



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, February 19, 2025

Time: 10:00 a.m. – 12:00 p.m.

Location: Zoom

- Members Present:**
1. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 2. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 3. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 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. Jennifer Nemhauser (*Plant Expert*)

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 10:02 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 January 22, 2025, meeting.
 - A member made a motion to approve the January 22, 2025, meeting minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the January 22, 2025, meeting minutes.
4. **OLD BUSINESS:**
 - At the January 22, 2025 meeting, Dr. Erasmus's BUA was approved pending completion of the required training. This BUA is still pending.
 - At the January 22, 2025 meeting, Dr. Hofstetter's BUA was approved pending successful completion of the lab inspection. This BUA is still pending
 - At the January 22, 2025 meeting, Dr. Huang's BUA was approved pending completion of the required training. This BUA is still pending.
 - At the January 22, 2025 meeting, Dr. Lieber's BUA was approved pending successful completion of the lab inspection and submission and review of the IACUC protocol. This BUA is still pending.
 - At the January 22, 2025 meeting, Dr. Pravetoni's BUA was approved pending submission and review of the IACUC protocol. This BUA is still pending.
 - At the January 22, 2025 meeting, Dr. Gopal's BUA was approved pending completion of the required training. 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. Rieke added a new room for work with previously approved agents on the BUA *Biophysical Mechanisms of Photo Detection*.
 - Dr. Yang added a new room for work with previously approved agents on the BUA *Modeling genetic cardiomyopathies with hiPSCs*.
 - Dr. Hakimian registered a clinical trial protocol that does not involve human gene transfer or pathogenic agents in humans on the BUA *A First In-Human (FIH) Study of Inhibitory Interneurons (NRTX-1001) in Drug Resistant Unilateral Mesial Temporal Lobe Epilepsy (MTLE)*.
 - Dr. Di Stilio added work with new species of transgenic plants on the BUA *Functional Evolution of Floral Pathway Genes*. (Section III-E)
 - Dr. Pan renewed work with human source material, non-human primate NIH source material, and rDNA on the BUA *Biodemography Lab*. (Section III-F)
 - Dr. Stacey registered a clinical trial protocol that does not use biohazardous agents or gene transfer in human subjects on the BUA *A Phase 2, Open-Label, Dose Escalation Trial Assessing the Safety, Tolerability, and Treatment Effect of Bel-sar*

(AU-011) with Suprachoroidal Administration in Subjects with Choroidal Metastasis from Breast or Lung Primary Tumors.

- Dr. Murphy added work with adenoviral vectors in vivo and in vitro on the BUA *Immunity to malaria infection*. This work was approved by the IBC in June 2023 pending the addition of the agents to the IACUC protocol. The agent is now being added to the IACUC protocol.
- Dr. Gundlach registered work with a Risk Group 1 wildtype organism on the BUA *Nanopore Biophysics Lab*.
- Dr. Korvatska took over work previously overseen by Dr. Raskind on the BUA *Genetic Studies of Neurologic and Dementing Disorders; Regulatory variation that affects splicing of the Alzheimer's disease risk gene TREM2; AD-protective regulatory APOE variation in ethnically diverse populations*. (Section III-D, 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. Capozzi added new rooms for work with previously approved agents on the BUA *Glucagon-insulin Hepatic Glycogen*.
- 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. Adams Waldorf added a new room for work with previously approved agents on the BUA *Experimental Model for Chorioamnionitis and Preterm Labor*.
- Dr. Morrell initiated work with SARS-CoV-2 clinical samples and human source material on the BUA *Lung Transplant Biorepository*.
- Dr. Pham renewed work with human source material in vitro on the BUA *Sample Processing for Clinical Research Studies*.
- Dr. Marcinek added use of the Immunology Cell Analysis Facility with previously approved agents on the BUA *Assessing mitochondrial function in relation to whole animal fitness and health*.
- 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. BSL-3 INACTIVATION REPORT

- Dr. Sims requested approval for UV light treatment inactivation of MERS-CoV samples.
- The subcommittee reviewed the procedures and inactivation data provided by the lab and approved their requests.
- The IBC Chair made a motion to approve this month's BSL-3 Inactivation Report.
- The committee unanimously voted to approve this month's BSL-3 Inactivation Report.

7. DURC REPORT

- One project received renewal approval for use of botulinum neurotoxin. The project does not meet the DURC definition.
- The IBC Chair sought a motion to approve this month's DURC Report.
- A member made a motion to approve this month's DURC Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's DURC Report.

8. INDIVIDUAL PROJECT REVIEWS

- a. Barria, Andres, change, *Regulation of Glutamatergic Synapses*
 - NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Barria lab is adding work with AAV vectors with oncogenes (ROR2) in vitro.
 - 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. Barria.
 - The Committee voted unanimously to approve the draft BUA for Dr. Barria.

