



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, August 16, 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. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 9. David Koelle, Allergy and Infectious Diseases
 10. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 11. Susan Parazzoli (*Community Member*)
 12. Jason Smith, Microbiology (*IBC Chair*)
 13. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
 14. Elyse Verstelle, Department of Immunology (*Laboratory Specialist*)

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. **PRESENTATION:** Autoclave and Shipping Medical Waste Audit, Esther Pellham
4. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the August 16, 2023, meeting.
 - A member made a motion to approve the August 16, 2023, minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the August 16, 2023, meeting minutes, with one abstention.
5. **OLD BUSINESS:**
 - At the July 19, 2023, meeting, Dr. Gordon's BUA was approved pending successful completion of the lab inspection response. This BUA has been sent.
 - At the July 19, 2023, meeting, Dr. Kwon's BUA was approved pending completion of successful completion of the lab inspection response. This BUA is still pending.
 - At the July 19, 2023, meeting, Dr. Seshadri's BUA was approved pending revision of the BUAL to list samples from mice and NHPs exposed to Mycobacterium tuberculosis. This BUA has been sent.
6. **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. Hoofnagle added new rooms for use with previously approved agents to the BUA *Analysis of human samples for the development of novel diagnostic assays in the clinical laboratory and for the investigation into nutrition, obesity, kidney disease, cardiovascular disease, and neurodegenerative diseases.*
 - Dr. Stempien-Otero renewed in vitro work with human source material and rDNA to the BUA *Macrophages in Cardiac Fibrosis* (Section III-F).
 - Dr. Silber renewed in vitro work with human source material and rDNA to the BUA *Banking and characterization of human brain tumor tissue* (Section III-F).
 - Dr. Hawkins updated rooms for use with previously approved agents to the BUA *Research, Development, and Manufacturing of Pluripotent Stem Cells and Differentiated Cells for the Treatment of Human Disease.*
 - Dr. Vaisar was approved for in vitro work with human and NHP source material and rDNA with and without enhanced gene delivery methods to the BUA *Studies of HDL Function* (Sections III-E and III-F).
 - Dr. Adams Waldorf added a room for use with previously approved agents to the BUA *Experimental Model of Viral-Induced Brain Injury.*
 - Dr. Adams Waldorf added a room for work with previously approved agents to the BUA *Influenza and Coronavirus Model of Immunity in Pregnancy.*

- Dr. Hawn added new rooms for use with previously approved agents to the BUA *Innate Immunity and Susceptibility to Infectious Disease*.
- Dr. Oberst added the use of fixed/inactivated SARS-CoV-2 in previously approved rooms and the use of diphtheria toxin in vivo to the BUA *Programmed Cell Death and Immunity*.
- Dr. Duthie added recombinant/synthetic DNA/RNA in rats (the IBC reviewed the same agent in mice in July 2022) to the BUA *Immune modulators for treatment of infection* (Section III-D).
- Dr. Mack administratively moved previously approved research from another project to the BUA *FXR1 gene therapy in DMD rat models* (Section III-D).
- 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.

7. INDIVIDUAL PROJECT REVIEWS

- a. Fuller, Deborah, renewal, *Vaccines and minibinders against global health threats*
 - Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Fuller lab aims to develop a vaccine to protect against regular seasonal flu strains and those that could cause a pandemic, develop a vaccine to protect against COVID-19, develop a nucleic acid vaccine to protect against Hepatitis B virus (HBV), and identify protein minibinders that can mitigate disease progression.
 - This lab works with rDNA and SARS-CoV-2 nucleic acid in vivo and in vitro. They also work with influenza virus, non-pathogenic strains of E. coli, and human and NHP source material in vitro.
 - There was a discussion to confirm that staff are not required to use respirators when working with NHP with circulating human flu vaccine. There was additional discussion around *NIH Guidelines* section F-II-C and if it is the entire toxin or subunits that fit into this regulation.
 - 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 influenza virus.
 - 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. Fuller.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller, pending clarification of adjuvant containment and updated language on the BUA letter.
- b. Keel, Sioban, renewal, *Mechanisms of marrow failure and anemia*
 - Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Keel lab aims to characterize the genetics and molecular mechanisms of several blood- and bone marrow-related diseases.
 - This lab does in vitro work with gammaretroviral vectors, lentiviral vectors, and rDNA with and without oncogenic inserts and enhanced gene delivery methods.

