



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, January 22, 2025

Time: 10:00 a.m. – 12:00 p.m.

Location: Zoom

- Members Present:**
1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
 2. Jason Cantera (*Community Member*)
 3. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 4. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 5. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 6. Richard Grant, Washington National Primate Research Center
 7. Jennifer Iwamoto, Office of Animal Welfare (*Animal Containment Expert*)
 8. David Koelle, Allergy and Infectious Diseases
 9. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 10. Susan Parazzoli (*Community Member*)
 11. Jason Smith, Microbiology (*IBC Chair*)

Commonly Used Abbreviations

AAV: adeno-associated viral vector

BSL: biosafety level

BSL-2w/3: BSL-2 with BSL-3 practices

BSO: biosafety officer

BUA: Biological Use Authorization

DURC: Dual Use Research of Concern

IACUC: Institutional Animal Care and Use Committee

IBC: Institutional Biosafety Committee

iPSCs: induced pluripotent stem cells

NHP: non-human primate

NIH: National Institutes of Health

PI: Principal Investigator

rDNA: recombinant or synthetic DNA/RNA

RG: Risk Group

SOP: standard operating procedure

Source material: blood, tissue, body fluids, and cell lines

1. **CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:02 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. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the December 11, 2024, meeting.
 - A member made a motion to approve the December 11, 2024, meeting minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the December 11, 2024, meeting minutes.
4. **OLD BUSINESS:**
 - At the December 11, 2024 meeting, Dr. Orsborn's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the December 11, 2024 meeting, Dr. Prabha's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the December 11, 2024 meeting, Dr. Queitsch's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the December 11, 2024 meeting, Dr. Regnier's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the December 11, 2024 meeting, Dr. Shih's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
5. **BIOSAFETY OFFICER (BSO) REPORT:** The Biosafety Officer Report includes projects involving: (1) recombinant or synthetic nucleic acids covered under Sections III-E and III-F of the *NIH Guidelines*, (2) non-recombinant biological agents requiring BSL-2 with BSL-3 practices containment or lower, and (3) administrative updates, such as room additions.
 - a. Biosafety Officer Report
 - Dr. Cangelosi renewed work with Risk Group 1 and 2 agents in vitro on the BUA *Novel Detection of Bacterial, Viral, and Parasitic Pathogens in Clinical and Environmental Samples*. (Section III-E, III-F)
 - Dr. Akilesh added new rooms for work with previously approved agents on the BUA *Kidney Disease Genomics*.
 - Dr. Vasquez registered work with drosophila cells in core facilities on the BUA *Regulation of organ form and function*.
 - Dr. Branch initiated work with human source material on the BUA *CORE Lab*.
 - Dr. Ferreira added new rooms for work with previously approved agents on the BUA *Tissue Bank for the Investigation of the Genetics and Basic Biology of Human Vascular Malformations and Skull base tumors*.
 - Dr. Levitt added new rooms for work with previously approved agents on the BUA *Cerebrovascular pathobiology*.
 - Dr. Temkin renewed work with human source material on the BUA *Track*.
 - Dr. White initiated a new BUA for shared lab space for clinical investigators to use for processing human source material samples on the BUA *HRT Translational Research Lab*.

- Dr. Bhatraju initiated work with human source material and rDNA on the BUA *Critical Illness Translational Research*. (III-F)
- Dr. Fuller added work with fixed SARS-CoV-2 samples to a core facility on the BUA *Nucleic Acid Mediated Protein Expression*.
- Dr. Basso registered a permit on the BUA *Changes across the lifespan in the use of heuristics to guide decision-making (NHPs)*.
- Dr. Savan removed work with LCMV WE strain from the BUA *Innate immune responses to virus infections*.
- Dr. Brewer renewed work with E. coli, rDNA, and *Saccharomyces cerevisiae* on the BUA *Genome Maintenance in Yeast*. (III-F)
- Dr. Soge renewed work with human source material, rDNA, and *Neisseria* species on the BUA *Surveillance of antimicrobial resistance in Neisseria gonorrhoeae and diagnostic test development for sexually transmitted infections*. (Section III-F)
- 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.

6. BSL-3 INACTIVATION REPORT

- Dr. Sims requested approval for 8M Urea, Trizol, and 2:1 chloroform:methanol (MPLEX) inactivation of MERS-CoV samples.
- Dr. Seshadri requested approval for 1% Paraformaldehyde inactivation of Mycobacterium tuberculosis samples with a 24-hour contact time.
- The subcommittee reviewed the procedures and inactivation data provided by the labs and approved their requests.
- The IBC Chair made a motion to approve this month's BSL-3 Inactivation Report.
- The committee unanimously voted to approve this month's BSL-3 Inactivation Report.

7. FY24 METRICS

- The EH&S biosafety team shared IBC and biosafety lab inspection metrics for fiscal year 2024 (FY24), including number and types of BUAs reviewed, schools/departments submission breakdowns, biosafety incident response, BSL-3 inactivation reports, lab inspection numbers and activity, and categories of inspection findings.
- 353 BUAs were approved in FY2024.

