



# INSTITUTIONAL BIOSAFETY COMMITTEE

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UNIVERSITY *of* WASHINGTON

## Meeting Minutes

**Date:** Wednesday, October 16, 2024

**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. Richard Grant, Washington National Primate Research Center
  6. Jennifer Iwamoto, Office of Animal Welfare (*Animal Containment Expert*)
  7. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
  8. Scott Meschke, Environmental & Occupational Health Sciences
  9. Susan Parazzoli (*Community Member*)
  10. Jason Smith, Microbiology (*IBC Chair*)
  11. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)

### 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 10:01 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. **APPROVAL OF MINUTES:**
  - The IBC Chair sought a motion to approve the minutes from the September 18, 2024, meeting.
  - A member made a motion to approve the September 18, 2024, meeting minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the September 18, 2024, meeting minutes with two members abstaining.
4. **OLD BUSINESS:**
  - At the September 18, 2024 meeting, Dr. Bornfeldt's BUA was approved pending successful completion of the inspection. This BUA has been sent.
  - At the September 18, 2024 meeting, Dr. Giacani's BUA was approved pending NIH Guidelines Section determination by the NIH and development of a medical management plan. This BUA is still pending.
  - At the September 18, 2024 meeting, Dr. Laursen's BUA was approved pending successful completion of the lab inspection. The BUA has been sent.
  - At the September 18, 2024 meeting, Dr. Mack's BUA was approved pending responses to the lab inspection. The BUA has been sent.
  - At the September 18, 2024 meeting, Dr. Oberst's BUA was approved pending BUA application edits. The BUA has been sent.
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. Ingalls renewed work with Risk Group 1 marine microorganisms and rDNA on the BUA *Analyzing metabolites from marine microorganisms*. (III-E, III-F)
    - Dr. Kiem registered previously approved work with rDNA with enhanced gene delivery methods in NHPs at ABSL-2 on the BUA *Strategies to Improve Hematopoietic Stem Cell Transduction*. (III-D, III-E)
    - Dr. Riffell started new work with *Plasmodium yoelii* in mosquitos on the BUA *The Influence of Plasmodium Infection on Mosquito Behaviors*.
    - Dr. Horwitz registered work with new gene inserts in previously approved viral vectors on the BUA *Neurophysiology of Vision*. (III-D)
    - Dr. Woodward registered work with an additional multidrug-resistant strain of *Acinetobacter baumannii* at BSL-2 on the BUA *Targeted bacterial eradication using designed chimeric molecules*. (III-D)
    - Dr. Capozzi added new rooms to the BUA *Glucagon-insulin Hepatic Glycogen*. (III-D)
    - Dr. Adams Waldorf added in vitro work with Oropouche virus at BSL-2 on the BUA *Experimental Model of Viral Induced Brain Injury*.

- Dr. Adams Waldorf added work with additional influenza strains in vitro and in NHPs at A/BSL-2 on the BUA *Influenza and Coronavirus Model of Immunity in Pregnancy*.
- Dr. Yeung renewed work with human source material at BSL-2 and rDNA on the BUA *Extended Culture of Kidney MPS and Organoids to Model Acute and Chronic Exposure to Drugs and Environmental Toxins*. (III-F)
- Dr. Hebert renewed work with human source material at BSL-2 on the BUA *Obstetric Fetal Pharmacology Research Unit Lab*.
- Dr. Nietz registered work with non-biohazardous materials on the BUA *light driven analgesia*.
- Dr. Brakenridge renewed work with human source material at BSL-2 on the BUA *Sample Processing for Clinical Research Studies*.
- Dr. Riffell registered work with transgenic mosquito cells at the Immunology Cell Analysis Facility on the BUA *Mosquito olfaction*.
- Dr. Wander renewed work with rDNA and human source material at BSL-2 on the BUA *Circulating miRNA signatures of beta-cell response in youth validation study*. (III-F)
- Dr. del Zoppo started new work with human source material at BSL-2 on the BUA *Modulation of thrombin generation in the CNS confers resilience to AD*.
- 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. INDIVIDUAL PROJECT REVIEWS

