



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, December 11, 2024

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. Jennifer Iwamoto, Office of Animal Welfare (*Animal Containment Expert*)
 8. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 9. Scott Meschke, Environmental & Occupational Health Sciences
 10. Jennifer Nemhauser, Biology (*Plant Expert*)
 11. Susan Parazzoli (*Community Member*)
 12. Jason Smith, Microbiology (*IBC Chair*)
 13. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)

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 10:00 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 November 13, 2024, meeting.
 - A member made a motion to approve the November 13, 2024, meeting minutes. Another member seconded the motion.
 - The committee voted to approve the November 13, 2024, meeting minutes with two abstentions.
4. **OLD BUSINESS:**
 - At the November 13, 2024 meeting, Dr. Basso's BUA was approved pending submission and review of the IACUC protocol. This BUA is still pending.
 - At the November 13, 2024 meeting, Dr. Basso's BUA was approved pending submission and review of the IACUC protocol. This BUA is still pending.
 - At the November 13, 2024 meeting, Dr. Fuller's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the November 13, 2024 meeting, Dr. Keene's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the November 13, 2024 meeting, Dr. Nghiem's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the November 13, 2024 meeting, Dr. Pun's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the November 13, 2024 meeting, Dr. Grivas's BUA was approved pending completion of the required trainings. This BUA has been sent.
 - At the November 13, 2024 meeting, Dr. Harris's BUA was approved pending completion of the required trainings. This BUA has been sent.
 - At the November 13, 2024 meeting, Dr. Hyde's BUA was approved pending successful completion of the lab inspection and edits to the BUA application. 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. Hotchkiss added new oncogenic gene inserts with previously approved lentiviral vectors in NHPs on the BUA *Umoja: Lentiviral Vectors in NHP*. (Section III-D)
 - Dr. Pravetoni added work with mRNA with lipids *in vitro* on the BUA *Expression of recombinant monoclonal antibodies*. (Section III-E)
 - Dr. Mu added work with mouse cells transduced with third generation lentiviral vectors and added a room on the BUA *Combination therapeutic nanoparticles for enhanced cancer treatment*. (Sections III-E and III-F)
 - Dr. Fuller added work with previously approved agents in new spaces the BUA *Vaccines and minibinders against global health threats*. (Section III-D)

- Dr. Sniadecki removed a room from their BUA *Cell therapy in mice and rats*.
- Dr. Fuhrmeister added work with previously approved agents in a core facility on the BUA *Environmental Reservoirs of Enteric Pathogens and Antimicrobial Resistance*.
- Dr. Hawn added work with wild-type Mycobacterium abscessus in vitro at BSL-2 on the BUA *Innate Immunity and Susceptibility to Infectious Disease*.
- Dr. Greninger registered work with additional wild-type HPAI H5 clinical isolates covered on existing BUA *Isolation, propagation, and characterization of clinically relevant human viral pathogens*.
- Dr. Moreno added work with previously approved agents in a core facility on the BUA *Mechanisms of Aging*.
- Dr. Nemhauser renewed work with transgenic plants, E. coli and rDNA on the BUA *Manipulation and Dissection of Growth Control Networks*. (Sections III-E and III-F)
- Dr. Asbury was approved for work with E. coli, rDNA and yeast on the BUA *Kinetochore reconstitution*. (Sections III-E and III-F)
- Dr. Khaledi renewed work with human source material including cells transduced with AAV at BSL-2 on the BUA *Analysis of Human and Mammalian Tissue and Blood Samples for Lysosomal Storage Diseases*. (Section III-E)
- Dr. Rashidi registered work with storing human clinical samples on the BUA *FMT to prevent acute GVHD*.
- Dr. Reed renewed work with human source material at BSL-2, and rDNA on the BUA *Extracellular Matrix in Aging*. (Section III-F)
- Dr. Singh was approved for work with human source material in vitro at BSL-2 on the BUA *COPE -COVID19 Outcomes in Physical Health*.
- Dr. Schindler registered work with mouse stool on the BUA *Exploring the Role of the Gut Microbiome in Blast Polytrauma*.
- 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 voted to approve this month's Biosafety Officer Report with one recusal.

6. 2024 UPDATES TO UW BIOHAZARDOUS WASTE MANAGEMENT PLAN

- An EHS Biosafety Officer presented annual updates to the UW Biohazardous Waste Management Plan.
- A committee member suggested to add a description of "yellow" for trace chemo waste containers.
- The IBC Chair made a motion to approve the 2024 Updates to UW Biohazardous Waste Management Plan.
- The committee voted unanimously to approve the updates to the waste plan.

7. INDIVIDUAL PROJECT REVIEWS

- a. Altemeier, William, change, *Inflammation, injury and resolution in lung pathobiology*
 - NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Altemeier lab is adding the use of recombinant nucleic acids in mice.

