



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, January 18, 2023

Time: 10:00 AM – 12:00 PM

Location: Zoom

- Members Present:**
1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
 2. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 3. Jason Cantera (*Community Member*)
 4. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 5. Richard Grant, Washington National Primate Research Center
 6. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 7. David Koelle, Allergy and Infectious Diseases
 8. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 9. Susan Parazzoli (*Community Member*)
 10. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
 11. Elyse Verstelle, Department of Immunology (*Laboratory Specialist*)

Commonly Used Abbreviations

IBC: Institutional Biosafety Committee

BSO: Biological Safety Officer

BUA: Biological Use Authorization

BSL: biosafety level

PI: Principal Investigator

IACUC: Institutional Animal Care and Use Committee

NHP: Non-human Primate

NIH: National Institutes of Health

DURC: Dual Use Research of Concern

1. **CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:01 a.m. A quorum was present.
2. **REMINDER:** The IBC Chair reminded attendees that any notes that they retain are subject to public disclosure. A statement was also made about conflict of interest and voting on research proposals as described in the IBC Charter. This includes sharing a grant or a familial relationship.
3. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the December 14, 2022, meeting.
 - A member made a motion to approve the December 14, 2022, minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the December 14, 2022, meeting minutes, with one member abstaining.
4. **OLD BUSINESS:**
 - At the December 14, 2022, meeting, Dr. Ailion's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the December 14, 2022, meeting, Dr. Grant's BUA was approved pending the addition of wildtype agent to the BUA letter. This BUA has been sent out.
 - At the December 14, 2022, meeting, Dr. Johnsen's BUA was approved pending one correction to the to the BUA letter. This BUA has been sent out.
 - At the December 14, 2022, meeting, Dr. Paik's BUA was approved pending one update to the to the BUA letter. This BUA has been sent out.
5. **BIOSAFETY OFFICER (BSO) REPORT:** The Biosafety Officer Report includes (1) projects involving recombinant or synthetic nucleic acids covered under section III-E and III-F of the *NIH Guidelines*, (2) proposals involving non-recombinant biohazardous agents requiring BSL-1 and BSL-2 containment, and (3) administrative updates, such as room additions.
 - a. Biosafety Officer Report
 - Dr. Armbrust registered in vitro work with environmental strains of bacteria to the project *PCR Products (NIH Guidelines Section III-F or N/A)*. This work does not require a BUA.
 - Dr. Kelly registered work characterizing DNA from the environment to the project *Kelly Lab Environmental DNA Analysis (NIH Guidelines Section III-F or N/A)*. This work does not require a BUA.
 - Dr. Morris registered work with environmental strains of bacteria on the project *Marine Bacteria (NIH Guidelines Section III-F or N/A)*. This work does not require a BUA.
 - Dr. Rocab registered work characterizing marine microbes to the project *Genetic and functional diversity of marine microbes (NIH Guidelines Section III-F)*. This work does not require a BUA.
 - Dr. Murphy removed a previously approved room to the BUA *Immunity to malaria infection (NIH Guidelines Section N/A)*.
 - Dr. Kanabolo was approved for work in vitro with human blood, tissue, body fluids, and cells lines on the project *Assessment of Urostomy Parastomal Herniation Forces and Prevention Strategies (NIH Guidelines Section N/A)*.

- Dr. Liu renewed the BUA *Cytogenomic microarray analysis* working with human blood, tissue, body fluids, cell lines, and non-viral recombinant or synthetic DNA/RNA, in-vitro (*NIH Guidelines* Section III-F or N/A).
- Dr. Cornell added new rooms for work with previously approved agents to the BUA *Dissecting the Transcriptional Network Governing Differentiation of Periderm* (*NIH Guidelines* Section N/A).
- Dr. Gundlach was approved for in vitro work with non-pathogenic strains of *Escherichia coli* and non-viral recombinant or synthetic DNA/RNA on the BUA *Nanopore Biophysics Lab* (*NIH Guidelines* Section III-E and III-F).
- Dr. Hyde moved previously approved agents from one approved room to a new room on the BUA *Pathogenesis studies of alphaviruses and +ssRNA viruses* (*NIH Guidelines* Section N/A).
- The IBC Chair made a motion to approve this month's Biosafety Officer Report.
- A member made a motion to approve this month's Biosafety Officer Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's Biosafety Officer Report.

