INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, August 21, 2024
Time: 10:00 a.m. – 12:00 p.m.

Location: Zoom

Members Present:

1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
2. Jason Cantera *(Community Member)*
3. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
4. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
5. Erin Heiniger, Department of Bioengineering *(Laboratory Specialist*)
6. Richard Grant, Washington National Primate Research Center
7. Kevin Hybiske, Allergy and Infectious Diseases *(IBC Vice Chair)*
8. Stephen Libby, Laboratory Medicine *(Animal Containment Expert)*
9. Scott Meschke, Environmental & Occupational Health Sciences
10. Susan Parazzoli *(Community Member)*
11. Jason Smith, Microbiology (*IBC Chair*)
12. 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 10:01 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 July 17, 2024, meeting.
   - A member made a motion to approve the July 17, 2024, meeting minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the July 17, 2024, meeting minutes.

4. **OLD BUSINESS:**
   - At the July 17, 2024 meeting, Dr. Cirulli's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
   - At the July 17, 2024, meeting, Dr. Davis's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
   - At the July 17, 2024, meeting, Dr. de la Iglesia's BUA was approved pending a response to the lab inspection. This BUA has been sent.
   - At the July 17, 2024, meeting, Dr. del Alamos's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the July 17, 2024, meeting, Dr. Perkel's BUA was approved pending a response to the lab inspection. This BUA is still pending.
   - At the July 17, 2024, meeting, Dr. Rasmussen's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the July 17, 2024, meeting, Dr. Andersons's BUA was approved pending successful completion of the lab inspection and occupational health review. This BUA has been sent.
   - At the July 17, 2024, meeting, Dr. Freedman's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the July 17, 2024, meeting, Dr. Polyak's BUA was approved pending addition of the respiratory protection requirement to the BUA letter. 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. Perlmutter added new rooms for in vitro work with previously approved agents and registered new gene inserts to the BUA *Neural Plasticity for Learning and Rehabilitation.*
      - Dr. Smith added new wildtype strains of influenza virus A for in vitro work on the BUA *Antiviral Mechanisms of Defensins*.
      - Dr. Beliveau added previously approved agents to approved laboratory rooms on the BUA *Probing the dynamics of chromosome organization in single cells*.
      - Dr. Rayner started a new project with human source material and rDNA on the new BUA *Hemodynamic Contributions to Vascular Dysfunction in Pulmonary Arterial Hypertension.* (Section III-F)

- Dr. Savan transferred agents and rooms from Dr. Gale's BUA, including many Risk Group 2 microorganisms, to his existing BUA *Innate immune responses to virus infections*.
- Dr. Chamberlain added use of a core facility with previously approved agents to the BUA *Gene Therapy for Neuromuscular Disorders*.
- Dr. Robinson renewed work with human source material at BSL-2 on the BUA *Sample Processing for Clinical Research Studies*.
- Dr. Unadkat added a new room for work with human source material at BSL-2 on the BUA *Mechanisms of drug disposition*.
- Dr. Ratner renewed work with human source material at BSL-2 on the BUA *Ratner Biomaterials*.
- 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 voted to approve this month's Biosafety Officer Report, with one member recusing themselves from the vote.

6. BSL-3 INACTIVATION REPORT

- Dr. Greninger requested approval for three inactivation protocols for samples containing Mpox: heat inactivation, nucleic acid extraction buffer inactivation, and inactivation by fixatives.
- 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 voted unanimously to approve this month's BSL-3 Inactivation Report.

7. FOR YOUR INFORMATION: A short presentation was given about new federal regulatory oversight for purchasing of synthetic nucleic acids and associated equipment.

8. INDIVIDUAL PROJECT REVIEWS

a. Abitua, Philip, renewal, *Abitua: General Research*

- Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Abitua lab studies the evolution of developmental novelties by comparing homologous cells across distantly related spaces whose embryos have adapted to survive extreme environmental conditions.
- The lab uses rDNA and CRISPR/Cas9-mediated genome editing to create transgenic killifish and zebrafish expressing fluorescent tags for live imaging of embryos.
- 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. Abitua.
- The Committee voted unanimously to approve the draft BUA for Dr. Abitua.

b. Gale, Michael, change, The Host Response to Virus Infection/NHP Host Immunity to Zika Virus Infection

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Gale lab is transferring ongoing research from other projects onto this BUA and adding new lab rooms.
- The lab is also adding work with new recombinant mouse-adapted influenza viruses at BSL-2.
- The lab inspection is scheduled for after the IBC meeting.
- All required trainings are complete.
- There are occupational health requirements for work with influenza virus.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gale.
- The Committee voted unanimously to approve the draft BUA for Dr. Gale, pending successful completion of the lab inspection.

c. Hallstrand, Teal, renewal, *Asthma and Translational Research Core*

- Section III-D, III-E, III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Hallstrand lab studies the underlying basis of asthma using patient samples and cell culture model systems to further understand the airway epithelium and how it interacts with immune cells to regulate inflammation.
- The lab works with lentiviral vectors, respiratory syncytial virus (RSV), human rhinoviruses, and human course material at BSL-2. They also work with rDNA including enhanced gene delivery methods.
- 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. Hallstrand.
- The Committee voted unanimously to approve the draft BUA for Dr. Hallstrand.

d. Koelle, David, change, *Koelle Laboratory at UW*

- Section III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Koelle lab is adding a recombinant strain of Treponema pallidum expressing green fluorescent protein (GFP) for in vitro use at BSL-2.
- A lab inspection was not required as the lab was recently inspected.
- All required trainings are complete.
- There is a medical management plan in place for work with T. pallidum.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Koelle.
- The Committee voted unanimously to approve the draft BUA for Dr. Koelle.

e. Najafian, Behzad, renewal, *Non-invasive biomarkers and models of kidney disease*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.

