



# INSTITUTIONAL BIOSAFETY COMMITTEE

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## UNIVERSITY of WASHINGTON

### Meeting Minutes

**Date:** Wednesday, February 21, 2024

**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. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
  7. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
  8. Jennifer Nemhauser, Department of Biology (*Plant Expert*)
  9. Susan Parazzoli (*Community Member*)
  10. Jason Smith, Microbiology (*IBC Chair*)
  11. Paul Swenson, Seattle-King Co. Dept. of Public Health

#### 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

iPS: 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 10:01 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. **2024 IBC CHARTER UPDATE REVIEW:**
  - The IBC Chair sought a motion to approve the 2024 IBC Charter Update Review.
  - A member made a motion to approve the 2024 IBC Charter Update Review. Another member seconded the motion.
  - The committee voted unanimously to approve the 2024 IBC Charter Update Review, with one member not voting.
4. **2024 UW ADMINISTRATIVE POLICY STATEMENT (APS) 12.3 UPDATE REVIEW:**
  - The IBC Chair sought a motion to approve the 2024 UW Administrative Policy Statement (APS) 12.3 Update Review.
  - A member made a motion to approve the 2024 UW Administrative Policy Statement (APS) 12.3 Update Review. Another member seconded the motion.
  - The committee voted unanimously to approve the 2024 UW Administrative Policy Statement (APS) 12.3 Update Review, pending an update to the biohazard definition.
5. **APPROVAL OF MINUTES:**
  - The IBC Chair sought a motion to approve the minutes from the January 17, 2024 meeting.
  - A member made a motion to approve the January 17, 2024 minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the January 17, 2024 meeting minutes, with one abstention.
6. **OLD BUSINESS:**
  - At the January 17, 2024 meeting, Dr. Cookson's BUA was approved pending an update to the BUA letter. This BUA is still pending.
  - At the January 17, 2024 meeting, Dr. Greenberg's BUA was approved pending successful completion of the lab inspection. This BUA has been sent out.
  - At the January 17, 2024 meeting, Dr. Ho's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
  - At the January 17, 2024 meeting, meeting, Dr. Meeske's BUA was approved pending successful completion of the lab inspection. This BUA has been sent out.
  - At the January 17, 2024 meeting, Dr. Swalla's BUA was approved pending completion of the required training and successful completion of the lab inspection. This BUA is still pending.
  - At the January 17, 2024 meeting, Dr. Thomas' BUA was approved pending successful completion of the lab inspection. This BUA has been sent out.
7. **BIOSAFETY OFFICER (BSO) REPORT:** The Biosafety Officer Report includes projects involving: (1) recombinant or synthetic nucleic acids covered under section 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. Kachikis was approved for in vitro work with human source material on the BUA *Maternal Immunizations in Low- and High-risk Pregnancies*.
- Dr. Rajakovich added the use of wild type bacterial strains in vitro work to the BUA *Discovery and characterization of enzymes and metabolism in microbiomes*.
- Dr. Gray was approved for in vitro work with human source material on the BUA *UW Pregnancy Biorepository*.
- Dr. Lockwood renewed in vitro work with human source material on the BUA *Genetics and Solid Tumors Laboratory* (Section III-F).
- Dr. Powers was approved for in vitro work with human source material and rDNA with and without enhanced gene delivery methods on the BUA *The role of Filamin C in regulating cardiomyocyte structure and function* (Sections III-E and III-F).
- Dr. Kim renewed in vitro work with human source material and rDNA with and without enhanced gene delivery methods on the BUA *IKKBeta Mediated Impairment of Endothelial Nitric Oxide Production* (Sections III-E and III-F).
- Dr. Lutz added a room for in vitro work with previously approved agents, they also removed a room on the BUA *Pathogen Diagnostic Development*.
- Dr. Marsillach registered work with transgenic mice. This work does not require a BUA (Section III-F).
- Dr. Ferreira added new rooms for in vitro work with previously approved agents, they also removed old rooms on the BUA *Tissue Bank for the Investigation of the Genetics and Basic Biology of Human Vascular Malformations and Skull base tumors*.
- Dr. Marchand added in vitro work with wildtype RG 1 agents to a previously approved room on the BUA *Development of synthetic biology tools for non-standard nucleic acids*.
- Dr. Stevens added in vitro work with NHP source material to a previously approved room on the BUA *Heart Regenerative Technologies*.
- Dr. Nyangahu was approved for work with human feces and pathogenic strains of E. coli in mice on the BUA *Gut Microbiota, Inflammation and Enteric Pathogens*.
- Dr. Mitchell added in vitro work with wildtype Simian rotavirus to the BUA *Evolutionary, genetic, and molecular basis of host-pathogen interactions*.
- Dr. Willing registered work with wildtype RG 1 organisms and rDNA exempt under NIH guidelines to the project *Forest mycobiome research*.
- Dr. Gulsuner renewed in vitro work with human source material and rDNA with and without enhanced gene delivery methods on the BUA *Gulsuner Lab Research* (Sections III-E and III-F).
- Dr. Mougous added in vitro work with wildtype RG 2 microorganisms and several recombinant and wildtype RG 1 microorganisms to the BUA *Mechanisms and consequences of interbacterial interactions* (Section III-E).
- Dr. Gale renewed work with enhanced gene delivery of non-viral rDNA in NHPs and in vitro work with human source material and non-viral rDNA on the BUA *NHP Antivirals for Biodefense* (Sections III-D and III-F). This PI has had this usage of rDNA with enhanced gene delivery methods in NHPs previously reviewed and approved by the IBC at the June 2023 IBC meeting.
- Dr. Basso added a new room for in vitro work with previously approved agents and NHP source material to the BUA *Brain circuits of perceptual decision-making in mice*.
- Dr. Gundlach added a new room for in vitro work with previously approved agents to the BUA *Nanopore Biophysics Lab*.
- 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. INDIVIDUAL PROJECT REVIEWS