6. INDIVIDUAL PROJECT REVIEWS

- a. Akamatsu, Matthew, new, *Biomechanical forces in the actin cytoskeleton in cellular membrane bending and trafficking processes*
 - *NIH Guidelines* Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Akamatsu lab aims to understand the mechanical relationship between the actin cytoskeleton and mammalian endocytosis.
 - This lab includes work with adeno-associated viral vectors, lentiviral vectors, and non-pathogenic *E. coli* strains in vitro.
 - 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. Akamatsu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Akamatsu pending successful completion of the lab inspection. One member did not vote.
- b. Berndt, Andre, renewal, *Screening and engineering of fluorescent biosensors*
 - *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Berndt lab aims to engineer fluorescent proteins and sensors that detect the activity of ions, neurotransmitters, neuromodulators, hormones and intracellular signaling molecules.
 - This lab includes work with adeno-associated viral vectors including ones with oncogenic inserts, lentiviral vectors, and non-pathogenic *E. coli* strains. They also work with human induced pluripotent stem cell lines and non-viral recombinant or synthetic DNA/RNA with enhanced gene delivery methods. All work is in vitro.
 - 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. Berndt. The Committee voted unanimously to approve the draft BUA for Dr. Berndt.
- c. Carroll, Jeff, new, *ATN1-lowering Studies in a Novel Mouse Model of DRPLA*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Carroll lab will be treating a novel humanized mouse model of dentatorubral-pallidoluysian atrophy (DRPLA) with experimental drugs and assessing the impact this has on a range of disease-relevant symptoms in the mice.
 - This lab works with non-viral recombinant or synthetic DNA/RNA with enhanced gene delivery methods in mice as well as in vitro. They also work with non-pathogenic strains of *E. coli*.
 - The lab inspection will be 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. Carroll. The Committee voted unanimously to approve the draft BUA for Dr. Carroll pending successful completion of the lab inspection. One member did not vote.
- d. Corey, Eva, change, *Pre-Clinical Models, Mechanisms, and Markers of Prostate Cancer and Prostate Cancer Metastasis*
- *NIH Guidelines* Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Corey lab is adding the use of siRNA with enhanced gene delivery methods for in vivo work at ABSL-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. Corey. The Committee voted unanimously to approve the draft BUA for Dr. Corey.
- e. Hansen, John, renewal, *IL-26 Immunity*
- *NIH Guidelines* Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Hansen lab aims to use zebrafish as a model organism to study the function and assess the role of IL-26 (cytokine produced by cells of the immune system in humans) in host immunity to microorganisms.
 - This research includes working with a fish pathogen that could cause opportunistic infections in humans.
 - A lab inspection has been performed and is still pending a response.
 - The 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. Hansen. The Committee voted unanimously to approve the draft BUA for Dr. Hansen, pending successful completion of a lab inspection response, with one member recused from the vote and one member not voting.
- f. Horwitz, Marshall, renewal, *Genetics of Hematopoietic Malignancy*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The aim of the Horwitz lab is to investigate the molecular genetic basis for why some people are genetically predisposed to develop bone marrow failure and or bone marrow cancers.
 - This research includes working with gammaretroviral vectors, lentiviral vectors, and human cells transduced with Sendai viral vectors with oncogenes. They also work with non-pathogenic strains of E. coli and recombinant DNA with and without enhanced gene delivery methods. All work is in vitro.
 - 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. Horwitz. The Committee voted unanimously to approve the draft BUA for Dr. Horwitz, pending successful completion of a lab inspection response.
- g. Jayadev, Suman, renewal, *Inflammatory Mediators of Neurodegeneration*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Jayadev lab aims to include the characterization of inflammatory and/or neurodegenerative mechanisms that contribute to dementia.
 - This research includes in vitro work handling human induced pluripotent stem cells, lentiviral vectors, and recombinant or synthetic non-viral DNA/RNA with enhanced gene delivery methods. Additionally, the in vitro work includes murine cells transduced with foamy viral vectors or lentiviral vectors.
 - 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. Jayadev.
 - The Committee voted unanimously to approve the draft BUA for Dr. Jayadev pending successful completion of a lab inspection.
- h. Johnson Erickson, Danielle, renewal, *Predicting Therapy Response*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Johnson Erickson lab aims to develop improved protocols for the clinical treatment of cancer patients who receive x-ray, proton, or neutron treatments.
 - This work includes in vivo work with mice and rats and handling of human blood and tissue samples.
 - 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. Johnson Erickson.
 - The Committee voted unanimously to approve the draft BUA for Dr. Johnson Erickson pending successful completion of a lab inspection response, with one member not voting.
- i. Kong, Jennifer, new, *Signaling pathways in the context of development, disease, and regeneration*
- *NIH Guidelines* Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Kong lab aims to identify regulatory components of highly conserved signaling pathways and better understand the role of these regulatory components in embryonic development and adult regeneration.
 - This lab does in vitro work using third generation lentiviral vectors, non-viral recombinant or synthetic DNA/RNA, and non-pathogenic strains of E. coli.
 - 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. Kong.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kong, with two members not voting.
- j. Ligabue, Alessio, renewal, *Develop of new method to purify/enrich sub population of human cells*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Ligabue lab aims to develop new methods to purify and/or enrich human cell sub-types, specifically human leukocytes (white blood cells).
 - This lab does in vitro work using adeno-associated viral vectors, lentiviral vectors, non-viral recombinant or synthetic DNA/RNA with and without enhanced gene delivery methods, and non-pathogenic strains of E. coli.
 - 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. Ligabue.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ligabue.
- k. Mougous, Joseph, change, *Type VI secretion-dependent interbacterial interactions*
- *NIH Guidelines* Sections III-D and III-E
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Mougous lab is adding the use of recombinant and wild-type bacteria to previously approved rooms.
 - 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. Mougous.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mougous.
- I. Mullins, James, renewal, *HIV-1 and Host Cell Changes in Disease Progression*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Mullins lab aims to investigate virus-host interactions during HIV-1, SIV, or SHIV infection to gain insight into the design of more effective therapeutic strategies and vaccines.
 - This research includes in vitro work using primate lentivirus, non-viral recombinant or synthetic DNA/RNA with and without enhanced gene delivery methods, and non-pathogenic strains of *E. coli*.
 - 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. Mullins.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mullins.
- m. Reniere, Michelle, renewal, *Redox regulation and virulence in bacterial pathogens*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Reniere lab aims is to investigate virulence regulation in *Listeria monocytogenes* and *Staphylococcus aureus* in response to changing conditions.
 - This research includes in vitro and in vivo work in mice with *Listeria monocytogenes* and in vitro work with *Staphylococcus aureus*, lentiviral vectors, non-viral recombinant or synthetic DNA/RNA with and without enhanced gene delivery methods, and non-pathogenic strains of *E. coli*.
 - A discussion occurred regarding a tumor suppressor gene insert on the lentiviral vectors. If the tumor suppressor is being knocked down, the biosafety level for work with that lentiviral vector will need to be increased.
 - 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. Reniere.
 - The Committee voted unanimously to approve the draft BUA for Dr. Reniere pending clarification of the tumor suppressor gene insert.
- n. Seelig, Georg, renewal, *Seelig lab for synthetic biology*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Seelig lab aims to understand how biological organisms process information using complex biochemical networks and how such networks can be engineered to program cellular behavior.

