



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, November 19, 2025

Time: 10:00 a.m. – 12:00 p.m.

Location: Zoom

- Members Present:**
1. Jason Cantera (*Community Member*)
 2. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 3. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 4. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 5. Richard Grant, Washington National Primate Research Center
 6. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 7. David Koelle, Allergy and Infectious Diseases
 8. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 9. Susan Parazzoli (*Community Member*)
 10. Jason Smith, Microbiology (*IBC Chair*)
 11. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
 12. 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 10:02 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 October 15, 2025, meeting.
 - A member made a motion to approve the October 15, 2025, meeting minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the October 15, 2025, meeting minutes, with one abstention.
4. **OLD BUSINESS:**
 - At the October 15, 2025 meeting, Dr. Pravetoni's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the October 15, 2025 meeting, Dr. Veessler's BUA was approved pending clarification of bat cell line testing/screening. 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. Grady renewed work with human source material in vitro on the BUA *Gastrointestinal Cancer Resource (GICaRes) Biorepository*.
 - Dr. Akilesh renewed work with rDNA, E. coli, and human source material on the BUA *Kidney Disease Genomics*. (Section III-E and III-F)
 - Dr. Neitz renewed work with human and NHP source material, E. coli, and rDNA on the BUA *Gene therapy and retinal circuits*. (Section III-E and III-F)
 - Dr. Chun took over work previously overseen by Dr. Disis on the BUA *A Phase II Trial of the Immunogenicity of a DNA Plasmid-Based Vaccine (STEMVAC) Encoding Th1 Selective Epitopes from Five Antigens Associated with Breast Cancer Stem Cells (MDM2, YB1, SOX2, CDH3, CD105) in Patients with Metastatic Triple-Negative Breast Cancer*.
 - Dr. Wang added work with *Bacillus subtilis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus thermophilus*, and E. coli on the BUA *Ultrasound treatment of Abscesses*. (Section III-E and III-F)
 - Dr. Adams Waldorf added a new room for work with previously approved agents on the BUA *Experimental Model of Viral-Induced Brain Injury*.
 - Dr. Adams Waldorf added a new room for work with previously approved agents on the BUA *Experimental Model for Chorioamnionitis and Preterm Labor*.
 - Dr. Adams Waldorf added a new room for work with previously approved agents on the BUA *Nonhuman primate model of congenital toxoplasmosis*.
 - Dr. Adams Waldorf added a new room for work with previously approved agents on the BUA *Influenza and Coronavirus Model of Immunity in Pregnancy*.
 - Dr. Liu renewed work with rDNA, E. coli, and human source material on the BUA *DNA and RNA aptamer development*. (Section III-F)

- Dr. King added new rooms for work with previously approved agents on the BUA *Institute for Protein Design: King Lab*.
- Dr. Pravetoni renewed work with human source material on the BUA *Clinical Trials of Multivalent Opioid Vaccine Components*.
- Dr. Beers initiated work with human source material on the BUA *Beers Lab - Drug Metabolism and Pharmacokinetic Studies*.
- Dr. Raftery renewed work with human and NHP source material on the BUA *Cell Metabolomics*.
- Dr. Stayton renewed work with human and NHP source material and rDNA on the BUA *Drug Carriers*. (Section III-E and III-F)
- Dr. Doty added work with *Sphingobium yanoikuyae* on the BUA *Microbiology Research Projects*.
- Dr. Jain added work with human source material, a core facility, and a new room for work with previously approved agents on the BUA *Neuronal regulation of tissue immunity*.
- Dr. Hunter took over work previously overseen by Dr. Disis on the BUA *A phase II study of STEMVAC vaccine therapy for patients with hormone receptor positive metastatic breast cancer*.
- Dr. Hunter took over work previously overseen by Dr. Vinayak on the BUA *A Phase II Randomized Study of Safety and Efficacy of a Multiple Antigen Vaccine (STEMVAC) in Non-Small-Cell Lung Cancer Patients*.
- Dr. Pollack initiated work with human source material on the BUA *Role of Exclusion Zone water (EZ) in cancer*.
- Dr. Meschke added work with rDNA and various wildtype RG1 and RG2 organisms on the BUA *Detection and Characterization of Pathogens in Environmental Media*. (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. IRE DURC-PEPP REPORT