- b. Berg, Celeste, renewal, *Regulation of tubulogenesis in the Drosophila ovary*
 - NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Berg lab investigates mechanisms that cells used to communicate to control the growth and shape of tube formations critical to development of the fruit fly *Drosophila*.
 - The lab works with transgenic *Drosophila* fruit flies, *E. coli* K-12 strains, and rDNA.
 - 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. Berg.
 - The Committee voted unanimously to approve the draft BUA for Dr. Berg.

- c. Cornell, Robert, renewal, *Dissecting the Transcriptional Network Governing Differentiation of Periderm*
 - NIH Guidelines Sections III-D and III-F
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - The Cornell lab aims to identify members of gene regulatory network involved in orofacial development to study increased risk of orofacial clefts as well as investigating regulatory networks controlling melanocyte stem cell development.
 - The lab works with human cells at BSL-2 and with transgenic zebrafish, *E. coli* and rDNA 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. Cornell.
 - The Committee voted unanimously to approve the draft BUA for Dr. Cornell, pending submission and review of the IACUC.

- d. Duan, Zhijun, renewal, *Development of Cell Growth Switch*
 - NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Duan lab studies how the organization of the human genome is required for healthy development and what disruptions to the organization contribute to disease developing.

- The lab works with human cells and cell lines at BSL-2 and third-generation lentiviral vectors, E. coli, and mouse stem cells 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. Duan.
 - The Committee voted unanimously to approve the draft BUA for Dr. Duan, pending successful completion of the lab inspection.
- e. Fang, Ferric, renewal, *Salmonella Pathogenesis and Immunity*
- NIH Guidelines Sections III-D, III-E, and III-F
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - The Fang lab studies bacterial pathogens, their mechanisms of pathogenesis, and mammalian host response.
 - The lab works with rDNA with enhanced gene delivery, human cell lines, and RG2 wildtype and recombinant microorganisms at BSL-2. They also administer recombinant and wildtype Salmonella species and Staphylococcus aureus to mice at ABSL-2.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - There are occupational health requirements for work with Salmonella Typhi.
 - 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. Fang.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fang.
- f. Giacani, Lorenzo, renewal, *Studies on the pathogenesis of syphilis and human treponematoses*
- NIH Guidelines Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Giacani lab researches the pathogenesis of human treponematoses infections to develop effective vaccines.
 - The lab works with human source material, Borrelia burgdorferi, Treponema carateum, T. pallidum, and tetracycline-resistant strains of T. pallidum at BSL-2. Recombinant and wildtype Borrelia and Treponema species are administered to rabbits at ABSL-2.
 - The committee discussed whether the lab is planning to use the antibiotic-resistant strains of T. pallidum in rabbits. If so, occupational health needs to review to determine any occupational health requirements for animal care personnel who may handle the exposed rabbits.
 - The lab was inspected, and no deficiencies were noted.
 - All required trainings are complete.
 - A medical management plan (MMP) is in place for Treponema.
 - 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. Giacani.

- The Committee voted unanimously to approve the draft BUA for Dr. Giacani, pending clarification of whether antibiotic-resistant strains of *T. pallidum* will be used in rabbits and occupational health review if so, with one recusal.
- g. Horwitz, Greg, renewal, *Neurophysiology of Vision*
- NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Horwitz lab aims to understand the relationship between vision and electrical activity in the brain.
 - The lab works with AAV, lentiviral vectors, attenuated herpes simplex virus (HSV) vectors, avian pseudotyped rabies viral vectors, and Sindbis viral vectors in NHPs at ABSL-2. They also use viral vectors in vitro with human and NHP cells at BSL-2.
 - A discussion took place clarifying that the HSV vector is considered replication competent but is attenuated and not neurovirulent. No concerns or action items were identified.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - There are occupational health requirements for acyclovir resistant HSV strains.
 - 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. Horwitz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Horwitz.
- h. Kojima, Yoshiko, renewal, *A Neuronal Process of the Error Signal That Drives Saccade Adaptation*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Kojima lab research includes implementing optical manipulation of electrical activity in the brain by optimizing viral vectors and injection techniques in NHPs.
 - The lab works with adeno-associated viral vectors in macaques at ABSL-2.
 - 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. Kojima.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kojima, pending successful completion of the lab inspection.
- i. Sasamoto, Yuzuru, new, *Biology of ocular surface*
- NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Sasamoto lab researches ocular surface mechanisms in humans and mice and studies their maintenance.
 - The lab works with human cell lines and third generation lentiviral vectors with and without oncogenic inserts at BSL-2, and murine cell lines and *E. coli* K-12. They administer human cells transduced with third generation lentiviral vectors to mice at ABSL-2.
 - 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. Sasamoto.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sasamoto, pending successful completion of the lab inspection.
- j. Shankland, Stuart, renewal, *(Re)building Kidney (RBK) and Kidney Aging*
- NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Shankland lab studies diseases that affect podocytes by combining therapeutics to enhance the body's ability to repair and regenerate the specialized cells.
 - The lab works with human kidney cell lines and third generation lentiviral vectors with and without oncogenic inserts at BSL-2.
 - 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. Shankland.
 - The Committee voted unanimously to approve the draft BUA for Dr. Shankland.
- k. Stokes, Caleb, renewal, *Pathogenic mechanisms of flavivirus encephalitis*
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Stokes lab researches how viral infection and immune responses alter brain function to develop drugs that can prevent brain injury and reverse neuroinflammation.
 - The lab works with recombinant West Nile virus and the SA-14-14-2 vaccine strain of Japanese encephalitis virus (JEV) in mice at BSL-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 JEV vaccine.
 - 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. Stokes.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stokes.
- l. Theberge, Ashleigh, renewal, *Studying cell signaling and cell-microenvironment interactions with new analytical tools*
- NIH Guidelines Sections III-D, III-E and III-F
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - The Theberge lab studies interactions between chemicals, microbes, and host cells.
 - The lab works with wildtype RG2 bacteria, lentiviral vectors, AAV, influenza virus, human and NHP source material at BSL-2.
 - A lab inspection has been performed and is still pending a response.
 - All required trainings are complete.