- This research includes in vitro work using adeno-associated viral vectors, lentiviral vectors, non-viral recombinant or synthetic DNA/RNA with or without enhanced gene delivery methods, and non-pathogenic strains of E. coli.
 - 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. Seelig.
 - The Committee voted unanimously to approve the draft BUA for Dr. Seelig pending a response to the lab inspection.
- o. Sellers, Drew, renewal, *Stem Cells and Regeneration of the Spinal Cord*
- *NIH Guidelines* Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Sellers lab aims to understand the genetic programs that allow axons to re-grow in an injury environment and the plasticity exhibited by stem cells and oligodendrocytes to reprogram plasticity and functional regeneration.
 - This research includes using human induced pluripotent stem (iPS) cells, gammaretroviral vectors, adeno-associated viral vectors, and lentiviral vectors, both in vitro and in vivo in mice.
 - 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. Sellers.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sellers pending clarification of tumor suppressor gene insert, if recombinant DNA will be used in mice, and successful completion of a lab inspection response.
- p. Soge, Olusegun, renewal, *Horizontal Gene Transfer in Chlamydia*
- *NIH Guidelines* Sections III-A, III-D, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Soge lab is interested in collaborative research conducting lateral gene transfer of the tetC gene from tetracycline resistant strains of *Chlamydia suis* to strains of *Chlamydia trachomatis* through recombination techniques.
 - This research includes in vitro work with several *Chlamydia* strains including *Chlamydia trachomatis*, TetRCT at BSL-2 with BSL-3 practices.
 - The lab inspection is scheduled for after the IBC meeting.
 - All required trainings are complete.
 - A medical management plan is in place for tetracycline resistant strains of *Chlamydia trachomatis*.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Soge.
 - The Committee voted unanimously to approve the draft BUA for Dr. Soge pending completion of a successful lab inspection.

