INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, July 16, 2025
Time: 10:00 a.m. – 12:00 p.m.

Location: Zoom

Members Present:

1. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
2. Erin Heiniger, Department of Bioengineering *(Laboratory Specialist*)
3. Kevin Hybiske, Allergy and Infectious Diseases *(IBC Vice Chair)*
4. Jennifer Iwamoto, Office of Animal Welfare *(Animal Containment Expert)*
5. David Koelle, Allergy and Infectious Diseases
6. Stephen Libby, Laboratory Medicine *(Animal Containment Expert)*
7. Susan Parazzoli *(Community Member)*
8. Jason Smith, Microbiology (*IBC Chair*)
9. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
10. Ana Weil, Allergy and Infectious Diseases

Commonly Used Abbreviations
AAV: adeno-associated viral vector
BBP: bloodborne pathogens
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. The Chair also announced administrative changes impacting the IBC as determined by the UW Attorney General's Office that the committee is no longer subject to the Washington State Open Public Meetings Act.

3. **APPROVAL OF MINUTES:**
   - The IBC Chair sought a motion to approve the minutes from the June 18, 2025, meeting.
   - A member made a motion to approve the June 18, 2025, meeting minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the June 18, 2025, meeting minutes.

4. **OLD BUSINESS:**
   - At the June 18, 2025 meeting, Dr. Duran-Struuck's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
   - At the June 18, 2025 meeting, Dr. Freedman's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the June 18, 2025 meeting, Dr. Sprenger's BUA was approved pending adding third generation lentiviral vectors with non-oncogenic inserts at BSL-1 to the BUA letter. This BUA has been sent.
   - At the June 18, 2025 meeting, Dr. Young's BUA was approved pending successful completion of the lab inspection and completion of training. This BUA is still pending.
   - At the June 18, 2025 meeting, Dr. Babu's BUA was approved pending additional master cell bank testing results. This 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. Thomas added work with wildtype Pseudomonas aeruginosa in previously approved spaces on the BUA *Biological Adhesion in Flow and under Force.*
      - Dr. Venkatesh initiated work with human feces in mice on the BUA *Causal roles for the gut microbiota.*
      - Dr. Stoll renewed work with E. coli and rDNA in vitro on the BUA *Proteins for EPR Spectroscopy.* (Section III-E and III-F)
      - Dr. Bajjalieh renewed work with E. coli, rDNA, human and nonhuman primate source material in vitro on the BUA *Membrane trafficking at presynaptic terminals.* (Section III-E and III-F)
      - Dr. Marchand added work with Streptomyces sioyaensis in vitro to previously approved spaces on the BUA *Development of synthetic biology tools for non-standard nucleic acids.* (Section III-E)
      - Dr. Villen removed a room from their BUA *Cell signaling and proteomics.*

- Dr. Fuller added a core facility for in vitro work with previously approved agents on the BUA *Prophylactic SHIV Vaccines in NHP.*
- Dr. Fuller added a core facility for in vitro work with previously approved agents on the BUA *Identification of T Cell Receptors, Epitopes, and Protective Responses that Occur During Coccidioidomycosis.*
- Dr. Adams Waldorf added a core facility for in vitro work with previously approved agents on the BUA *Experimental Model of Viral-Induced Brain Injury.*
- Dr. Adams Waldorf added a core facility for in vitro work with previously approved agents on the BUA *Experimental Model for Chorioamnionitis and Preterm Labor.*
- Dr. Adams Waldorf added a core facility for in vitro work with previously approved agents on the BUA *Nonhuman primate model of congenital toxoplasmosis.*
- Dr. Sweet added additional rooms for use with previously approved agents on the BUA *WISH HMC/NWH Facilities.*
- Dr. Shah added an additional space for work with previously approved agents on the BUA *Immunology and Genetics of Infectious Diseases and Vaccines.*
- Dr. Fuller removed the use of BSL-3 containment for SARS-CoV-2 and risk group 3 influenza on the BUA on the BUA *Mouse Models for Prophylaxis and Therapy.*
- Dr. McGuire added new WaNPRC Vivarium locations for work with previously approved agents on the BUA *Proof of Concept for an EBV Vaccine.*
- Dr. Hyde added new WaNPRC Vivarium locations for work with previously approved agents on the BUA *Establishment of NHP model of VEEV infection.*
- Dr. Sodora added new WaNPRC Vivarium locations for work with previously approved agents on the BUA *SIV Immunopathology and therapies.*
- Dr. Bekris initiated work with human source material, E. coli, and rDNA on the BUA *Adult Neurodegenerative Disease Biomarker Discovery.* (Section III-E and III-F)
- Dr. Shears added work with wildtype Plasmodium cynomolgi in NHPs on the BUA *Shears NHP studies.*
- Dr. Morrissey initiated work with human source material and rDNA in vitro on the BUA *Knockdown of TEAD1 and INSM1 in neuroendocrine prostate cancer.* (Section III-E)
- Dr. Mitchell added work with Pixuna virus, Ross River virus, and Venezuelan equine encephalitis virus TC-83 strain on the BUA *Evolutionary, genetic, and molecular basis of host-pathogen interactions.*
- Dr. Carlson renewed work with E. coli, human source material, and rDNA on the BUA *Synaptic Laminin and the Calcium Channel.* (Section III-E and III-F)
- Dr. Koelle added work with HSV-2 in mice on the BUA *Koelle Laboratory at UW.* (Section III-F)
- Dr. Nadal took over work previously overseen by Dr. Hawley on the BUA *Phase 1/2 Dose-Escalation and Cohort Study of STEAP1 CART with Enzalutamide in Participants with mCRPC.* (Section III-C)
- 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.
- <u>The Committee unanimously voted to approve this month's Biosafety Officer Report.</u>

