



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, October 19, 2022

Time: 10:00 AM – 12:00 PM

Location: Zoom

- Members Present:**
1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
 2. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 3. Jason Cantera (*Community Member*)
 4. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 5. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 6. Richard Grant, Washington National Primate Research Center
 7. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 8. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 9. David Koelle, Allergy and Infectious Diseases
 10. Scott Meschke, Environmental & Occupational Health Sciences
 11. Jason Smith, Microbiology (*IBC Chair*)
 12. 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

NHP: Non-Human Primates

NIH: National Institutes of Health

DURC: Dual Use Research of Concern

1. **CALL TO ORDER:** The Institutional Biosafety Committee (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. **NATIONAL BIOSAFETY MONTH:** A presentation was given by EH&S regarding National Biosafety Month and how the University is participating.
4. **IBC CHARTER UPDATES:** Minor updates were made to the IBC Charter. The updates were presented to the committee, which voted unanimously to approve.
5. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the September 21, 2022, meeting.
 - A member made a motion to approve the September 21, 2022, minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the September 21, 2022, meeting minutes.
6. **OLD BUSINESS:**
 - At the September 21, 2022, meeting, Dr. Dichek's BUA was pending clarification of ABSL-2 hold time for rabbits. This BUA This BUA has been sent out.
 - At the September 21, 2022, meeting, Dr. Ferguson's BUA was pending confirmation of ABSL-2 locations in the vivarium for use. This BUA is still pending.
 - At the September 21, 2022, meeting, Dr. Hawkin's BUA was pending a successful response to their lab inspection. This BUA has been sent out.
 - At the September 21, 2022, meeting, Dr. McLean's BUA was pending a successful response to their lab inspection. This BUA has been sent out.
 - At the September 21, 2022, meeting, Dr. Shear's BUA was pending clarification of the recombinant malaria information. This BUA has been sent out.
 - At the September 21, 2022, meeting, Dr. Wakimoto's BUA was pending completion of a successful lab inspection. This BUA has been sent out.
 - At the September 21, 2022, meeting, Dr. Waterston's BUA was pending completion of a successful lab inspection. This BUA has been sent out.
 - At the September 21, 2022, meeting, Dr. Gale's BUA was pending an updated medical management plan. This BUA has been sent out.
 - At the September 21, 2022, meeting, Dr. Veessler's BUA was pending removal of monkeypox work. This BUA has been sent out.
7. **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. Gough registered a new project (*Gough Lab Protocols*) working with Risk Group 1 environmental organisms (*NIH Guidelines*, Sections III-F).

- Dr. Lidstrom renewed the BUA *Lidstrom Lab* doing work with several Risk Group 1 environmental organisms (*NIH Guidelines* Sections III-E and III-F).
- Dr. Sen renewed the BUA *Identification and characterization of E. coli, Campylobacter and Salmonella present in wetland water and crow feces within the Bothell Campus* working with Risk Group-2 environmental and clinical bacterial and non-pathogenic E. coli samples in vitro (*NIH Guidelines* Section III-F or N/A).
- Dr. Akilesh renewed the BUA *Kidney Disease Genomics* working with human blood, tissue, body fluids, and cell lines and various Risk Group 1 agents in vitro (*NIH Guidelines* Sections III-E and III-F or N/A).
- Dr. Steinbrenner renewed the BUA *Function and Evolution of Plant Immune Receptors* working with transgenic plants and Risk Group 1 agents in vitro and in plants (*NIH Guidelines* Section III-E or N/A).
- Dr. Quijano Rubio was approved for work with human blood involving non-pathogenic E. coli on the BUA *Biosensor Testing in Blood* (*NIH Guidelines* Sections III-E and III-F or N/A).
- Dr. Paik renewed the BUA *GNAC facility* working with Risk Group 1 and 2 bacteria in mice (*NIH Guidelines* N/A).
- Dr. Sokourenko renewed the BUA *Molecular Adaptation of Uropathogenic E. coli; Properties of Bacterial Adhesins; Pathogenic Adaptation of Microbial Adhesins, New Statistical Methods for Neutral Phylogenetic Reconstruction; Mechanism of Acquisition and Spread of antimicrobial resistance; Epidemiology and clonality of SARS-CoV-2, including SNP-based typing* working with Risk Group 1 and 2 microorganisms and clinical samples (*NIH Guidelines* Section III-F or N/A).
- Dr. Hung was approved for work with Risk Group 2 mouse-adapted influenza virus in mice and in vitro, as well as rDNA (non-viral) (*NIH Guidelines* Section III-F or N/A).
- Dr. Gale added work with third generation lentiviral vectors and the use of Zika virus infected cell supernatant in sealed plates (*NIH Guidelines* Section III-D or N/A). The change also includes the use of fixed/inactivated SARS-CoV and monkeypox virus as well as monkeypox virus nucleic acid (*NIH Guidelines* Section III-D) to the BUA *The Host Response to Virus Infection*. The third generation lentiviral vectors (III-D) were approved outside of an IBC meeting because the lab already had approval for older generation lentiviral vectors.
- Dr. Lieber added the use of HIV in mice and in vitro to the BUA *Stem cell and gene therapy of cancer and hematological diseases* (*NIH Guidelines* N/A).
- Dr. Rabinowitz registered a new BUA *Monkeypox and Pets Study* collecting samples from household pets of people suspected of monkeypox infection (*NIH Guidelines* N/A).
- The IBC Chair 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.

