INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, November 15, 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 Colby, Comparative Medicine *(Animal Containment Expert)*
5. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
6. Richard Grant, Washington National Primate Research Center
7. Erin Heiniger, Department of Bioengineering *(Laboratory Specialist*)
8. David Koelle, Allergy and Infectious Diseases
9. Stephen Libby, Laboratory Medicine *(Animal Containment Expert)*
10. Scott Meschke, Environmental & Occupational Health Sciences
11. Jennifer Nemhauser, Department of Biology (*Plant Expert*)
12. Jason Smith, Microbiology (*IBC Chair*)
13. Paul Swenson, Seattle-King Co. Dept. of Public Health

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
iPS: 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 October 18, 2023, meeting.
   - A member made a motion to approve the October 18, 2023, minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the October 18, 2023, meeting minutes, with one abstention and two members not voting.

4. **OLD BUSINESS:**
   - At the October 18, 2023, meeting, Dr. Capozzi's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
   - At the October 18, 2023, meeting, Dr. Iritani's BUA was approved pending additional occupational health review. This BUA is still pending.
   - At the October 18, 2023, meeting, Dr. Lee's BUA was approved pending successful completion of the lab inspection response. This BUA is still pending.
   - At the October 18, 2023, meeting, Dr. Nemhauser's BUA was approved pending successful completion of the lab inspection response. This BUA has been sent.
   - At the October 18, 2023, meeting, Dr. Sherman's BUA was approved pending successful completion of the medical management plan. 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 section 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. Yeung renewed in vitro work with human source material and rDNA to the BUA *Liver Tumor Research* (Section III-F).
      - Dr. Wei was approved for in vitro work with human source material, and non-pathogenic strains of E. coli, and rDNA to the BUA *Northwest Genomics Center* (Sections III-E and III-F).
      - Dr. Cao was approved for in vitro work with NHP source material to the BUA *Mucosal Immunoengineering and Microbiome Pharmaceutics*.
      - Dr. Polyak added the wild-type and attenuated strains of Chikungunya, Mayaro, Ross River, Sindbis, and Venezuelan equine encephalitis virus for in vitro to the BUA *Virus-Host Interactions in Cell Culture.*
      - Dr. Barria renewed in vitro work human and NHP source material, non-pathogenic strains of E. coli, and rDNA to the BUA *Regulation of Glutamatergic Synapses* (Sections III-E and III-F).
      - Dr. Meschke renewed in vitro work with several bacterial and viral strains including non-pathogenic strains of E. coli, adenovirus, SARS-CoV-2, and monkeypox virus; and rDNA to the BUA *Detection and Characterization of Pathogens in Environmental Media* (Section III-F).

- Dr. Seshadri added wild-type Epstein-Barr virus for in vitro work to the BUA *Immune Profiling in Infectious Diseases.*
- Dr. Glass renewed in vitro work with human source material and rDNA to the BUA *Laboratory of Developmental Biology* (Section III-E).
- Dr. Cabernard registered work to add a flow cytometry core facility to the BUA *Cellular and molecular mechanisms of asymmetric cell division*.
- Dr. Ueda was approved for in vitro work with human source material, and non-pathogenic strains of E. coli, and rDNA to the BUA *Institute for Protein Design Translational Investigators* (Section III-F).
- Dr. Di Stilio renewed work with transgenic Ceratopteris richardii, Thalictrum species, Agrobacterium tumefaciens, and disarmed Tobacco rattle virus (TRV1/TRV2) in plants; and in vitro work with rDNA to the BUA *Functional Evolution of Floral Pathway Genes* (Sections III-E and III-F).
- Dr. Doty renewed work with non-pathogenic bacterial endophyte isolates in plants and in vitro. They also renewed additional in vitro work with several wild-type fungal species and rDNA to the BUA *Microbiology Research Projects* (Section III-E and III-F).
- Dr. Shree renewed in vitro work with human source material and rDNA to the BUA *Shree Lab: Reproductive Sciences* (Section III-F).
- Dr. Smith renewed in vitro work with inactivated samples of MERS-CoV, SARS-CoV, and SARS-CoV-2 to the BUA *Pathology of Human Disease*.
- 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.
- <u>The Committee unanimously voted to approve this month's Biosafety Officer Report, with two recusals and one member not voting.</u>

6. **BSL-3 INACTIVATION REPORT:** There was no BSL-3 Inactivation Report to present this month.