6. INDIVIDUAL PROJECT REVIEWS

a. Bair, Wyeth, renewal, *Functional circuitry in the macaque visual system*

- NIH Guidelines Sections III-D
- The assigned IBC Secondary Reviewer presented the Primary Review.
- The Bair lab researches how populations of neurons in the visual cortex process and represent information about the visual world.
- The lab works with AAV in macaques at BSL-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 Secondary Reviewer made a motion to approve the draft BUA for Dr. Bair.
- The Committee voted unanimously to approve the draft BUA for Dr. Bair.

b. Chen, Eleanor Y, renewal, *Druggable pathways in rhabdomyosarcoma*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Chen lab studies novel molecular pathways that drive tumor formation to identify drug targets.
- The lab works with transgenic zebrafish at BSL-1 and with human cells transduced with third generation lentiviral vectors with and without oncogenes and human cells transfected with rDNA in mice at BSL-2. They also use third generation lentiviral vectors with oncogenic inserts and human source material in vitro at BSL-2 and rDNA and E. coli K-12 strains at BSL-1.
- 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. Chen.
- The Committee voted unanimously to approve the draft BUA for Dr. Chen, pending successful completion of the lab inspection.

c. Dhaka, Ajay K, renewal, *Dhaka Zebrafish*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Dhaka lab researches how neural crest cells pain sensation, and neurodevelopment disorders in a zebrafish model.
- The lab works with transgenic zebrafish, rDNA, and E. coli at BSL-1.
- 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. Dhaka.
- The Committee voted unanimously to approve the draft BUA for Dr. Dhaka.

d. Fink, Susan, change, *Host-Pathogen Interactions*

- NIH Guidelines Section III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Fink lab is adding work with Mayaro virus, Ross River Virus, Sindbis virus (SINV), and Venezuelan equine encephalitis virus TC-83 strain in vitro at BSL-2. They are also adding alphavirus replicons without structural proteins and SINV pseudo-infectious particles.
- 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. Fink.
- The Committee voted unanimously to approve the draft BUA for Dr. Fink.

e. Heath, James, change, *Delivering Biologic Therapies with Novel taRNA*

- NIH Guidelines Sections III-D
- The assigned IBC Secondary Reviewer presented the Primary Review.
- The Heath lab is developing a novel trans-amplified RNA delivery system for expressing therapeutic biologic proteins in vivo. The trans-amplifying RNA (taRNA) will drive expression of therapeutic proteins or reporter genes.
- The lab works with trans-amplifying RNA in mice and rats.
- 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 Secondary Reviewer made a motion to approve the draft BUA for Dr. Heath.
- The Committee voted unanimously to approve the draft BUA for Dr. Heath.

f. Heshmati, Mitra, renewal, *Mechanisms of anesthesia and delirium*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Heshmati lab researches the cellular, circuit, and behavioral mechanisms of arousal from general anesthesia to inform development of mechanistically targeted interventions.
- The lab works with AAV and rDNA in vitro and AAV mice at BSL-1.
- 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. Heshmati.
- The Committee voted unanimously to approve the draft BUA for Dr. Heshmati, pending successful completion of the lab inspection.

g. Hybiske, Kevin, renewal, *Chlamydia pathogenesis and immune evasion*

- NIH Guidelines Sections III-B, III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Hybiske lab studies host-pathogen interactions on the molecular, genetic, and cellular level and pathogenesis strategies of chlamydial pathogens with their hosts.