- 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. Keel.
 - The Committee voted unanimously to approve the draft BUA for Dr. Keel, pending successful completion of the lab inspection.
- c. Kennedy, Scott, renewal, *Somatic mutagenesis in aging and diseases*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Kennedy lab aims to understand the role of mutations in nuclear and mitochondrial genomes and their effect on lifespan and disease risk.
 - This lab works with transgenic *Drosophila* and does in vitro work with rDNA and human and NHP source material.
 - 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. Kennedy.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kennedy, pending successful completion of the lab inspection response.
- d. Murphy, Sean, change, *NHP study*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Murphy lab is adding a recombinant version of *Plasmodium berghei*, a Risk Group 1 protozoa, both in vitro and in NHPs. The recombinant plasmodium is modified to express malaria vaccine antigens.
 - 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. Murphy.
 - The Committee voted unanimously to approve the draft BUA for Dr. Murphy.
- e. Ponnalagu, Devasena, new, *Intracellular chloride channels in metabolic disorder and associated cardiovascular diseases*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Ponnalagu lab aims to understand the mechanisms by which chloride channels present in intracellular organelles and how they contribute to the development of heart disease and diabetes.
 - This lab works with non-pathogenic strains of *E. coli*, lentiviral vectors, rDNA, 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. Ponnalagu.

- The Committee voted unanimously to approve the draft BUA for Dr. Ponnalagu.
- f. Ruohola-Baker, Hannele, new, *Characterizing Pluripotent Stem Cells Derived from Distinct Developmental Stages*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Ruohola-Baker lab aims to take a multi-pronged approach at understanding the molecular mechanisms of how cancers and other human diseases occur, to gain practical knowledge of human stem cells in culture, and how to develop therapies derived from an individual's own stem cells.
 - This lab uses replication deficient Sendai viral vectors with oncogenic inserts to create induced pluripotent stem cells. Cells are then administered to animals.
 - 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. Ruohola-Baker.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ruohola-Baker.
- g. Servetnick, Marc, renewal, *Role of T-box genes in development of the sea anemone Nematostella vectensis.*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Servetnick lab aims to understand the roles of specific genes in the development of embryos of the sea anemone Nematostella vectensis.
 - This lab works with transgenic Nematostella vectensis. They also conduct in vitro work using non-pathogenic strains of E. coli and non-viral rDNA.
 - 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. Servetnick.
 - The Committee voted unanimously to approve the draft BUA for Dr. Servetnick, pending successful completion of the lab inspection, with one member not voting.
- h. Tait Wojno, Elia, change, *Regulation of immunity and inflammation at mucosal surfaces.*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Tait Wojno lab is adding recombinant Salmonella typhimurium in vitro and in vivo in mice. This recombinant Salmonella typhimurium (SL1344 ssaR) lacks the SPI-II secretion system.
 - The lab was inspected, and no deficiencies were noted.
 - 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. Tait Wojno.

- The Committee voted unanimously to approve the draft BUA for Dr. Tait Wojno, with one recusal and one member not voting.
- i. Trapnell, Bruce, renewal, *Trapnell Lab General Operations*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Trapnell Lab aims to discover novel regulators that govern cellular transitions by utilizing single-cell genomics.
 - This lab does in vitro work with lentiviral vectors, rDNA (with and without enhanced gene delivery methods), non-pathogenic strains of E. coli, and inactivated SARS-CoV-2 samples.
 - 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. Trapnell.
 - The Committee voted unanimously to approve the draft BUA for Dr. Trapnell, with one member not voting.
- j. Valdmanis, Paul, renewal, *Mitigating host responses for effective gene therapy*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Valdmanis lab aims to develop safe gene therapy approaches for liver and brain disorders.
 - This lab works with rDNA and AAV both in vivo in mice and in vitro. They also work with lentiviral vectors, non-pathogenic strains of E. coli, and human source material 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. Valdmanis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Valdmanis, 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 sharps injury from a needle that was contaminated with a recombinant strain of *Pseudomonas aeruginosa*.

11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

- Please email the IBC Coordinator any potential, relevant experts to present at an IBC meeting. Topic ideas include gene drives, oncogene, and viral vector field, and registering for the ABSA viral vector webinar.
- Please email the IBC Coordinator with feedback about the new Primary Review form.

- A subcommittee has been formed to review the new BUA application. Information will be provided in the coming weeks. Thank you for the help!
- The NIH released proposed changes to the *NIH Guidelines*. A summary of the proposed changes will be sent out in the coming week, and we will be soliciting feedback from the committee members. UW EH&S will submit feedback to the NIH on behalf of the University.

12. MEETING ADJOURNED AT APPROXIMATELY 11:31 A.M.