- The lab is adding work with non-viral rDNA in mice at ABSL-1 with enhanced gene delivery methods.
 - 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. Altemeier.
 - The Committee voted unanimously to approve the draft BUA for Dr. Altemeier.
- b. den Hartigh, Laura, renewal, *Inflammation, Obesity and Atherosclerosis***
- NIH Guidelines Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The den Hartigh lab researches how lipids and hormones change during disease states by using AAV to study how they impact metabolic diseases.
 - The lab works with AAV, rDNA, and a variety of wildtype RG1 bacteria in mice at ABSL-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. den Hartigh.
 - The Committee voted unanimously to approve the draft BUA for Dr. den Hartigh.
- c. Disis, Mary, renewal, *Evaluation of Immunity to Cancer in a Rodent Model***
- NIH Guidelines Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Disis lab aims to develop diagnostic, preventative, and treatment strategies to combat cancer by researching nucleic acid vaccines, mouse and human cell cultures and third generation lentiviral vectors.
 - The lab works with third generation lentiviral vectors, human source material, and RG2 bacteria in vitro and in mice at BSL-2.
 - A lab inspection was not required as the lab was recently inspected.
 - All required trainings are complete.
 - There are occupational health requirements for work with *Streptococcus pneumoniae*.
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. Disis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis.
- d. Greninger, Alex, change, *Discovery and Characterization of Pathogen-Host Interactions and Determination of Antiviral Drug Resistance***
- NIH Guidelines Sections III-D.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Greninger lab deploys a variety of next generation sequencing to address questions regarding viral evolution in different contexts and pathogen evolution.

- The lab is adding work with recombinant Nyavirus somateriae (also called Jeremy Point virus) 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. Greninger.
 - The Committee voted unanimously to approve the draft BUA for Dr. Greninger.
- e. Neidig, Lauren, new, *Vet Services Large Animal Surgery Core*
- NIH Guidelines Sections III-D.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Neidig lab studies a new vaccine device to deliver vaccines intradermally using pig models.
 - The lab works with rDNA in pigs.
 - 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. Neidig.
 - The Committee voted unanimously to approve the draft BUA for Dr. Neidig.
- f. Orsborn, Amy, renewal, *Adaptive neural interfaces for treating neurological disorders and probing neural function*
- NIH Guidelines Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Orsborn lab develops neural interfaces to restore sensorimotor function in NHPs by using viral vectors to deliver promoters and genes.
 - The lab works with lentiviral vectors and AAV in NHPs and in vitro at BSL-2.
 - The lab inspection is scheduled for after the IBC meeting.
 - 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. Orsborn.
 - The Committee voted unanimously to approve the draft BUA for Dr. Orsborn, pending successful completion of the lab inspection.
- g. Prabha, Swayam, new, *Targeting Solid Tumors Using Nano-Engineered MSCs*
- NIH Guidelines Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Prabha lab researches antitumor efficacy of new constructs of mesenchymal stem cells (MSCs) and modified nanoparticles in lung and ovarian tumor models.
 - The lab works with human cells transduced with first- or second-generation lentiviral vectors in mice and in vitro at BSL-2, and enhanced gene delivery methods in vitro and in mice
 - 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. Prabha.
 - The Committee voted unanimously to approve the draft BUA for Dr. Prabha, pending successful completion of the lab inspection.
- h. Queitsch, Christine, renewal, *Genomics and synthetic biology*
- NIH Guidelines Sections III-D, III-E, and III-F
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - The Queitsch lab studies the genomes of yeast, flies, human cells, and plants to understand the causes of human diseases.
 - The lab works with transgenic plants and fruit flies at BSL-1.
 - The lab inspection is scheduled for after the IBC meeting.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - The IBC Secondary Reviewer made a motion to approve the draft BUA for Dr. Queitsch.
 - The Committee voted unanimously to approve the draft BUA for Dr. Queitsch, pending successful completion of the lab inspection.
- i. Regnier, Michael, renewal, *Rodent Striated Muscle*
- NIH Guidelines Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Regnier lab studies ways to support cardiac muscle contractility using human, mouse, and rat cell lines.
 - The lab works with human source materials and AAV with oncogenic inserts in mice and rats at ABSL-2. The lab also works with adenoviral vectors in vitro at BSL-2.
 - 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. Regnier.
 - The Committee voted unanimously to approve the draft BUA for Dr. Regnier, pending successful completion of the lab inspection.
- j. Shih, Han-Wei, new, *Cell and Developmental Biology of Giardia lamblia*
- NIH Guidelines Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Shih lab studies cell signaling in *Giardia lamblia* focused on regulation of cytoskeleton and development into resting cysts.
 - The lab works with *Giardia lamblia* at BSL-2 and *E. coli* K-12 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. Shih.
 - The Committee voted unanimously to approve the draft BUA for Dr. Shih, pending successful completion of the lab inspection.
- k. Sidorova, Julia, new, *Subcellular localization of STING protein*
- NIH Guidelines Sections III-D, III-E, and III-F