- The lab works with tetracycline-resistant Chlamydia trachomatis (previously approved by NIH as Section III-A) and C. trachomatis LGV strains at BSL-2w/3. Other RG 2 strains of Chlamydia are used at BSL-2 as well as human and non-human primate source material. They also use rDNA and E. coli lab strains at BSL-1.
- 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. Hybiske.
- The Committee voted unanimously, with one recusal, to approve the draft BUA for Dr. Hybiske, pending successful completion of the lab inspection.

h. Lood, Christian, renewal, *Neutrophil contribution to inflammation and autoimmunity in rheumatic disease*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Secondary Reviewer presented the Primary Review.
- The Lood lab researches novel mechanisms of how neutrophils and mitochondria contribute to the development of inflammation and disease in rheumatic disorders.
- The lab works with human source material in vitro at BSL-2, and with third generation lentiviral vectors, E. coli, and rDNA in vitro 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 Secondary Reviewer made a motion to approve the draft BUA for Dr. Lood.
- The Committee voted unanimously to approve the draft BUA for Dr. Lood.

i. Mack, David L, renewal, *FXR1 gene therapy in DMD rat models*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Secondary Reviewer presented the Primary Review.
- The Mack lab researches new models of Duchenne muscular dystrophy in rats for disease modeling and gene therapy studies.
- The lab works with Sendai viral vectors with oncogenes and human source material to generate iPSCs at BSL-2. They also use AAV in vitro and in rats and rDNA in vitro at BSL-1.
- 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 Secondary Reviewer made a motion to approve the draft BUA for Dr. Mack.
- The Committee voted unanimously to approve the draft BUA for Dr. Mack, pending successful completion of the lab inspection.

j. McLean, Jeffrey S, renewal, *Mechanisms underlying the variation in rate and levels of gingival inflammatory responses among the human population*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The McLean lab researches oral microbiome genomics and the biology and pathogenesis of bacterial pathogens.

- The lab works with Porphyromonas gingivalis, human source material, and wildtype human oral bacteria in vitro at BSL-2, and with E. coli and rDNA 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. McLean.
- The Committee voted unanimously to approve the draft BUA for Dr. McLean.

k. Ojo, Kayode, change, *Development of target-based inhibitors of Giardia intestinalis/Giardia lamblia, Trichomonas vaginalis as new treatment options*

- NIH Guidelines Section III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Ojo lab is adding work with wildtype Mycoplasma genitalium in mice and in vitro along with additional recombinant P. falciparum strains and B. divergens in vitro at BSL-2.
- There was a question raised about if the strain of M. genitalium the lab is using may be multidrug resistant.
- The lab was inspected, and all deficiencies have been corrected.
- All required trainings are complete.
- There are occupational health requirements for work with Plasmodium falciparum.
- 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. Ojo.
- The Committee voted unanimously to approve the draft BUA for Dr. Ojo, pending clarification from PI regarding M. gentialium drug resistance.

l. Phillips, Paul E. M., renewal, *Phasic Dopamine Release during Motivated Behavior in Rats*

- NIH Guidelines Section III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Phillips lab researches substance abuse disorder and studies how overexpression of ion channel genes affects neurochemical activity.
- The lab works with AAV and canine adenoviral vectors in rats at BSL-1.
- 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. Phillips.
- The Committee voted unanimously to approve the draft BUA for Dr. Phillips.

m. Raible, Dave, renewal, *Regulation of Zebrafish Development*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Raible lab works with zebrafish models to understand how mechanosensory hair cells develop, respond to damage, and regenerate.
- The lab works with transgenic zebrafish, E. coli, and rDNA in vitro at BSL-1.
- The lab was inspected, and all deficiencies have been corrected.
- 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. Raible.
- The Committee voted unanimously to approve the draft BUA for Dr. Raible pending submission and review of the IACUC.