8. INDIVIDUAL PROJECT REVIEWS

- a. Adair, Jennifer, renewal, *In vivo CRISPR engineering of B cells to produce anti-HIV broadly neutralizing antibodies using novel nanoparticles*
 - NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Adair lab studies genetic insertion of broadly neutralizing antibody genes against HIV in nonhuman primate models by injecting NHPs with gold nanoparticles with CRISPR components.
 - Adair lab works with primate lentivirus at BSL-2w/3 and rDNA at BSL-2 in nonhuman primate macaques.
 - A lab inspection was not required as all work takes place inside a vivarium.

- 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. Adair.
 - The Committee voted unanimously to approve the draft BUA for Dr. Adair.
- b. An, Jonathan, new, *Targeting P. gingivalis and Periodontitis***
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The An lab investigates the role of lipid A modifications as a mechanism for evading immune responses that may contribute to periodontal disease progression in a mouse model.
 - The An lab will administer recombinant and wildtype *Porphyromonas gingivalis* to mice at ABSL-2.
 - A lab inspection was not required as all work takes place inside a vivarium.
 - 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. An.
 - The Committee voted unanimously to approve the draft BUA for Dr. An.
- c. Durant, Andrea, new, *Ammonia sensing and hydromineral balance by mosquitoes***
- NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Durant lab studies transgenic mosquitos to understand ammonia sensing mutations, host-seeking, digestion of blood, and reproduction.
 - The Durant lab works with transgenic mosquitos at BSL-2, and rDNA and E. coli at BSL-1.
 - A discussion occurred regarding the potential for wild caught mosquitoes to harbor pathogens. The Arthropod Containment Guidelines recommend ACL-1 containment for mosquitoes caught from the local geographic area regardless of whether there is active vector borne disease transmission in locale.
 - 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. Durant.
 - The Committee voted unanimously to approve the draft BUA for Dr. Durant.
- d. Erasmus, Jesse, renewal, *RNA Vaccines***
- NIH Guidelines Sections III-D
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - The Erasmus lab develops self-amplifying RNA vaccine and studies immune responses in mice models.
 - The Erasmus lab works with Enterovirus B and D and vaccine strains of Japanese encephalitis virus (JEV) (SA-14-14-2) and Rift valley fever virus (MP-12) strain in mice at ABSL-2.
 - They also administer rDNA with enhanced gene delivery methods to mice at BSL-1.
 - A lab inspection was not required as all work takes place inside a vivarium.

- The required trainings are still pending.
 - There are occupational health requirements for work with JEV.
 - 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. Erasmus.
 - The Committee voted unanimously to approve the draft BUA for Dr. Erasmus, pending completion of the required trainings.
- e. Hofstetter, Christoph, new, *Repair after spinal cord injury*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Hofstetter lab researches treatment for paralysis caused by spinal cord injuries by developing novel biomaterial that serves as protective structure to support nerve growth and regeneration through rat models.
 - The lab uses AAV in rats at BSL-1 and AAV with oncogenes in rats at BSL-2.
 - The lab inspection is scheduled for after the IBC meeting.
 - 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. Hofstetter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hofstetter, pending successful completion of the lab inspection.
- f. Huang, Sui, new, *Instability of Cancer Cell States*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Huang lab will transport human cells transduced by lentiviral vectors to a core facility at the University of Washington to perform flow cytometry and cell sorting at BSL-2.
 - A lab inspection was not required as the lab was recently inspected.
 - The required trainings are still pending.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Huang.
 - The Committee voted unanimously to approve the draft BUA for Dr. Huang, pending completion of the required trainings.
- g. Lieber, Andre, renewal, *Stem cell and gene therapy of cancer and hematological diseases*
- NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Lieber lab works with adenovirus to identify how the virus binds to and interacts with coagulation factors. They also work on hematopoietic stem cell gene therapies for diseases in vivo.
 - The lab works with HIV at BSL-2w/3 practices and adenoviral vectors in vitro and in mice at BSL-2. They also work with human and NHP source material at BSL-2.
 - A lab inspection has been performed and is still pending a response.
 - All required trainings are complete.
 - The IACUC protocol is still pending.

- The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Lieber.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lieber, pending successful completion of the lab inspection and submission and review of the IACUC protocol.
- h. Pravetoni, Marco, change, *Expression of recombinant monoclonal antibodies*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Pravetoni lab is working to develop medical interventions against substance use disorders by developing vaccines and other interventions to treat or prevent use disorders and overdose.
 - The lab is adding rDNA with enhanced gene delivery in rats and mice at ABSL-1.
 - The lab was inspected, and no deficiencies were noted.
 - All required trainings are complete.
 - The IACUC protocol is still pending.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Pravetoni.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pravetoni, pending submission and review of the IACUC protocol.
- i. Steinmetz, Nick, renewal, *Neural mechanisms underlying visual perception, cognition and action in mice*
- NIH Guidelines Sections III-D
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - The Steinmetz lab studies neural mechanistic function through electrophysiology in mice.
 - The lab works with AAV 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. Steinmetz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Steinmetz.
- j. Stella, Nephi, renewal, *Regulation of 2-AG Signaling in Mouse Neurons*
- NIH Guidelines Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Stella lab studies the endocannabinoid signaling system to characterize and develop novel therapeutics to target this system.
 - The lab works with human cells at BSL-2 and AAV and E. coli at BSL-1.
 - 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. Stella.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stella.