- One project was assessed for use of botulinum neurotoxin. It does not meet Category 1 or Category 2 research criteria of the DURC-PEPP policy, and the PI has approval to proceed with the research.
- The IBC Chair sought a motion to approve this month's IRE DURC-PEPP Report.
- A member made a motion to approve this month's IRE DURC-PEPP Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's IRE DURC-PEPP Report.

7. INDIVIDUAL PROJECT REVIEWS

- a. Ailion, Michael, renewal, *Dense-core vesicles*
 - NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Ailion lab researches genes involved in the release of peptide hormones such as insulin.

- The lab works with lentiviral vectors and human and NHP source material in vitro at BSL-2, and with transgenic *Caenorhabditis* species, *E. coli*, *S. cerevisiae*, and rDNA in vitro at BSL-1.
 - The 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. Ailion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ailion, pending successful completion of the lab inspection.
- b.** Johnsen, Jill, renewal, *Studies of variation impacting traits and disease in classical hematology*
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Johnsen lab studies blood-associated traits and disorders, such as genetic variants that lead to blood-based phenotypes.
 - The lab works with lentiviral vectors, Epstein-Barr virus, human and NHP source material in vitro at BSL-2, and with *E. coli* and rDNA in vitro 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. Johnsen.
 - The Committee voted unanimously to approve the draft BUA for Dr. Johnsen, pending successful completion of the lab inspection.
- c.** Ladiges, Warren, change, *Alzheimer's Disease Intervention*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Ladiges lab is adding work with AAV in vitro and in crickets.
 - 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. Ladiges.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ladiges.
- d.** Lieber, Andre, renewal, *In vivo HSC gene therapy in NHPs*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Lieber lab researches gene therapy with gutless adenoviral vectors in an NHP model.
 - The lab works with primate lentivirus in NHPs at BSL-2w/3 and with adenoviral vectors in NHPs at BSL-2. They also work with HIV in vitro at BSL-2w/3 practices and with adenoviral vectors and human and NHP source material in vitro 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 of the IACUC protocol.
- e. Liu, Qinghang, renewal, *Liu Lab Research Program*
- NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Liu lab researches molecular mechanisms of cardiac remodeling and heart failure.
 - The lab works with AAV, adenoviral vectors, and third generation lentiviral vectors with oncogenic inserts in mice at BSL-2 and with AAV and third generation lentiviral vectors without oncogenic inserts in mice at BSL-1. In vitro, they work with the viral vectors with oncogenes and human source material at BSL-2 and the viral vectors without oncogenes, E. coli, S. cerevisiae, and rDNA 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. Liu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Liu.
- f. MacLellan, Robb, change, *Cardiac Development, Growth, and Regeneration*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The MacLellan lab is adding work with AAV in rats.
 - 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. MacLellan.
 - The Committee voted unanimously to approve the draft BUA for Dr. MacLellan.
- g. Oberst, Andrew, change, *Programmed cell death and immunity*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Oberst lab is adding work with recombinant human herpes virus 8 and wildtype Sindbis virus and Venezuelan equine encephalitis (TC-83 strain) 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. Oberst.
 - The Committee voted unanimously to approve the draft BUA for Dr. Oberst.
- h. Panyam, Jay, change, *Anticancer studies in mice models*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Panyam lab is adding work with mouse cells transduced with lentiviral vectors at BSL-2 and mouse cells transfected with rDNA at BSL-1, both 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. Panyam.
 - The Committee voted unanimously to approve the draft BUA for Dr. Panyam.
- i. Prabha, Swayam, change, *Targeting Solid Tumors Using Nano-Engineered MSCs*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Prabha lab is adding human cells transfected with rDNA into mice.
 - A lab inspection was not required as the lab was recently inspected.
 - 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. Prabha.
 - The Committee voted unanimously to approve the draft BUA for Dr. Prabha.