- The Najafian lab strives to understand mechanisms of development and progression of kidney diseases and to identify biomarkers for monitoring such diseases using various microscopy techniques, molecular biology, and genetics.
- This lab works with human source material, third generation lentiviral vectors, E. coli K-12 strains, and rDNA with and without enhanced gene delivery methods.
- The lab was inspected, and no deficiencies were noted.
- All required trainings are complete.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Najafian.
- The Committee voted unanimously to approve the draft BUA for Dr. Najafian.

f. Paredez, Alexander, renewal, *Cell and Developmental Biology of Giardia lamblia*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Paredez lab studies cell signaling in the parasite Giardia lamblia with a focus on regulation of the cytoskeleton and development into resting cysts.
- This lab works with recombinant Giardia lamblia and wildtype Trichomonas vaginalis at BSL-2. They also work with recombinant Risk Group 1 yeast species, E. coli K-12 strains, and rDNA 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. Paredez.
- The Committee voted unanimously to approve the draft BUA for Dr. Paredez, pending a response to the lab inspection.

9. SUBCOMMITTEE REPORTS:

g. Gauthier, Jordan, new, *An Open-label, Phase 1 Safety and Phase 2 Randomized Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (017004)*

- 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, multicenter, phase 1/2 clinical trial of a CAR T cell product for chronic lymphocytic leukemia or small lymphocytic lymphoma. This application is for a re-opening of the trial to enroll a new cohort. This phase will build upon other ongoing studies to evaluate the tolerability, in vivo expansion potential, and antitumor activity of the study product.
- Patient-derived T cells will be genetically modified ex-vivo with third generation lentiviral vectors and administered back to the human subjects.
- All required trainings are complete.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Gauthier. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Gauthier.

h. Greninger, Alex, renewal, *Discovery and Characterization of Virus-Host Interactions and Determination of Antiviral Drug Resistance*

- Section III-D, III-E, and III-F
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The primary goals of this Greninger research project are to improve understanding of human pathogens using a variety of approaches that focus on pathogen-host interactions, antimicrobial resistance, pathogen and host evolution and drivers of pathogen pathogenesis.
- The lab works with human immunodeficiency virus types 1 and 2 (HIV-1, HIV-2), human T-lymphotropic virus type 1 (HTLV-1), and simian immunodeficiency virus (SIV) at BSL-2 with BSL-3 practices. They work with many recombinant and wildtype Risk Group 2 microorganisms at BSL-2, including herpes simplex viruses, influenza viruses, measles virus, RSV, and Treponema pallidum.
- The lab inspection is scheduled for after the IBC meeting.
- All required trainings are complete.
- There are occupational health requirements in place for work with influenza virus, polio virus, measles virus, and vaccinia virus, and there is a medical management plan for work with HTLV-1.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Greninger. Another member seconded the motion.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Greninger, pending successful completion of the lab inspection.</u>

i. Polyak, Steve, renewal, *Virus-Host Interactions in Cell Culture*

- Section III-D, III-E, and III-F
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The Polyak lab studies how viruses interact with host cells with a current focus on Risk Group 2 human coronaviruses and SARS-CoV-2.
- The lab works with SARS-CoV-2 at BSL-3 and with Hepatitis C virus and HIV-1 at BSL-2 with BSL-3 practices. They also work with many Risk Group 2 viruses at BSL-2, including a vaccine strain of Chikungunya virus, Hepatitis B virus, Mayaro virus, Ross River virus, and Zika virus. The lab also has approval for drug resistance studies in Risk Group 2 human coronaviruses using non-rDNA methods at BSL-2 with respiratory protection when working with potentially drug-resistant viruses, including handling and transport.
- The lab was inspected, and all deficiencies have been corrected.
- There are occupational health requirements for work with Hepatitis B virus and Zika virus, and a medical management plan is in place for SARS-CoV-2.
- All required trainings are complete.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Polyak. Another member seconded the motion.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Polyak.</u>

j. Sims, Amy, new, *Efficacy and Evaluation of Host-Targeted Antiviral Therapeutics (UW)*

- Section III-D

- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The goal of this research project is to understand the mechanism by which antivirals antagonize MERS-CoV and SARS-CoV-2.
- The lab works at BSL-3 with recombinant strains of MERS-CoV and SARS-CoV-2 that are engineered to express luciferase and a mutant MERS-CoV with multiple attenuating gene deletions. They also use human and non-human primate cells lines.
- The BSL-3 facility is inspected quarterly and not in association with BUAs/projects.
- A medical management plan is in place for both MERS-CoV and SARS-CoV-2.
- All required trainings are complete.
- 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. **ISSUES FROM THE FLOOR & PUBLIC COMMENTS:** There were no issues from the floor, and no public comments.

11. **MEETING ADJOURNED AT APPROXIMATELY 11:14 a.m.**