7. SUBCOMMITTEE REPORTS:

- q. King, Gentry (George Teng), new, *A Phase 1/2 open-label study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity of OTX-2002 as a single agent and in combination with standard of care in patients with hepatocellular carcinoma and other solid tumor types known for association with the MYC oncogene (MYCELANGELO I)*
- NIH Guidelines Section III-C
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a new application for an industry-sponsored (Omega Therapeutics), two-center, phase 1/2, open-label trial of OTX-2002 for HCC and other solid cancers.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. King. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. King.
- r. Maloney, David, new, *A Phase 2 study of PHE885, B-cell maturation Antigen (BCMA)-directed CAR-T Cells in adult participants with relapsed and refractory multiple myeloma.*
- NIH Guidelines Section III-C
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a new application for an industry-sponsored (Novartis), single-arm, phase 2 study to examine the efficacy of PHE885 for relapsed/refractory multiple myeloma.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Maloney. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Maloney.
- s. Zhen, David, new, *A Phase 1, Open-Label, Dose Escalation and Expansion, Multicenter Study of Claudin 18.2-Targeted Chimeric Antigen Receptor T-cells in Subjects with Unresectable, Locally Advanced, or Metastatic Gastric, Gastroesophageal Junction (GEJ), Esophageal, or Pancreatic Adenocarcinoma*
- NIH Guidelines Section III-C
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a new application for an industry-sponsored (Legend Biotech), multi-center, phase 1, open-label trial of Claudin-targeted CAR-T therapy (LB1908) for patients with advanced/metastatic GI cancers.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Zhen. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Zhen.

10. FOR YOUR INFORMATION:

- **NIH Incident Reports:**
 - The NIH has responded that no further information or action was required for recent incidents involving:
 - A bite from a rat previously exposed to AAV during a routine cage change at ABSL-1.
 - A needlestick from a needle used with a NHP previously exposed to a gutless adenoviral vector at BSL-2.
 - A potential splash to the eye of blood from a mouse previously exposed to recombinant Risk Group 1 mouse plasmodium that is non-infectious to humans at ABSL-1.
 - The following incidents have been submitted to the NIH or are currently being investigated:
 - An incident involving a needlestick from a needle potentially contaminated with recombinant *Listeria monocytogenes*.
 - An incident involving a sharps injury from a stylet that had been used to collect cerebrospinal fluid from an NHP previously exposed to SIV.
 - An incident involving a scratch from an NHP previously exposed to SHIV while distributing food treats.
 - An incident involving a needlestick from a needle that may have been contaminated with human cells transduced with third generation lentiviral vectors (non-HIV pseudotyped, replication deficient) with oncogenic inserts.

11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS: A reminder was made to maintain appropriate housekeeping of records.

12. MEETING ADJOURNED AT APPROXIMATELY 11:38 A.M.