8. SUBCOMMITTEE REPORTS:

- j. Gwin, William Rayford, renewal, *A Phase II Study of Concurrent WOKVAC Vaccination with Neoadjuvant Chemotherapy and HER2-Targeted Monoclonal Antibody Therapy*
- 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 an academically sponsored, single-site, non-first-in-humans clinical trial study of a plasmid DNA vaccine for patients with HER2(+) breast cancer.
 - An rDNA vaccine 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. Gwin. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gwin.
- k. Krakow, Elizabeth F, renewal, *Phase I study of adoptive immunotherapy with CD8* and CD4* memory T cells transduced to express an HA-1- specific T cell receptor (TCR) for children and adults with recurrent acute leukemia after allogeneic hematopoietic stem cell transplantation (HCT).*
- 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 a commercially funded, single-site, first-in-humans clinical trial study for patients with relapsed acute leukemia after hematopoietic stem cell transplantation.
 - Human cells transduced with third generation lentiviral vector (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. Krakow. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Krakow.
- I. Lee, Sylvia, new, *Phase 1/2 study evaluating genetically modified autologous T cells expressing a T-cell receptor recognizing a cancer/germline antigen as monotherapy or in combination with nivolumab in patients with recurrent and/or refractory solid tumors (ACTengine® IMA203-101)*
- 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 an industry-sponsored, multi-site, first-in-human clinical trial study for patients with recurrent and/or refractory solid tumors.
 - Human cells transduced with third generation lentiviral vector (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. Lee. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lee.
- m. Psutka, Sarah, new, *An Expanded Access Program of Cretostimogene Grenadenorepvec in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG)*
- 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 clinical trial study for patients with non-muscle invasive bladder cancer.
 - A conditionally replication competent adenoviral vector study product will be administered to human study participants.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A medical management plan is in place for Cretostimogene Grenadenorepvec.
 - A member made a motion to approve the draft BUA letter for Dr. Psutka. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA and medical management plan for Dr. Psutka.
- n. Shadman, Mazyar, renewal, *A Phase I/II Study to Evaluate the Safety of Cellular Immunotherapy Using Autologous T cells Engineered to Express a CD20-Specific Chimeric Antigen Receptor for Patients with Relapsed or Refractory B-cell Non-Hodgkin Lymphomas*
- 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 an industry-supported, academically sponsored single-site, non-first-in-humans clinical trial study for a subset of lymphomas.

- Human cells transduced with third generation lentiviral vector (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. Shadman. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Shadman.
- o. Sims, Amy, new, *Evaluation of Host-Targeted Small Molecules for Antiviral Activity and Mechanistic Profiling*
- NIH Guidelines NIH Guidelines Sections III-D and III-F
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Sims lab researches test compounds for antiviral efficacy and to identify intracellular host proteins targeted by host-based antiviral compounds during Hantavirus and MERS-CoV infection of human cells.
 - The lab works with several Hantavirus strains and MERS-CoV in vitro at BSL-3. They also work with human and NHP source material and rDNA in vitro in the BSL-3 facility.
 - BSL-3 labs are inspected quarterly and not in association with BUAs/projects.
 - All required trainings are complete.
 - A medical management plan is in place for MERS-CoV, and a medical management plan is in review for Hantavirus.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Sims. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sims.

10. FOR YOUR INFORMATION:

- EH&S has submitted the following incident to the NIH for review:
 - An individual experienced a needlestick from a needle used on a mouse that had previously been administered cells transfected with rDNA. During the investigation, it was discovered that the PI had not received IBC approval for research under Section III-D to administer rDNA (including transfected cells) to mice. The root cause of the needlestick was determined to be an improperly set up workflow without a sharps container within reach. EH&S also educated the PI about when IBC approval is required.
- EH&S is investigating the following incident:
 - An individual experienced an abrasion to their finger from an NHP squeeze cage while working with an NHP previously administered recombinant SIV and an mRNA vaccine.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:16 a.m.