8. BSL-3 INACTIVATION REPORT

- There were no BSL-3 Inactivation Reports this month.

9. DURC REPORT

- The Dual Use Research of Concern Institutional Review Entity (DURC IRE) did not meet this month because there were no applications to review.

10. INDIVIDUAL PROJECT REVIEWS

- a. Cabernard, Clemens, renewal, *Cellular and molecular mechanisms of asymmetric cell division*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Cabernard lab aims to investigate how fruit fly cells accurately position the molecular machinery that is required for cell division.
 - This research includes working with recombinant *E. coli* and transfection of *Drosophila melanogaster* by injection.
 - A lab inspection has been performed and is still pending a response.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Cabernard.
 - The Committee voted unanimously to approve the draft BUA for Dr. Cabernard pending successful completion of the lab inspection.
- b. Curnow, Eliza, new, *TNPO2 Project*
- *NIH Guidelines* Sections III-D and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Curnow lab aims to develop nonhuman primate (NHP) embryo and stem cell resources that carry point mutations.
 - Work in this lab includes collection and processing of NHP blood samples and surgical procedures for recovery of in vivo matured oocytes.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Curnow.
 - The Committee voted unanimously to approve the draft BUA for Dr. Curnow.
- c. Derdeyn, Cynthia, new, *Virus neutralization, diversity, and B cell immunology*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Derdeyn lab focuses on gaining a comprehensive understanding of how B cells and antibodies are elicited during infection and vaccination, how B cells respond and protect against infection to viruses, and how antibody responses impact viral evolution and persistence.
 - Research in this lab includes in vitro work with viruses such as HIV, primate lentivirus, vaccinia virus, and blood, tissues, body fluids, and cells from human and non-human primates.
 - The lab inspection is scheduled for after the IBC meeting.
 - All required trainings are complete.
 - Occupational health requirements for work with vaccinia virus have been communicated to the lab.
 - The draft BUA letter was shown.

- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Derdeyn.
 - The Committee voted unanimously to approve the draft BUA for Dr. Derdeyn pending successful completion of the lab inspection.
- d. Doulatov, Sergei, renewal, *Hematopoiesis from cord blood and pluripotent stem cells*
- *NIH Guidelines* Sections III-D and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Doulatov lab aims to study the biology of human hematopoietic stem cells, and to generate hematopoietic cells from induced pluripotent stem cells (iPSCs).
 - Research in this lab includes working with primary human cell lines and administering third generation lentiviral vectors to mice.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Doulatov.
 - The Committee voted unanimously to approve the draft BUA for Dr. Doulatov.
- e. Liu, Hong Yan, new, *RGD siRNA carriers in vivo assessment*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Liu lab is working to develop siRNA carriers for translational drug applications such as cancer treatment.
 - The project includes use of tumor cell lines administered to mice.
 - A discussion occurred regarding the PI for this BUA. Dr. Ennis was the original PI for the protocol but retired from UW. The scientist that is responsible for the scientific work and decision making, Dr. Hong Yan Liu, does not have a UW affiliation and thus cannot be the PI for the animal protocol. The person assigned as PI for the animal protocol, Ulysis Rivera, does not meet the requirements to be a PI under the IBC rules. In this case, the PI for the animal protocol will be different than the PI for the BUA.
 - The lab was inspected, and all deficiencies have been corrected.
 - The required trainings are complete.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Liu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Liu.
- f. Maly, Dustin James, change, *Study of Intracellular Protein Kinases*
- *NIH Guidelines* Sections III-D and III-E apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Maly lab is adding amphotropic gammaretroviral vectors at BSL-2 and with oncogenic inserts at BSL-2 with BSL-3 practices.
 - The lab inspection is scheduled for after the IBC meeting.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Maly.

- The Committee voted unanimously to approve the draft BUA for Dr. Maly pending successful completion of the lab inspection.
- g. Marcinek, David, renewal, *Assessing mitochondrial function in relation to whole animal fitness and health*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goals of the Marcinek lab are to test two different exercise strategies for their ability to overcome fatigue, muscle impairments, and disruption of muscle energetics in virally suppressed HIV subjects, and to test whether changes in mitochondrial function in muscle and blood cells reflect whole body health and fitness.
 - This work includes isolation of blood cells from whole blood.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Marcinek.
 - The Committee voted unanimously to approve the draft BUA for Dr. Marcinek.
- h. Pepple, Kathryn, renewal, *The role of the innate and adaptive immune system in a novel model of uveitis*
- *NIH Guidelines* Sections III-D and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Pepple lab aims to better understand the mechanisms of ocular inflammation and develop new treatments for patients.
 - This research includes working with adeno-associated viral vectors and pertussis toxin in vitro and in mice.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Pepple.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pepple.
- i. Rea, Shane, renewal, *Maintaining Mitochondrial Health into Old Age*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Rea lab aims to define molecular mechanisms that can be used to counter mitochondrial dysfunction into old age.
 - The work in this lab includes flow cytometry, centrifugation and administering Risk Group 1 and 2 microorganisms to *C. elegans*.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Rea.
 - The Committee voted unanimously to approve the draft BUA for Dr. Rea.