- There are occupational health requirements for work with *S. pneumoniae* and Influenza virus.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Theberge.
 - The Committee voted unanimously to approve the draft BUA for Dr. Theberge, pending successful completion of the lab inspection.
- m. Zhang, Miqin, renewal, *Molecular MR Imaging of Tumors*
- NIH Guidelines Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Zhang lab investigates the biological performance of iron oxide, gadolinium, carbon-based, and liposomal nanoparticle systems in treating cancer and other diseases.
 - The lab works with ecotropic gammaretroviral vectors with oncogenic inserts, third generation lentiviral vectors with oncogenic inserts, human cells and tissues, and RG2 wildtype microorganisms at BSL-2. They also work with mouse and rat source material and *E. coli*.
 - 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. Zhang.
 - The Committee voted unanimously to approve the draft BUA for Dr. Zhang, pending submission and review of the IACUC.

9. SUBCOMMITTEE REPORTS:

- n. Colby, Lesley, renewal, *Department of Comparative Medicine SLU 3.1 BSL3/ABSL3 Facility*
- NIH Guidelines Sections III-D
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a renewal of a core approval for the SLU 3.1 BSL-3/ABSL-3 where research is performed with biological agents requiring BSL-3 or ABSL-3, including select agents. Individual investigators are required to obtain their own BUA approval for their research.
 - The BSL-3 facility is inspected quarterly.
 - All required trainings are complete.
 - A medical management plan is established for each biological agent that requires BSL-3 containment approved under an investigator's individual BUA.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Colby. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Colby, with one recusal.
- o. Hall, Evan, renewal, *An Open-Label, Multicenter, Phase 1/2 Study of RP1 as a Single Agent and in Combination with PD1 Blockade in Patients with Solid Tumors*

- 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, multicenter phase 1/2 open-label study of RP1 as monotherapy and in combination with nivolumab to treat cancer patients with solid tumors.
 - Oncolytic recombinant HSV-1 is administered to human study participants.
 - All required trainings are complete.
 - A medical management plan is in place for work with RP1.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Hall. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hall.
- p. Lee, Scott, new, *A Phase 1/2a, Open Label, Dose Escalation Study to Evaluate the Safety and Preliminary Efficacy of TRX103 in Subjects with Moderate to Severe Treatment-Refractory Crohn's Disease*
- 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 company-sponsored, multi-site, first-in-humans, dose escalation, non-placebo-controlled trial of allogeneic adoptive cell therapy for Crohn's disease.
 - Human cells transduced with third generation lentiviral vectors are 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.
- q. Lee, Sylvia, new, *A prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator's choice of treatment in patients with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301)*
- 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, non-placebo-controlled, non-first-in-humans, multi-site clinical trial of autologous TCR-transduced T-cell therapy for melanoma.
 - Human cells transduced with third generation lentiviral vectors are administered to human study participants.
 - The required trainings are still pending.
 - 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, pending completion of required trainings.

- r. Sims, Amy, renewal, *Venezuelan Equine Encephalitis As a Vector for Heterologous Gene Expression*
- NIH Guidelines 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 Sims lab investigates host response to wildtype and attenuated virus strains of Venezuelan equine encephalitis virus and viral protein expression using virus strains.
 - The lab works with select agent and RG 3 subtypes of VEEV at BSL-3, select agent excluded RG 2 VEEV strains at BSL-2, and human and non-human primate source material at BSL-2.
 - Work with VEEV subtypes IAB and IC and its RNA is regulated by the Federal Select Agent Program (FSAP). FSAP approval has been obtained.
 - 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 VEEV.
 - 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 with one recusal.
- s. Wuliji, Natalie, new, *The CALiPSO-1 Study: A Study of CNTY-101, a CD19-targeted CAR iNK Cell Product, in Participants with Refractory B cell-mediated Autoimmune Diseases*
- 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 of an allogeneic cell product CNTY-101, designed to cause B cell depletion and remission of antibody-associated autoimmune diseases in patients.
 - Human cells transfected with rDNA are 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. Wuliji. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wuliji.

10. FOR YOUR INFORMATION: No updates.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:59 a.m.