7. **DURC REPORT:** The Dual Use Research of Concern Institutional Review Entity (DURC IRE) did not meet this month because there were no applications to review.

8. **INDIVIDUAL PROJECT REVIEWS**

   a. Abkowitz, Janis, renewal, *The role of FLVCR in hematopoiesis and iron homeostasis*
   - Sections III-D, III-E, and III-F
   - The assigned IBC Primary Reviewer presented the Primary Review.
   - The aim of the Abkowitz lab is to understand the role of heme and FLVCR in blood cell development, the role of heme and FLVCR in maintaining body iron balance, cellular homeostasis, and to develop model systems of normal and abnormal cell development.
   - This lab works with lentiviral vectors and gammaretroviral vectors in mice and in vitro. They also work with rDNA, Sendai viral vectors and human and NHP source material in vitro.
   - 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. Abkowitz.
- The Committee voted unanimously to approve the draft BUA for Dr. Abkowitz pending successful completion of the lab inspection, with one member not voting.

b. Bitto, Alessandro, renewal, *Pharmacological Approaches to Aging and Mitochondrial Disease*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Bitto lab aims to understand the role of mitochondrial (dys)function in aging, metabolism, and disease.
- This lab works with AAV in mice and in vitro. They also work with lentiviral vectors and rDNA 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. Bitto.
- The Committee voted unanimously to approve the draft BUA for Dr. Bitto pending successful completion of the lab inspection response, with one member not voting.

c. Bryers, James, renewal, *Injectable Hydrogel Depots for Self-replicating mRNA Vaccine Delivery*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Bryers lab aims to generate a self-immunizing biomaterials technology that is superior in immunization with a single dose versus repeated systemic bolus injections.
- This lab works with enhanced gene delivery methods, Pseudomonas aeruginosa, and Staphylococcus aureus in mice and in vitro.
- 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. Bryers.
- The Committee voted unanimously to approve the draft BUA for Dr. Bryers pending application updates, with one member not voting.

d. Chamberlain, Jeff, change, *Gene Therapy for Neuromuscular Disorders*

- Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Chamberlain lab is adding the use of recombinant nucleic acid molecules 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. Chamberlain.

- The Committee voted unanimously to approve the draft BUA for Dr. Chamberlain, with one member not voting.

e. Greninger, Alex, change, *Quantification and sequencing of viral nucleic acids for surveillance and anti-viral drug discovery*

- Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Greninger lab is adding the use of inactivated Risk Group 4 nucleic acids for RT-qPCR and sequencing. Work with the nucleic acids is approved at BSL-2 and inactivation certificates will be provided by the collaborator prior to receipt.
- 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, with one member not voting.

f. Hawkins, Brian, renewal, *Research, Development, and Manufacturing of Pluripotent Stem Cells and Differentiated Cells for the Treatment of Human Disease*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Hawkins lab aims to research, develop, and manufacture pluripotent stem cells and differentiated cells for the treatment of human disease.
- This lab works with AAV, lentiviral vectors, and rDNA 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. Hawkins.
- The Committee voted unanimously to approve the draft BUA for Dr. Hawkins, with one member not voting.

g. MacLellan, Robb, renewal, *Cardiac Development, Growth and Regeneration*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The MacLellan lab aims to understand cellular and molecular mechanisms underlying the development of congestive heart failure.
- This lab works with AAV and human source material in vitro and in mice. They also work with rDNA in vitro.
- The lab inspection is scheduled for after the IBC meeting.
- All required trainings are complete.
- The 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 pending updates to the application and successful completion of the lab inspection, with one member not voting.

h. Papayannopoulou, Thalia, change, *Gene therapy for hemoglobinopathies:bone marrow conditioning*

- Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Papayannopoulou lab is adding the use of enhanced gene delivery in mice.
- 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. Papayannopoulou.
- The Committee voted unanimously to approve the draft BUA for Dr. Papayannopoulou, with one member not voting.