### a. Dhaka, Ajay, renewal, *Dhaka mouse*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Dhaka lab aims to understand how differential somatosensory input is coded at the first relay synapse in the dorsal horn of the spinal cord as well as higher order neurons in both the spinal cord and brain.
- This lab works with avian-pseudotyped rabies virus vector and AAV in mice. They also work with rDNA with and without enhanced gene delivery methods, non-pathogenic K-12 strains of E. coli, and human source material in vitro.
- 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. Dhaka.
- The Committee voted unanimously to approve the draft BUA for Dr. Dhaka.

### b. Fuller, Deborah, renewal, *Design and Optimization of a Clinical Gene Gun*

- Section III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Fuller lab aims to develop a clinical-grade gene gun for delivery of nucleic acid vaccines (NAV).
- This lab works with RG2 influenza A and B strains at BSL-2, an attenuated RG3 Influenza A strain at BSL-2 with BSL-3 practices, and rDNA with and without enhanced gene delivery methods in mice.
- A lab inspection was not required as all work takes place inside a vivarium.
- The required trainings are still pending.
- 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. Fuller
- The Committee voted unanimously to approve the draft BUA for Dr. Fuller, pending completion of the required trainings.

### c. Fuller, Deborah, change, *Nucleic Acid Mediated Protein Expression*

- Section III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Fuller lab is adding recombinant Plasmodium cynomolgi that encodes antigens from other Plasmodium species both in vitro and in NHPs.
- A lab inspection was not required as the lab was recently inspected.
- 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. Fuller.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- d. Hofstetter, Christoph, renewal, *Viral Neuronal Tracing in Rodents with Spinal Cord Injury*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Hofstetter lab aims to develop clinical guidelines and strategies to limit the effects of secondary injury following a traumatic spinal cord injury.
  - This lab works with AAV in rat.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - The required trainings are still pending.
  - 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 completion of the required trainings.
- e. Kerr, Benjamin, renewal, *Host-Specific Plasmid Evolution*
- Sections III-D and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Kerr lab aims to understand the role of plasmids and host gene requirements for plasmid maintenance.
  - This lab works with *Klebsiella pneumoniae* and *Salmonella Typhimurium* at BSL-2 and non-pathogenic strains of *E. coli* and rDNA at BSL-1.
  - 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. Kerr.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kerr, pending successful completion of the lab inspection and an update to the BUA letter.
- f. Kiem, Hans-Peter, change, *Cell and Gene Therapy for HIV Cure*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Kiem lab is adding human cells transduced with third generation lentiviral vectors to NHPs.
  - 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. Kiem.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kiem.
- g. Kiem, Hans-Peter, change, *Strategies to Improve Hematopoietic Stem Cell Transduction*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.

