



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, June 18, 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. Richard Grant, Washington National Primate Research Center
 4. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 5. Jennifer Iwamoto, Office of Animal Welfare (*Animal Containment Expert*)
 6. David Koelle, Allergy and Infectious Diseases
 7. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 8. Susan Parazzoli (*Community Member*)
 9. Jason Smith, Microbiology (*IBC Chair*)
 10. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
 11. 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 IBC Chair shared notes on updated NIH Guidelines related to transparency within meeting minutes.
3. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the May 21, 2025, meeting.
 - A member made a motion to approve the May 21, 2025, meeting minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the May 21, 2025, meeting minutes.
4. **OLD BUSINESS:**
 - At the May 21, 2025 meeting, Dr. Daggett's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the May 21, 2025 meeting, Dr. Fuller's BUA was approved pending submission and review of the IACUC protocol. This BUA is still pending.
 - At the May 21, 2025 meeting, Dr. Golden's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the May 21, 2025 meeting, Dr. Guo's BUA was approved review of antibiotic resistance markers. This BUA has been sent.
 - At the May 21, 2025 meeting, Dr. Ho's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the May 21, 2025 meeting, Dr. Som's BUA was approved pending successful completion of the lab inspection and pending submission and review of the IACUC protocol. This BUA is still pending.
 - At the May 21, 2025 meeting, Dr. Zweifel's BUA was approved pending submission and review of the IACUC protocol. 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. Sprenger took over work previously overseen by Dr. Plymate on the BUA *Mechanisms of transition to castrate resistant prostate cancer*.
 - Dr. Liao renewed work with murine cells transduced with lentiviral vectors, rDNA, and human source material on the BUA *Immune responses in gynecologic cancers*. (Section III-E and III-F)
 - Dr. Fowler added a new core facility room for work with previously approved agents on the BUA *Large-Scale Phenotyping of Tumor Suppressor Variants in Human Cells*.
 - Dr. Marchand renewed work with *E. coli*, rDNA, and *Streptomyces* species on the BUA *Development of synthetic biology tools for non-standard nucleic acids*. (Section III-E and III-F)
 - Dr. Wang added in vitro work with two new wildtype strains of *Neisseria* on the BUA *Ultrasound treatment of Abscesses*.

- Dr. Som initiated work with rDNA in vitro and human source material on the BUA *Som Lab Startup*. (III-E and III-F)
- Dr. Shechner added a core facility for work with previously approved agents on the BUA *Nuclear Architecture and the Noncoding Transcriptome*.
- Dr. Adams Waldorf added new rooms for work with previously approved agents on the BUA *Influenza and Coronavirus Model of Immunity in Pregnancy*.
- Dr. Adams Waldorf added new rooms for work with previously approved agents on the BUA *Experimental Model for Chorioamnionitis and Preterm Labor*.
- Dr. Adams Waldorf added new rooms for work with previously approved agents on the BUA *Experimental Model of Viral-Induced Brain Injury*.
- Dr. Fuller added new rooms for work with previously approved agents on the BUA *Vaccines and minibinders against global health threats*.
- Dr. Imoukhuede renewed work with rDNA and human source material on the BUA *Quantifying receptor protein expression and signaling in human and mouse cells*. (Section III-E and III-F)
- Dr. O'Connor added additional rooms for work with previously approved agents on the BUA *Emerging infectious diseases and SIV co-infections*.
- Dr. Parada initiated work with rDNA and human source material on the BUA *Meningioma Precision Therapy Using AI/Omics*. (Section III-F)
- Dr. Koelle registered work with new recombinant strains of Varicella Zoster Virus on the BUA *Koelle Laboratory at UW*.
- Dr. Sparkman-Yager renewed work with rDNA and human source material on the BUA *High throughput screening to discover RNA-targeting small molecule therapeutics*. (Section III-F)
- Dr. Liu renewed work with human source material on the BUA *Microscopy of Human Tissue Specimens*.
- Dr. Hoofnagle renewed work with human and NHP source material on the BUA *Analysis of human samples for the development of novel diagnostic assays in the clinical laboratory and for the investigation into nutrition, obesity, kidney disease, and cardiovascular disease and neurodegenerative diseases*.
- Dr. Sasamoto registered work with mouse source material in a new room on the BUA *Biology of ocular surface*.
- 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, with one recusal.

6. INDIVIDUAL PROJECT REVIEWS

- a. Bornfeldt, Karin E., renewal, *Cardiovascular Disease and Diabetes*
 - NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Bornfeldt lab studies mechanisms of diabetes that promote cardiovascular disease to develop new treatments and prevention strategies.