i. Qu, Feini, new, *Mechanisms of Complex Musculoskeletal Tissue Regeneration*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Qu lab aims to determine the cellular and molecular mechanisms that restore biological structure and function to promote complex musculoskeletal tissue regeneration after amputation injury.
- This lab works with rDNA, mouse iPS cells, third generation lentiviral vectors, and human source material 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. Qu.
- The Committee voted unanimously to approve the draft BUA for Dr. Qu pending successful completion of the lab inspection and an update to the BUA letter, with one member not voting.

j. Reniere, Michelle, change, *Redox regulation and virulence in bacterial pathogens*

- Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Reniere lab added the use of recombinant Listeria bacteriophages 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. Reniere.
- The Committee voted unanimously to approve the draft BUA for Dr. Reniere, with one member not voting.

k. Stolla, Massiel, new, *Autophagy and Erythropoiesis*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Stolla lab aims to identify the molecular mechanisms that contribute to normal and impaired red blood cell production.

- This lab works with lentiviral vectors, rDNA, and human source material 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. Stolla.
- The Committee voted unanimously to approve the draft BUA for Dr. Stolla pending successful completion of the lab inspection, with two members not voting.

l. Sancak, Yasemin, renewal, *Role of mitochondrial calcium uptake in health and disease*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Sancak lab aims to understand the role of mitochondrial calcium uptake in various biological processes and diseases, as well as investigating mitochondrial heterogenaity and mito-organellar interactions.
- This lab works with S. cerevisiae, rDNA, lentiviral vectors, and human source material 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. Sancak.
- The Committee voted unanimously to approve the draft BUA for Dr. Sancak, with two members not voting.

m. Savan, Ram, renewal, *Gene Regulation of Immune Genes and the Effect on Immune Response*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Savan lab aims to understand post transcriptional regulation involved in controlling immune genes during stimulation.
- This lab works with ecotropic gammaretroviral vectors, Influenza A virus strains, Vesicular stomatitis virus (VSV) Indiana Strain, lentiviral vectors, 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. Savan.
- The Committee voted unanimously to approve the draft BUA for Dr. Savan, with two members not voting.

n. Soetedjo, Robijanto, renewal, *Saccade Motor Control*

- Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Soetedjo lab aims to implement optical manipulation of electrical activity in the brain by optimizing viral vectors and injection techniques.
- This lab works with AAV in NHPs.
- A lab inspection was not required as all work takes place inside a vivarium.
- 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. Soetedjo.
- The Committee voted unanimously to approve the draft BUA for Dr. Soetedjo, with two members not voting.

o. Woodward, Joshua, renewal, *Pathogenesis of Listeria monocytogenes*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Woodward lab aims to characterize the mechanisms by which Listeria monocytogenes can infect and replicate within the eukaryotic host and to define the host innate immune response to infection by various bacteria.
- This lab works with Enterococcus faecalis, Listeria monocytogenes, Salmonella Typhimurim in vitro and in mice. They also work with Acinetobacter baumannii, Bacillus subtilis, replication deficient gammaretroviral vectors, lentiviral vectors, and herpes virus in vitro.
- 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. Woodward.
- The Committee voted unanimously to approve the draft BUA for Dr. Woodward pending confirmation of no frontline therapeutic antibiotic resistance in the herpes virus strains, with one member not voting.

9. SUBCOMMITTEE REPORTS:

p. Pamboukian, Salpy, new, *A phase 2, adaptive, double-blinded, placebo controlled, randomized, multicenter trial to evaluate the efficacy, safety and tolerability of intracoronary infusion of NAN-101 in adult subjects with New York Heart Association (NYHA) Class III heart failure and non-ischemic cardiomyopathy*

- 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, non-first-in-humans, multicenter trial of locally delivered therapy using an AAV vector designed to express a protein in the heart to address the problem of heart failure.
- An AAV2/8 capsid will be administered to humans.
- All required trainings are complete.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Pamboukian. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Pamboukian, with one member not voting.

10. FOR YOUR INFORMATION:

- The NIH has responded that no further information or action was required for a recent incident involving a scratch from a NHP that had been previously exposed to recombinant simian-human immunodeficiency virus (SHIV).

- The NIH has responded that no further information or action was required for a recent incident involving a splash to the eye when removing goggles that were worn while cleaning a room housing non-human primates. At least one of the animals had been previously exposed to recombinant simian-human immunodeficiency virus (SHIV) or recombinant vaccinia virus.

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

12. **MEETING ADJOURNED AT APPROXIMATELY 11:35 A.M.**