n. Riffell, Jeffrey A, renewal, *Mosquito olfaction*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Secondary Reviewer presented the Primary Review.
- The Riffell lab studies the olfactory basis of mosquito attraction to odors from hosts or nectar sources.
- The lab works with transgenic Aedes aegypti mosquitoes at ABSL-2, and with rDNA and E. coli in vitro at BSL-1.
- The lab inspection is scheduled for after the IBC meeting.
- All required trainings are complete.
- The draft BUA letter was shown.
- The IBC Secondary Reviewer made a motion to approve the draft BUA for Dr. Riffell.
- The Committee voted unanimously to approve the draft BUA for Dr. Riffell, pending successful completion of the lab inspection.

o. Robinson, Jenny, change, *Regeneration of the knee meniscus*

- NIH Guidelines Sections III-D and III-E
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Robinson lab is adding work with lentiviral vectors in vitro at BSL-2.
- 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. Robinson.
- The Committee voted unanimously to approve the draft BUA for Dr. Robinson.

p. Sanchez-Contreras, Monica, renewal, *Contribution of somatic mitochondrial DNA mutation to the transition from normal aging to Alzheimer's disease*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Sanchez-Contreras lab studies molecular and cellular events that accompany the accumulation of specific mutations related to Alzheimer's Disease in a mouse model.
- The lab works with human source material in vitro at BSL-2 and with AAV in vitro and in mice 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. Sanchez-Contreras.
- The Committee voted unanimously to approve the draft BUA for Dr. Sanchez-Contreras.

q. Smith, Jason, change, *Antiviral Mechanisms of Defensins*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Smith lab is adding work to administer recombinant and wildtype mouse adenoviruses to mice.
- 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. Smith.
- The Committee voted unanimously, with one recusal, to approve the draft BUA for Dr. Smith.

r. Yang, Kai-Chun Daniel, renewal, *Modeling genetic cardiomyopathies with hiPSCs*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Yang lab researches the molecular basis of hypertrophic, dilated and arrhythmogenic cardiomyopathies with human hiPSCs.
- The lab works with Sendai viral vectors with oncogenic inserts to generate hiPSCs, and human source material in vitro at BSL-2, and with AAV, rDNA with and without enhanced gene delivery methods, and E. coli cloning strains in vitro at BSL-1.
- 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. Yang.
- The Committee voted unanimously to approve the draft BUA for Dr. Yang, pending completion of the required trainings.

7. SUBCOMMITTEE REPORTS:

s. Gauthier, Jordan, new, *A multi-center single arm Phase II study to evaluate the safety and efficacy of genetically engineered autologous cells expressing anti-CD20 and anti-CD19 specific chimeric antigen receptor in subjects with relapsed and/or refractory diffuse large B cell lymphoma*

- 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, multi-site, non-first-in-humans study designed to treat subjects with diffuse large B-cell lymphoma.
- A CAR T-cell study product will be administered to human 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. Gauthier. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Gauthier.

t. Hawn, Thomas R., renewal, *Innate Immunity and Susceptibility to Infectious Diseases*

- NIH Guidelines NIH Guidelines Sections III-D, III-E and III-F

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The Hawn lab investigates molecular, cellular, and immunologic mechanisms of disease pathogenesis with an emphasis on genetic studies of the innate immune response to understand differences in individual susceptibility to infections.
- The lab works with Mycobacterium bovis and tuberculosis in vitro at BSL-3. They work with Legionella pneumophila, Listeria monocytogenes, Pseudomonas aeruginosa, Salmonella Typhimurium, other RG 2 Mycobacterium species, and human source material at BSL-2. They also use Sendai viral vectors with oncogenic inserts, amphotropic gammaretroviral vectors, third generation lentiviral vectors with oncogenic inserts at BSL-2, and third generation lentiviral vectors, E. coli lab strains, and rDNA in vitro at BSL-1.
- The lab was inspected, and all deficiencies have been corrected.
- All required trainings are complete.
- There are occupational health requirements for work with M. tuberculosis at BSL-3 and M. tuberculosis H37Ra strains.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Hawn. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Hawn.

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

11. **MEETING ADJOURNED AT APPROXIMATELY 11:38 a.m.**