- The Kiem lab is adding human cells transduced with third generation lentiviral vectors to NHPs.
  - 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. Kiem.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kiem.
- h. Pasupathy, Anitha, renewal, *2-photon imaging in awake monkey visual cortex*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Pasupathy lab aims to understand the relationship between brain activity and higher-level cognitive functions and how populations of neurons in the visual cortex process and represent information about the visual world.
  - This lab works with AAV in NHPs.
  - 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. Pasupathy.
  - The Committee voted unanimously to approve the draft BUA for Dr. Pasupathy.
- i. Shechner, David, renewal, *Nuclear Architecture and the Noncoding Transcriptome*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Shechner lab aims to understand the mechanisms by which mammalian cells build the structures within their nuclei, how noncoding RNAs (ncRNAs) contribute to these processes, and the ways in which these pathways are modulated among different cell types and diseased states.
  - This lab works with human source material, lentiviral vectors, non-pathogenic strains of E. coli, and rDNA in vitro.
  - The lab inspection is scheduled for after the IBC meeting.
  - The required trainings are complete.
  - 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 successful completion of the lab inspection, with one member not voting.
- j. Xu, Libin, renewal, *The roles of lipids in human diseases*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Xu lab aims to understand the roles of lipids in various human diseases, including the human metabolic disorder Smith-Lemli-Opitz syndrome and antibiotic resistance in bacteria.

- This lab works with RG 2 bacteria, non-pathogenic strains of E. coli, lentiviral vectors with and without oncogenic inserts, and rDNA with and without enhanced gene delivery methods in vitro.
- 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. Xu.
- The Committee voted unanimously to approve the draft BUA for Dr. Xu, pending successful completion of the lab inspection.

## 9. SUBCOMMITTEE REPORTS:

### k. Altemeier, William, renewal, *Inflammation, injury and resolution in lung pathobiology*

- Sections III-D, III-E, and III-F
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The Altemeier lab aims to determine the mechanisms by which lung inflammation, injury and extra-pulmonary organ dysfunction develop in a variety of different models.
- This lab uses SARS-CoV-2 in mice at BSL-3. They also use mouse-adapted strains of influenza virus, RG 1 and 2 strains of yeast and bacteria, and human rhinovirus in mice. In vitro work includes rDNA with and without enhanced gene delivery methods, lentiviral vectors, and human source material.
- The lab inspection is scheduled for after the IBC meeting. The BSL-3 facility is inspected on a routine basis and not in association with BUAs/projects.
- 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. Altemeier. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Altemeier, pending successful completion of the lab inspection and an edit to the application.

### l. Greninger, Alex, change, *Monkeypox Viral Isolation from Clinical Specimens*

- Section III-E
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The Greninger lab is adding the use of SARS-CoV-2 and human cells transduced with third generation lentiviral vectors in the BSL-3 facility.
- The BSL-3 facility is inspected on a routine basis and not in association with BUAs/projects.
- All required trainings are complete.
- 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.