- a. Bruchas, Michael, renewal, *Neuromodulation in Affective Behavior*
  - NIH Guidelines Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Bruchas lab utilizes pharmacological, optogenetic, genetic, viral, imaging, behavioral, and engineering approaches to discover how G-protein coupled receptors function in the context of stress, depression, addiction, and pain.
  - The lab uses an avian pseudotyped rabies viral vector and pseudorabies virus in mice at ABSL-2 and human source material at BSL-2. They also use AAV and canine adenoviral vectors in mice, and AAV, E. coli K-12, and rDNA including enhanced gene delivery in vitro at BSL-1.
  - A 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. Bruchas.
  - The Committee voted unanimously to approve the draft BUA for Dr. Bruchas, pending successful completion of the lab inspection.
  
- b. Chao, Jennifer, change, *In vitro models of retinal degenerative diseases*
  - NIH Guidelines Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.

- The Chao lab works to establish in vitro models of retinal degenerative diseases and to use those models to screen for pro-survival drug compounds.
  - The lab is adding work with AAV with adenovirus at BSL-2. They are also adding new gene inserts in previously approved viral vectors.
  - A lab inspection was not required as the lab was recently inspected.
  - 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. Chao.
  - The Committee voted unanimously to approve the draft BUA for Dr. Chao.
- c. Disis, Mary, renewal, *UW Gene and Cell Therapy Lab*
- NIH Guidelines Sections III-D and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The UW Gene and Cell Therapy Lab is a core facility that provides translation services for UW investigator- and industry-sponsored studies of gene and cell therapy products.
  - As a core facility, the lab works with various biological agents approved by EH&S and the IBC using BSL-1 and BSL-2 containment and practices. Specific biological agents are approved per investigator prior to use in the core facility.
  - The lab was inspected and no deficiencies were noted.
  - 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. Disis.
  - The Committee voted unanimously to approve the draft BUA for Dr. Disis.
- d. Gamble, Lara, new, *MAF (Molecular Analysis Facility) Core for Preparation of Various Received BSL2 samples*
- NIH Guidelines Section: N/A
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Gamble lab is a core facility that provides electron and light microscopy sample preparation services for UW investigators.
  - The lab works with various biological agents approved by EH&S and the IBC using BSL-1 and BSL-2 containment and practices. Specific biological agents are approved per investigator prior to use in the core facility.
  - The lab has been 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. Gamble.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gamble.
- e. Gerner, Michael, renewal, *Organization of Immunity*
- NIH Guidelines Sections III-D and III-E
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Gerner lab works to better understand how immune cell positioning affects immunological responses by studying the structure and function of immune organs in mice and in vitro.
  - This lab works with Risk Group 2 influenza viruses, *Listeria monocytogenes*, *Pseudomonas aeruginosa*, mouse cells transduced with lentiviral vectors, vesicular

stomatitis virus (Indiana strain) in mice and in vitro at BSL-2. They also work with rDNA including enhanced gene delivery methods and murine cells transduced with gammaretroviral vectors (ecotropic) in mice and in vitro at BSL-1.

- A lab inspection has been performed and all deficiencies have been corrected.
- All required trainings are complete.
- There are occupational health requirements for work with influenza virus and diphtheria toxin.
- 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. Gerner.
- The Committee voted unanimously to approve the draft BUA for Dr. Gerner.

f. Mougous, Joseph, new, *Microbial Interactions & Microbiome Center*

- NIH Guidelines Section: N/A
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Mougous lab is a core facility that provides bench space and instruments for UW investigators studying microbiomes.
- The lab works with various biological agents approved by EH&S and the IBC using BSL-1 and BSL-2 containment and practices. Specific biological agents are approved per investigator prior to use in the core facility.
- The lab was inspected and all deficiencies have been corrected.
- 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. Mougous.
- The Committee voted unanimously to approve the draft BUA for Dr. Mougous.

