. Hu received a change BUA involving human source material.
- Dr. Lingappa’s project *“International Clinical Research Center, Repository”* received a BUA renewal.
- Dr. Wood received a change BUA adding *F. hepatica*.
- Dr. Keene received a new BUA for *“Neurodegenerative Disease & Disorder.”*
- Dr. Horwitz added a new room to his BUA letter.
- 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. DUAL USE RESEARCH OF CONCERN (DURC) REPORT: The DURC IRE (Dual Use Research of Concern Institutional Review Entity) did not meet this month because there were no applications to review.

7. SECTION III-D AMENDMENTS

- a. Manicone, Anne, change, *MMPs in Repair and Immunity***
- The biosafety officer presented the project.
 - This amendment requests to add the use of *Staphylococcus aureus* in transgenic mice. This agent was already approved for in vitro use on Dr. Manicone’s BUA.
 - The lab was inspected and no deficiencies were identified.
 - 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. Manicone.
 - The Committee voted unanimously to approve the draft BUA for Dr. Manicone.

8. INDIVIDUAL PROJECT REVIEWS

- b. Clark, Edward, change, *Lymphocyte Activation (Role of CD22 & Syk Kinase)***
- The assigned IBC Secondary Reviewer presented the Primary Review.
 - This change adds attenuated strains of *Salmonella Typhimurium*, aroA mutant, to vaccinate mice.
 - No lab inspection is needed for this change.
 - All of the required trainings have been completed.

- The draft BUA letter was shown.
 - The IBC Secondary Reviewer made a motion to approve the draft BUA for Dr. Clark.
 - The Committee voted unanimously to approve the draft BUA for Dr. Clark.
- c. Dichek, David, change, *Gene transfer in vascular disease*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change is to add a third generation lentiviral vector in vitro and in mice. It also adds previously approved agents to the core facility.
 - The lab was inspected and no deficiencies were identified.
 - 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. Dichek with modifications.
 - The Committee voted unanimously to approve the draft BUA for Dr. Dichek pending changing the third generation lentiviral in vitro work to BSL 1 instead of BSL 2.
- d. Freedman, Benjamin, renewal, *Differentiation of Human Pluripotent Stem Cells into Kidney Cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - Recombinant cell lines are engineered into stem cells, which are then introduced into immunodeficient rodents by transplantation.
 - Recombinant DNA use is the greatest biohazard risk identified by the PI.
 - Lab inspection issues are being addressed. An additional inspection will be performed once the BSO is notified that the lab is ready.
 - Trainings are complete, but expiring soon, and will need to be renewed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Freedman.
 - The Committee voted unanimously to approve the draft BUA for Dr. Freedman pending lab inspection issues and an additional inspection.
- e. Parrish, Jay, renewal, *Extrinsic signals required for maintenance of dendrite coverage*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal for a project using *Drosophila* to understand how the growth of sensory neurons is coordinated with overall animal growth.
 - The lab was inspected and no deficiencies were identified.
 - 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. Parrish.
 - The Committee voted unanimously to approve the draft BUA for Dr. Parrish with the addition on nonexempt recombinant *E.coli* listed under NIH section III-E.
- f. Patel, Anoop, new, *Heterogeneity in Glioblastoma*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project seeks to work with human post-operative glioblastoma tissue, human cell lines, and recombinants to understand how tumor heterogeneity leads to treatment resistance.

- The culture of human cells, cell lines, and cells transduced with lentiviral vectors containing oncogenic insert are considered the greatest biohazards, with paraformaldehyde and formalin fixing agents also in use.
 - The lab was inspected and deficiencies identified are being addressed. The BSO will do a final inspection once notified by the lab.
 - 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. Patel.
 - The Committee voted unanimously to approve the draft BUA for Dr. Patel pending adequate addressing of lab inspection deficiencies and a final lab inspection. Third generation lentiviral vectors without oncogenes are to be listed at BSL 1 on the BUA letter.
- g.** Perkel, David, renewal, *Neural circuits for auditory and vocal processing*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This renewal is for research to better understand neural mechanisms of auditory processing, motor skill learning, and variability generation through the study of neural circuits of Zebra Finches.
 - Filling and handling the pipette with the viral vectors during the surgical procedure has been declared as the greatest risks by the PI.
 - A question was asked if the PI is buying third generation lentiviral vectors, and this was confirmed by the BSO. The BSO also stated that their inspection verified that only Zebra Finch were in the lab.
 - The lab was inspected and no deficiencies were identified.
 - 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. Perkel.
 - The Committee voted unanimously to approve the draft BUA for Dr. Perkel once other bird species are removed from the description in BUA application.
- h.** Raskind, Wendy, renewal, *Genetic Contributions to Endophenotypes of Dyslexia; Gene Discovery in Neurogenetic Disorders; Spinocerebellar-Ataxia Type 14: Animal models of human disease; Raising Healthy Children; Genetics of Autism; Genetics of Human Diseases*
- The assigned IBC Secondary Reviewer presented the Primary Review.
 - The goal of this project renewal is to study inherited human diseases to identify the genes that causes them and to study the effect of mutations on the function of the genes.
 - The greatest biohazardous risk is culturing the cell line MCVU that contains non-recombinant EBV.
 - The BSO stated that there are no concerns if oncogenes on plasmids or the Sendai vector. The BSO also stated that there is no need to increase the biosafety level because of the Sendai vector since it is a non-integrating vector.
 - The lab inspection is pending.
 - All of the required trainings have been completed.
 - The approval is pending the IACUC submission.
 - Occupational Health shared their new intake process for employees working with human cells that contain EBV.

- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Raskind.
- The Committee voted unanimously to approve the draft BUA for Dr. Raskind once the third generation lentiviral vectors are changed to BSL 1 and a comment is added to the BUA letter stating the occupational health recommendation that laboratory personnel undergo an EBV consultation.

9. SUBCOMMITTEE REPORTS:

- i. Maloney, David, new, *An Open-Label, Phase 1 Safety and Phase 2 Randomized Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (017004)*
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - T cells are being tested at all stages on chronic lymphocytic leukemia (CLL) and small lymphocytic leukemia (SLL) patients. The project is looking for recommended dose and anti-tumor activity. T cells are being administered in patient, but no production is being done at UWMC. JCAR017 modified T cells have been used in humans before and the safety profile is known, so it is not necessary to review again.
 - Minimal biosafety issues have been stated. Other pathogens can be activated, but this is a minimal risk.
 - The BSO stated that the BUA letter is correct that the project is non-HIV and meets third generation lentiviral criteria.
 - 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.

10. FOR YOUR INFORMATION:

- **SLU 3.2 opening:** The first phase of labs are approved for SLU 3.2 occupancy. Labs will be moving from July through August 2018.
- **S. epidermidis subcommittee:** An IBC subcommittee will be formed to review and conduct formal risk assessment and determine containment levels for S. epidermis. The subcommittee will present at the August IBC meeting.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:13 A.M.