- The lab works with lymphocytic choriomeningitis virus (LCMV) and human source material in vitro and in mice at BSL-2. The lab also works with rDNA and AAV in vitro and in mice 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 lymphocytic choriomeningitis virus (LCMV).
 - 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. Bornfeldt.
 - The Committee voted unanimously to approve the draft BUA for Dr. Bornfeldt.
- b. Crudele, Julie, change, *Gene therapy in mice***
- NIH Guidelines Sections III-D and III-E
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab is adding work with human cell-derived vesicles containing rDNA in vitro and in 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. Crudele.
 - The Committee voted unanimously to approve the draft BUA for Dr. Crudele.
- c. Darvas, Martin, renewal, *Genetic analysis of mouse behavior***
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Darvas lab researches how genes and neuropathologic proteins affect the function of the nervous system and regulate animal behavior in a mouse model.
 - The lab works with herpes simplex virus type 1 (HSV-1) and human source material in vitro at BSL-2, and with lentiviral vectors, AAV, and canine adenoviral vectors (CAV) in vitro and in mice at BSL-1.
 - 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. Darvas.
 - The Committee voted unanimously to approve the draft BUA for Dr. Darvas, with one recusal.
- d. Duran-Struuck, Raimon, new, *Allogenic and xenogeneic cellular studies in NHPs***
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - The Duran-Struuck lab studies the safety, functionality, and translational value of chimeric antigen receptor (CAR) T cells and novel immunotherapies in vitro and in vivo.

- The lab works with human and non-human primate source material in vitro at BSL-2 and administers human, NHP, and porcine cells transduced with third generation lentiviral vectors to macaques at ABSL-2. They also work with third generation lentiviral vectors in vitro 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. Duran-Struuck.
 - The Committee voted unanimously to approve the draft BUA for Dr. Duran-Struuck, pending successful completion of the lab inspection.
- e. Duthie, Malcolm, renewal, *Immune modulators for treatment of infection*
- NIH Guidelines Sections III-D
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - The Duthie lab develops innate immune agonists as broad-spectrum antivirals.
 - The lab works with an influenza virus Vietnam strain that is not regulated as a select agent in mice at ABSL-2w/3 and with respiratory syncytial virus (RSV) and influenza virus PR8 backbone strain in mice at ABSL-2.
 - A lab inspection was not required as all work takes place inside a vivarium.
 - All required trainings are complete.
 - There are occupational health requirements for work with influenza virus.
 - 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. Duthie.
 - The Committee voted unanimously to approve the draft BUA for Dr. Duthie.
- f. Freedman, Benjamin, new, *Modeling Human Disease in a Dish (Plurexa)*
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Freedman lab creates laboratory models of human disease and regeneration using pluripotent stem cells.
 - The lab works with Sendai virus with oncogenic inserts and human source material in vitro at BSL-2 and with AAV, 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 Primary Reviewer made a motion to approve the draft BUA for Dr. Freedman.
 - The Committee voted unanimously to approve the draft BUA for Dr. Freedman, pending successful completion of the lab inspection.
- g. Fuller, Deborah, new, *Virology & Immunology Core*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Fuller lab is initiating a new core facility to cover NHP specimen processing and assay work performed in the WaNPRC Virology and Immunology Core (VIC).

- The lab will work with samples from NHPs that may have been previously exposed to biological agents requiring either BSL-2 or BSL-2w/3 practices as well as NHP source material. Specific biological agents will be approved on the investigator BUAs for use in this core.
 - 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. Fuller.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- h. Kraemer, Brian, new, *Targeted tau degradation*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Kraemer lab aims to reduce the toxic effects of tau by using proteins to bind to it and target it for degradation.
 - The lab works with AAV in mice 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. Kraemer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kraemer.
- i. Miller, Dana, renewal, *Stress homeostasis*
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Miller lab studies how cells and organisms sense and respond to stressful or changing conditions in their environment.
 - The lab works with transgenic *C. elegans*, *E. coli*, *S. cerevisiae*, 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. Miller.
 - The Committee voted unanimously to approve the draft BUA for Dr. Miller.
- j. Mitchell, Patrick, change, *Evolutionary, genetic, and molecular basis of host-pathogen interactions*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Mitchell lab is adding work with recombinant Sendai virus, Sindbis virus, Rhesus monkey rhadinovirus, and new genetic modifications to human herpesvirus 8 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. Mitchell.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mitchell.