- The assigned IBC Primary Reviewer presented the Primary Review.
 - The Sidorova lab studies the STING protein that broadcasts an emergency response signal to the cell if a virus has entered or if its genome has been damaged.
 - The lab works with human source material at BSL-2 and third generation lentiviral vectors 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. Sidorova.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sidorova.
- I. Ting, Jonathan, renewal, *Gene Therapy Vectors in NHP*
- NIH Guidelines Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Ting lab studies vectors for delivering therapies to the brain with AAV vectors and rDNA.
 - The lab uses AAV in NHPs.
 - 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. Ting.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ting.
- m. Weil, Ana, change, *Isolation of gut microbes from human stool/vomit, testing bacteria for pathogen interactions*
- NIH Guidelines Sections III-D, III-E
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab is adding recombinant strains of RG2 species of Bacteroides at BSL-2 and lab strains of E. coli and recombinant RG1 organisms at BSL-1.
 - 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. Weil.
 - The Committee voted unanimously to approve the draft BUA for Dr. Weil.
- n. Woodward, Joshua, renewal, *Staphylococcus aureus and Pseudomonas aeruginosa pathogenesis and host response*
- NIH Guidelines Sections III-D, III-E, and II-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Woodward lab researches the pathogenesis of various bacterial pathogens through in vitro and in vivo models.
 - The lab works with lentiviral and gammaretroviral vectors and human source material at BSL-2. They also work with Listeria monocytogenes, Pseudomonas aeruginosa, and Staphylococcus aureus in vitro and in mice at BSL-2.
 - 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. Woodward.
- The Committee voted unanimously to approve the draft BUA for Dr. Woodward.

8. SUBCOMMITTEE REPORTS:

- o. Disis, Mary, renewal, 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 Triple Negative Breast Cancer
 - NIH Guidelines Sections III-C, III-F
 - Two members of the IBC served as the Subcommittee Reviewers. Neither were in attendance; another IBC member presented the review.
 - This is a multicenter, phase II clinical trial using STEMVAC vaccines to stimulate Th1 immunity through Th1 epitopes to treat patients with triple negative breast cancer.
 - A plasmid-based vaccine is administered to 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. Disis. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis
- p. Fong, Larry, new, *A Phase 2, Randomized, Double-blind, Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab in the Adjuvant Treatment of Participants With Renal Cell Carcinoma*
 - NIH Guidelines Sections III-C
 - Two members of the IBC served as the Subcommittee Reviewers. Neither were in attendance; another IBC member presented the review.
 - This is a company sponsored, multicenter, phase II trial of a personalized neoepitope mRNA vaccine for renal cell carcinoma.
 - The lab prepares and administers an mRNA vaccine to 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. Fong. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fong.
- q. Vinayak, Shaveta, renewal, *A Phase II Randomized Study of Safety and Efficacy of a Multiple Antigen Vaccine (STEMVAC) in Non-Small-Cell Lung Cancer Patients*
 - NIH Guidelines Sections III-C
 - Two members of the IBC served as the Subcommittee Reviewers. Neither were in attendance; another IBC member presented the review.
 - This is a multicenter, phase II clinical trial using STEMVAC vaccines to stimulate Th1 immunity through Th1 epitopes to treat non-small-cell lung cancer patients.
 - A plasmid-based vaccine is administered to 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. Vinayak. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Vinayak.

10. FOR YOUR INFORMATION:

- The NIH has responded that no further information was required for a recent rDNA exposure involving a needlestick from a needle used with NHP that was exposed to recombinant simian-human immunodeficiency virus (SHIV), non-human primate cells transduced with third generation lentiviral vectors, and mRNA in lipid nanoparticles.
- EH&S is investigating the following rDNA incident and is preparing a report to submit to the NIH: There was a needlestick involving a needle used to pin a mouse carcass for tissue excision. The mouse had been experimentally infected with an attenuated recombinant strain of *Vibrio parahaemolyticus*. The employee washed the injury site for 15 minutes and has consulted with the UW Employee Health Center (EHC) for follow-up care and monitoring.
- EH&S is investigating the following rDNA incident and is preparing a report to submit to the NIH: There was a splash to the eye of urine from a rabbit that was experimentally exposed to an attenuated recombinant strain of *Treponema pallidum*. The employee washed at an eyewash for 15 minutes and has consulted with the UW Employee Health Center (EHC) for follow-up care and monitoring.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:36 a.m.