- m. Hladik, Florian, renewal, *Mechanisms of HIV-1 Transmission in Genital Mucosa of Women and the Role of Exosomes in Semen for HIV Infection in the Genital Mucosa of Women*
- Sections III-D, III-E, and III-F
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Hladik lab aims to understand how HIV gains entrance into the host at the host-virus interface (the female genital tract and the gastrointestinal tract) as well as mucosal immunity as involved with human immunodeficiency virus type 1 (HIV-1) infection and other sexually transmitted organisms.
  - This lab works with clinical samples of HIV-1, rDNA containing sequences from HIV-1, lentiviral vectors, rDNA with and without enhanced gene delivery methods, Zika virus, Herpes simplex viruses type 1 and 2, and other sexually transmitted pathogens in vitro.
  - The lab was inspected, and all deficiencies have been corrected.
  - All required trainings are complete.
  - There are occupational health requirements for work with Zika virus.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Hladik. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hladik.
- n. Hyde, Jenny, change, *Pathogenesis studies of alphaviruses and +ssRNA viruses*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Hyde lab is adding the use of previously approved Select Agent strains of Venezuelan equine encephalitis virus (VEEV) in mice.
  - The BSL-3 facility is inspected on a routine basis and not in association with BUAs/projects.
  - 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. Hyde. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hyde, pending IACUC concurrence.
- o. Liao, John, new, *A randomized, open label, two-arm, multicenter Phase 2 study to evaluate efficacy and safety of PRGN-2009 in combination with pembrolizumab versus pembrolizumab monotherapy in patients with recurrent or metastatic cervical cancer*
- Sections III-C and III-D
  - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is a new, industry-sponsored, multi-center phase 2 clinical trial of a therapeutic vaccine for patients with metastatic cervical cancer (positive for HPV16/18).
  - Adenoviral vector (E1a deleted), >2/3/ adenovirus genome (tested negative for RCL) will be administered to humans.
  - All required trainings are complete.
  - The draft BUA letter was shown.



- A member made a motion to approve the draft BUA letter for Dr. Liao. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Liao, with one member not voting.
- p. Milano, Filippo, new, *A Phase 1, Multicenter, Open-Label Study of CB-012, a CRISPR-Edited Allogeneic Anti-CLL-1 CAR-T Cell Therapy in Patients with Relapsed/Refractory Acute Myeloid Leukemia (AMpLify)*
- Section III-C
  - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is a multi-center, industry-sponsored, first-in-human, adult, dose-finding trial of an allogeneic cell-based therapy for acute myelogenous leukemia (AML).
  - AAV will be administered to humans.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Milano. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Milano.
- q. Mitchell, Patrick, renewal, *Evolutionary, genetic, and molecular basis of host-pathogen interactions*
- Sections III-D, III-E, and III-F
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Mitchell lab aims to characterize host-pathogen interactions. The lab is especially interested in a class of innate immune sensors that form inflammasomes and understanding how inflammasomes sense and respond to pathogens.
  - This lab works with wildtype *Citrobacter rodentium* and Dengue virus in mice. The lab also works with recombinant *Shigella flexneri*, *Vibrio cholerae*, and *Vibrio parahaemolyticus* in mice. Additionally, they work with AAV, gammaretroviral vectors, lentiviral vectors with and without oncogenic inserts, many wildtype and recombinant RG1 and RG2 viruses and bacteria, and rDNA with and without enhanced gene delivery methods in vitro.
  - 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.
  - A member made a motion to approve the draft BUA letter for Dr. Mitchell. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Mitchell, pending successful completion of the lab inspection response.

## 10. FOR YOUR INFORMATION:

- **EH&S is investigating the following incidents:**
  - A veterinary technician experienced a scratch to the hand from a non-human primate that had been previously exposed to a recombinant simian-human-immunodeficiency virus (SHIV). The veterinary technician washed the injury for

15 minutes with a herpes B scrub kit containing a chlorhexidine solution. They have consulted with the UW Employee Health Center (EHC) for follow-up care and monitoring.

- An airflow failure of a biosafety cabinet (BSC) occurred in the BSL-3 facility while a researcher was actively working with a recombinant *Mycobacterium tuberculosis*. All PPE was intact and functional, and no spills occurred. The researcher has consulted with the UW Employee Health Center (EHC) for follow-up care and monitoring.
- **NIH Incident Response:**
  - The NIH has responded that no further information or action was required for a recent incident involving a sharps injury from a stylet used for a bone marrow aspiration on a non-human primate that had been previously exposed to recombinant simian-human immunodeficiency virus (SHIV).

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:47 AM**