- j. Sakiyama-Ebert, Shelly, new, *Developing New Tools to Understand the Role of Interneurons in Rewiring After SCI*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Sakiyama-Ebert lab studies the role of interneurons in the recovery of function following spinal cord injury.
 - This research includes in vitro work with adeno-associated viral vectors and third generation lentiviral vectors.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Sakiyama-Ebert.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sakiyama-Ebert.
- k. Shendure, Jay, renewal, Shendure: General Research
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Shendure lab aims to advance the capabilities of next generation sequencing, and to use next generation sequencing to advance understanding of genetics in a variety of fields.
 - This research includes administering human cells transfected with recombinant or synthetic DNA or RNA to mice.
 - A lab inspection has been performed and is still pending a response.
 - All required trainings are complete.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Shendure.
 - The Committee voted unanimously to approve the draft BUA for Dr. Shendure pending successful completion of the lab inspection.
- l. Stayton, Patrick, renewal, *Stayton Laboratory Engineered Cells, Smart Proteins, and Intracellular Delivery*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goals of the Stayton lab are to develop new therapeutics for infectious disease, cancer, and inflammatory disease.
 - The research in this lab includes in vitro work with third generation lentiviral vectors.
 - A lab inspection has been performed and is still pending a response.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Stayton.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stayton pending successful completion of the lab inspection.

- m. Woodrow, Kim, renewal, *Primate Models to Evaluate HIV Preventions and Strategies*
- *NIH Guidelines* Sections III-D and III-E apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Woodrow lab's work supports endpoint measurements and assays from biological tissue and fluids obtained from studies of pre-exposure prophylaxis, treatment, cure, and vaccine interventions.
 - The research in this lab includes working with SHIV-infected NHP blood, tissue, cells and body fluids and lentiviral vectors.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Woodrow.
 - The Committee voted unanimously to approve the draft BUA for Dr. Woodrow.

11. SUBCOMMITTEE REPORTS:

- n. Disis, Mary (Nora), new, *A Phase 2 Study to Evaluate the Efficacy and Safety of an Adjuvant Therapeutic Cancer Vaccine (AST-301, pNGVL3-hICD) in Patients with HER2 Low Breast Cancer (Cornerstone-001)*
- *NIH Guidelines* Sections III-D and III-F apply.
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is an industry-sponsored (Aston Science), multi-center, phase II clinical trial of an adjuvanted cancer vaccine to treat patients with HER2 low breast cancer.
 - This work requires staff to prepare or handle the drug product and administer it intradermally.
 - A lab inspection was not required as the lab was recently inspected.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Disis. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis.
- o. Fink, Susan, renewal, *Host-Pathogen Interactions*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Fink lab aims to understand cellular pathways used by viruses and bacteria to cause infection and processes mediating immunity and inflammation.
 - The research in this lab includes working with Risk Group 2 and 3 microorganisms in vitro and administering Risk Group 3 microorganisms to mice at BSL-3.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.

- A medical management plan is in place for SARS-CoV-2. Occupational health requirements for Zika virus, SARS-CoV-2 clinical samples, and the yellow fever virus vaccine strain are referenced on the BUA letter.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Fink. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fink.
- p. Fuller, Deborah, new, *Identification of T Cell Receptors, Epitopes, and Protective Responses that Occur During Coccidioidomycosis*
- *NIH Guidelines*, Sections III-D, III-E, and III-F apply.
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Fuller lab aims to define the changes that occur in human and animal immune responses to coccidioidomycosis, also known as Valley Fever, and use this knowledge to design new vaccines and diagnostic tests.
 - This research includes working with human and NHP blood, tissue, cells, and body fluids from individuals infected with Valley Fever.
 - A lab inspection was not required as the in vitro rooms were recently inspected, and the in vivo rooms are in the vivarium.
 - All required trainings are complete.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Fuller. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- q. Tykodi, Scott, new, *A Phase 1a/1b, Open-Label, Multicenter Study Evaluating the Safety and Feasibility of ITIL-306 in Subjects with Advanced Solid Tumors*
- *NIH Guidelines*, Sections III-C
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is an industry-sponsored (InstilBio), multi-center phase I trial of ITIL-306-201 for relapsed/refractory advanced solid tumors. The drug product is an autologous, engineered, tumor-infiltrating lymphocyte (TIL) treatment with an anti-folate receptor (FOLR1) alpha costimulatory antigen receptor (CoStAR).
 - This work requires staff to prepare or handle the drug product and administer it via infusion.
 - The required trainings are still pending.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Tykodi. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Tykodi pending completion of PI training.

10. FOR YOUR INFORMATION:

- An update was provided on the NIH Reportable Incident that was submitted to NIH OSP in September 2022. The NIH reviewed the incident report and had no further questions or requirements.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:57 A.M.