9. SUBCOMMITTEE REPORTS:

- k. Fink, Susan, change, *Host-Pathogen Interactions*
- NIH Guidelines Sections III-D
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Fink Lab has requested to work with SARS-CoV-2 at BSL-2 based on the updated guidance from the CDC and NIH.
 - The subcommittee determined that BSL-2 is appropriate for most SARS-CoV-2 work, but additional review is required for certain scenarios, including enhanced virulence modifications, SARS-CoV/SARS-CoV-2 chimeras, non-human primate studies, and aerosolized infections.
 - The subcommittee determined that clinical samples from COVID patients can be used at BSL-2 as human source material, and SARS-CoV-2 nucleic acid and fixed or inactivated samples can be used at BSL-1.
 - A standard operating procedure for moving SARS-CoV-2 samples from BSL-3 to BSL-2 labs was reviewed and approved by the subcommittee.
 - There will be an occupational health requirement to offer the COVID vaccine prior to work.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - 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.
- l. Gopal, Ajay, new, *UB-VV111-01 A PHASE 1, MULTICENTER, OPEN-LABEL STUDY OF UB-VV111 IN COMBINATION WITH RAPAMYCIN IN RELAPSED OR REFRACTORY (R/R) CD19+ B-CELL MALIGNANCIES*
- NIH Guidelines Sections III-C
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is an industry-sponsored, multicenter, first-in-human, phase I clinical trial for a new delivery approach for an anti-CD19 CAR for relapsed/refractory B cell lymphomas. The investigational product is designed to engineer T cells in vivo.
 - Replication incompetent third generation lentiviral vectors will be administered to study participants.
 - 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. Gopal. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gopal, pending completion of the required trainings.
- m. Greninger, Alex, change, *Isolation, propagation, and characterization of clinically relevant human viral pathogens*

- NIH Guidelines Sections NA
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Greninger lab is seeking to add the use of wild-type Mpox Clade I samples at BSL-3. They are already approved for Mpox Clade II work at BSL-3.
 - All required trainings are complete.
 - A medical management plan is in review for Mpox.
 - Mpox Clade I is regulated by the Federal Select Agent Program (FSAP). FSAP approval has been obtained.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Greninger. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Greninger with one member not voting.
- n. Liu, Catherine, new, *Phase 1b/2a, Randomized, Double-blind Study to Investigate Safety, Tolerability, PK, PD, and Preliminary Efficacy of Oral Administration of SNIPRO01 in Patients with Hematologic Malignancy Scheduled for Allogeneic Hematopoietic Stem-Cell Transplantation Receiving Fluoroquinolone Prophylaxis and Harboring Fluoroquinolone-Resistant Escherichia coli Pre-Transplant*
- NIH Guidelines Sections III-C and III-E
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a company sponsored, 1:1 ratio placebo-controlled, multi-center, non-first-in-humans study of a “cocktail” of four engineered bacteriophage given to patients with hematologic cancers to help reduce levels of pathogenic E.coli in their intestinal flora.
 - Recombinant bacteriophage will be orally administered to study participants.
 - There was a discussion about potential increase of antibiotic resistance via horizontal gene transfer with the use of the engineered bacteriophage and potential shedding of the recombinant bacteriophage in the environment. Overall, the committee agreed that these risks were low and are outweighed by the potential benefit to the patients enrolled in the study.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Liu. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Liu.
- o. Wright, Johnathan, new, *A Phase 2 Open-label Randomized Study of V940 in Combination With BCG Versus BCG Monotherapy in Participants With High-risk Non-muscle Invasive Bladder Cancer (INTerpath-011)*
- NIH Guidelines Sections III-C and III-E
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a multi-center, company sponsored, non-first-in-humans trial of a cancer mRNA vaccine.
 - A novel mRNA individualized vaccine will be administered to study participants.
 - All required trainings are complete.

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

10. FOR YOUR INFORMATION:

- **NIH Incident Report:** The NIH has responded that no further information was required for a recent exposure involving a needlestick from a needle used on a mouse exposed to an attenuated recombinant strain of *Vibrio parahaemolyticus*.
- The NIH responded that no further information was required for a recent exposure involving a splash to the eye of urine from a rabbit exposed to an attenuated recombinant strain of *Treponema pallidum*.

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

12. MEETING ADJOURNED AT APPROXIMATELY 12:02 p.m.