



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, April 19, 2023

Time: 10:00 AM – 12:00 PM

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. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 7. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 8. Scott Meschke, Environmental & Occupational Health Sciences
 9. Susan Parazzoli (*Community Member*)
 10. Jason Smith, Microbiology (*IBC Chair*)
 11. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
 12. 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 10:02 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 March 15, 2023, meeting.
 - A member made a motion to approve the March 15, 2023, minutes. Another member seconded the motion.
 - The committee voted unanimously, with three members abstaining, to approve the March 15, 2023, meeting minutes.
4. **OLD BUSINESS:**
 - At the March 15, 2023, meeting, Dr. Catterall's BUA was approved pending successful completion of a lab inspection. This BUA is still pending.
 - At the March 15, 2023, meeting, Dr. Cui's BUA was approved pending successful completion of a lab inspection. This BUA is still pending.
 - At the March 15, 2023, meeting, Dr. Perlmutter's BUA was approved pending successful completion of a lab inspection and review of the IACUC protocol. 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 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. Armbrust consolidated work from multiple BUAs and added *Synechococcus* spp. to the BUA *Phytoplankton genome engineering* (Section III-E).
 - Dr. Harrington was approved for in vitro work with human source material on the BUA *Immunology in mothers and offspring*.
 - Dr. Allbritton renewed the BUA *Tissue culture in Allbritton Lab* for in vitro work with was approved for in vitro work with non-pathogenic strains of *E. coli*, non-viral rDNA, and wildtype RG 1 and 2 agents (Sections III-E and III-F).
 - Dr. Darvas was approved for in vitro work with rDNA and non-pathogenic strains of *E. coli* and in vivo work with herpes simplex virus 1 (HSV-1) on the BUA *PILRA, HSV and AD*. This research was reviewed by the IBC at the June 15, 2022, IBC meeting (Sections III-D, III-E, and III-F).
 - Dr. Kim registered work with wildtype RG1 agents to the BUA *Ecophysiology of plant-endophyte interactions*.
 - Dr. Stella was approved for in vitro work with rDNA and non-pathogenic strains of *E. coli* and in vivo work with AAV on the BUA *Regulation of 2-AG Signaling in Mouse Neurons* (Sections III-D, III-E, and III-F). This research was reviewed by the IBC at the February 15, 2023, IBC meeting.
 - Dr. Scatena added work with previously approved agents to a new core facility to the BUA *Endothelial cells for tissue engineering and osteoprotegerin in atherosclerosis*.

- Dr. Baker added and removed lab spaces for previously approved work to the BUA *Institute for Protein Design and Affiliate Investigators*.
- Dr. Weil added a new room with previously approved agents to the BUA *Isolation of gut microbes from human stool/vomitus, testing bacteria for pathogen interactions*.
- Dr. Dhaka added and removed lab spaces for previously approved work to the BUA *Transsynaptic Tracing of Somosensory Circuits*.
- Dr. Liu added and removed rooms for previously approved work to the BUA *Cytogenomic microarray analysis*.
- Dr. Altemeier added human rhinovirus A for work in vitro and in mice to the BUA *Inflammatory Response Modulation by Mechanical Ventilation*.
- Dr. Lieberman added work with human source material to the BUA *Development of rapid POC assays for infections and whole genome sequencing of leishmania*.
- Dr. Sweet renewed in vitro work with human source material on the BUA *Tissue Characterization*.
- Dr. Fink registered work with new wildtype SARS-CoV-2 strains on the BUA *Host-Pathogen Interaction*.
- 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. **BSL-3 INACTIVATION REPORT**

- Dr. Gale added Qiagen RLT Lysis Buffer as another RNA lysis buffer they can use for their SARS-CoV-2 inactivation protocol.
- The subcommittee reviewed procedure and inactivation data provided by the lab and approved the request.
- The IBC Chair a motion to approve this month's BSL-3 Inactivation Report.
- A member made a motion to approve this month's BSL-3 Inactivation Report. Another member seconded the motion.
- The committee voted unanimously, with one member abstaining, to approve this month's BSL-3 Inactivation Report with one member not submitting a vote.