- k. Oshima, Junko, renewal, *International Registry of Werner Syndrome*
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Oshima lab investigates the genetic causes and mechanisms of accelerated aging syndromes to understand the biology of aging.
 - The lab works with Epstein-Barr virus, third generation lentiviral vectors with oncogenic inserts, and human source material 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. Oshima.
 - The Committee voted unanimously to approve the draft BUA for Dr. Oshima.
- l. Polyak, Steve, change, *Virus-Host Interactions in Cell Culture*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab is adding work with wildtype non-polio enteroviruses, human rhinovirus B, and recombinant Enterovirus A71 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. Polyak.
 - The Committee voted unanimously to approve the draft BUA for Dr. Polyak.
- m. Sprenger, Cynthia, new, *Mechanisms of transition to castrate resistant prostate cancer*
- NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Sprenger lab develops inhibitors for different mechanisms of resistant prostate cancer.
 - The lab works with third generation lentiviral vectors with oncogenic inserts in vitro and human source material in vitro and in mice at BSL-2 and with third generation lentiviral vectors with non-oncogenic inserts, rDNA, and E. coli cloning strains in vitro at BSL-1.
 - The IBC chair noted the BUA letter needed an edit to include third generation lentiviral vectors with non-oncogenic transgenes 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. Sprenger.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sprenger, pending adding third generation lentiviral vectors with non-oncogenic inserts at BSL-1 to the BUA letter.
- n. Van Voorhis, Wesley, change, *Drugs for Apicomplexa parasites, Toxoplasma, and Cryptosporidium*
- NIH Guidelines Sections III-D

- The assigned IBC Primary Reviewer presented the Primary Review.
 - The Van Voorhis lab is adding cloning of nucleic acid sequences from RG 3 or 4 agents in E. coli K-12 and baculovirus in vitro at BSL-2. The sequences will not include toxins or virulence factors.
 - 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. Van Voorhis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Van Voorhis.
- o. von Moltke, Jakob, renewal, *Type 2 Immune Responses*
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The von Moltke lab researches type 2 immune responses that mammalian immune systems generate upon encountering parasitic worms or allergens.
 - The lab works with RG 2 influenza viruses, mouse adenovirus, and murine cells transduced with amphotropic gammaretroviral vectors in vitro and in mice at BSL-2. Wild type H. polygyrus, N. brasiliensis, T. muris, and Tritichomas spp. are administered to mice at BSL-1. Human source material and third generation lentiviral vectors with oncogenic inserts are used in vitro at BSL-2, and E.coli and rDNA are used 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 influenza virus.
 - 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. von Moltke.
 - The Committee voted unanimously to approve the draft BUA for Dr. von Moltke, with one recusal.
- p. Young, Jessica E, renewal, *Modeling late-onset sporadic Alzheimer's disease using human stem cells*
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Young lab researches human induced pluripotent stem cells to differentiate neuronal lineages to study genes that increase risk for late-onset sporadic Alzheimer's disease.
 - The lab works with human cells transduced with gammaretroviral vectors with oncogenic inserts at BSL-2w/3, human source material in vitro at BSL-2, and with third generation replication deficient lentiviral vectors, AAV, rDNA, and E. coli in vitro at BSL-1.
 - The lab inspection is scheduled for after the IBC meeting.
 - 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. Young.

- The Committee voted unanimously to approve the draft BUA for Dr. Young, pending completion of training and completion of inspection.

7. SUBCOMMITTEE REPORTS:

- q. Babu, Tara, new, *A Phase 1 Open-label Dose Escalation Study to Assess the Safety, Reactogenicity, and Immunogenicity of STX-S for Prevention of SARS-CoV-2 Infection as a Booster Dose*
- 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, first-in-humans study designed to assess the safety, reactogenicity, and Immunogenicity of STX-S for prevention of SARS-CoV-2 infections as a booster dose.
 - An exosome vaccine study product will be administered to human study participants.
 - The study product was prepared by transduction of human cells with second generation lentiviral vectors to express SARS-CoV-2 spike protein on their surface, and exosomes were purified from these transduced cells. Agnostic viral analysis for adventitious viral sequence on the master cell bank was performed, but the IBC determined that this method of replication competent virus detection is not specific enough to show that no lentiviral vector remains. The UW IBC has requested additional analysis of the master cell bank for viral vector packaging sequences. The result of this testing is pending.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Babu. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Babu, pending additional master cell bank testing results, with one recusal.
- r. Weiss, Michael D, new, *A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 TRIAL OF DESCARTES-08 IN PATIENTS WITH GENERALIZED MYASTHENIA GRAVIS (MG)*
- 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 study the efficacy of Descartes-08 as assessed by the proportion of Myasthenia Gravis Activities of Daily Living responders.
 - A CAR T-cell study product (created with CAR mRNA transfection) 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. Weiss. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Weiss.

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

11. MEETING ADJOURNED AT APPROXIMATELY 11:35 a.m.