g. Reh, Thomas, renewal, *Novel Regeneration Therapies in Optic Neuropathies*

- NIH Guidelines Section III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Reh lab studies retinal damage and regeneration, with the goal to create new methods for regeneration of damaged Muller glia cells.
- This lab works with AAV in NHPs and NHP source material at BSL-2. They also work with AAV, rDNA, and third generation lentiviral vectors.
- The lab inspection is scheduled for after the IBC meeting.
- 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. Reh.
- The Committee voted unanimously to approve the draft BUA for Dr. Reh with one member not voting, pending successful completion of the lab inspection.

h. Starita, Lea, renewal, *Brotman Baty Advanced Technology Lab: General Research*

- NIH Guidelines Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Starita lab studies the impact of genetic variation on human health by analyzing single nucleotide variants in disease genes, sequencing, and single cell combinatorial indexing.

- This lab works with human source material, NHP source material, and third generation lentiviral vectors with oncogenic inserts at BSL-2. They also work with third generation lentiviral vectors, rDNA including enhanced gene delivery methods, and E. coli K-12.
  - A lab inspection has been performed and all deficiencies have been resolved.
  - 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. Starita.
  - The Committee voted unanimously to approve the draft BUA for Dr. Starita, pending clarification on lab practices.
- i. Zhang, Miqin, change, *Molecular MR Imaging of Tumors*
- NIH Guidelines Sections III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Zhang lab investigates the biological performance and application of liposomal nanoparticle systems in the targeted treatment of cancer and other diseases.
  - This lab is adding in vitro work with third generation lentiviral vectors with oncogenic inserts at BSL-2 and without oncogenic inserts 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. Zhang.
  - The Committee voted unanimously to approve the draft BUA for Dr. Zhang.

## 7. SUBCOMMITTEE REPORTS:

- j. Banerjee, Rahul, new, *A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma*
- NIH Guidelines 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 new industry-sponsored, phase 3, randomized, open-label, multi-center clinical trial of a CAR T cell therapy targeting the extracellular D-domain of BCMA (ddBCMA) on malignant cells of patients with relapsed/refractory multiple myeloma.
  - The lab administers human cells transduced with third generation lentiviral vectors to patients.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Banerjee. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Banerjee.
- k. Kruse-Jarres, Rebecca, new, *A Phase 1/2 Dose Escalation and Expansion Study of BE-101 for the Treatment of Adults with Moderately Severe or Severe Hemophilia B*
- 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, first in humans, open-label, dose-escalation multicenter

trial of an autologous gene-modified B cell adoptive therapy, for adults with hemophilia B.

- The lab administers human cells transduced with AAV to patients.
- A member made a motion to approve the draft BUA letter for Dr. Kruse-Jarres. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Kruse-Jarres, pending confirmation of room locations.

#### **10. FOR YOUR INFORMATION:**

- **2024 Biosafety Month Presentation:** A BSO presented on biosafety at the University of Washington and the history of National Biosafety Month. The focus for 2024 is creating and maintaining clean and organized lab environments.
- EH&S is investigating the following rDNA incident and preparing a report to submit to the NIH: There was needlestick involving NHP blood. The NHP had previously been exposed to recombinant simian-human immunodeficiency virus (SHIV), recombinant CAR-T cells, and an mRNA encoding HIV envelope proteins. The employee washed the injury for 15 minutes with a herpes B scrub kit containing a chlorhexidine solution and then reported to the emergency department for treatment. They have consulted with the UW Employee Health Center (EHC) for follow-up care and monitoring.
- The NIH has responded that no further information was required for the recent rDNA incident involving a bite from a mouse that had previously been exposed to an avirulent, recombinant *Salmonella typhimurium*. The NIH recommends reminding all research staff that they should stop work and consult with or be evaluated by a medical care provider as soon as possible after an exposure incident.

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:28 a.m.**