7. **INDIVIDUAL PROJECT REVIEWS**

- a. Brockerhoff, Susan, renewal, *Determinants of Rod and Cone Response Characteristics*
 - Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Brockerhoff lab aims to show how the retina changes its metabolic state to meet the very different energy demands in light vs. darkness.
 - This lab works with transgenic zebrafish, non-viral rDNA, and non-pathogenic strains of E. coli.
 - 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. Brockerhoff.
 - The Committee voted unanimously to approve the draft BUA for Dr. Brockerhoff pending successful completion of the lab inspection.
- b.** Moritz, Chet, renewal, *Combined Stem Cell Transplantation and Targeted Microstimulation to Direct the Formation of Functional Connections and Neural Repair in Rats.*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Moritz lab aims to develop a treatment for damage to the brain, spinal cord, or bladder following traumatic brain injury, stroke, or spinal cord injury.
 - This lab works with adeno-associated vectors, lentiviral vectors, iPS cells, and RG 2 agents in rats.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required training is 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. Moritz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Moritz.
- c.** Scott, John, renewal, *AKAP structure and Function*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Scott lab aims to understand the roles of A kinase anchoring proteins (AKAPs) in heart disease, diabetic hypertension, fibrolamellar carcinoma (FLC), Cushings syndrome, kidney disease and neuronal function.
 - This lab works with human source material and rDNA in mice. Additionally, they work with several RG 2 viral vectors, NHP source material, and human iPS cells in vitro.
 - 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. Scott.
 - The Committee voted unanimously to approve the draft BUA for Dr. Scott, pending successful completion of the lab inspection response.
- d.** Sniadecki, Nathan, change, *Swine Model of Heart Disease and Novel Therapies*
- Sections III-D and III-E
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Sniadecki lab is adding transduction of human cells with Sendai viral vectors, transfection of human cells by liposome complex, and transplantation of transduced cells into pigs.
 - A discussion occurred regarding the biosafety level of human cells in pigs. The biosafety officer reminded the Committee that prior to administration to pigs, all human cells have been tested to be free of human bloodborne pathogens and human cells transduced with Sendai viral vectors are tested negative for Sendai virus.

- 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. Sniadecki.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sniadecki.
- e. Stewart, Tessandra, renewal, A multi-modal approach to biomarker discovery and understanding the underlying mechanisms of neurodegenerative diseases
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Stewart lab aims to identify biomarkers for neurodegenerative diseases and better understand the cellular mechanisms that underlie them.
 - This lab works with adeno-associated viral vectors with oncogenic inserts, lentiviral vectors with oncogenic inserts, and rDNA 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. Stewart.
 - The Committee voted unanimously, with one member not voting, to approve the draft BUA for Dr. Stewart, pending successful completion of the lab inspection.
- f. Wood, Gwen, renewal, *Multiple projects involving sexually transmitted bacterial pathogens*
- Sections III-D, III-E, and III-F.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Wood lab aims to investigate the genetics and pathogenesis of *Mycoplasma genitalium* and other reproductive tract pathogens.
 - This lab works with *Mycoplasma genitalium* in vivo and several RG 2 agents in vitro.
 - A discussion occurred regarding the use of recombinant *M. genitalium* with antibiotic resistance cassettes (tetracycline, gentamicin, and chloramphenicol) and the use of front-line antibiotics in the case of lab personnel infection. The committee has three main questions: (1) Do the antibiotic resistance cassettes in the recombinant *M. genitalium* (tetracycline, gentamicin, and chloramphenicol) compromise the ability of front-line? (2) Does selecting or enriching the TetR cassette affect the ability of front-line therapeutics? (3) Does any of this work (even with naturally occurring resistant strains) impact treatment if personnel are exposed? The committee asked the BSO to bring these questions to the Employee Health Center for occupational health review.
 - 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. Wood.
 - The Committee voted unanimously, with one member not voting, to approve the draft BUA for Dr. Wood, pending successful completion of the lab inspection and clarification of the antibiotic resistance work and potential development of a medical management plan.

- g. Veesler, David, change, *Expression of recombinant proteins using mammalian cell lines*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Veesler lab is adding recombinant filovirus glycoprotein ectodomains (Sudan Ebola virus glycoprotein, Zaire Ebola virus glycoprotein and Marburg virus glycoprotein) for expression in mammalian cells after amplifying the DNA in *E. coli*, to their BUA.
 - The recombinant DNA in this change cannot be used to generate infectious viruses.
 - 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. Veesler.
 - The Committee voted unanimously to approve the draft BUA for Dr. Veesler, pending updates to the BUA letter.

8. SUBCOMMITTEE REPORTS:

- h. Fuller, Deborah, change, *Mouse Models for Prophylaxis and Therapy*
- Section III-D
 - Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The IBC subcommittee updated the containment recommendation for the *C. posadasii* mutant strains approved at the February 15, 2023, IBC Meeting following the receipt of additional information from the institution providing the strains.
 - A lab inspection was not required as the lab was recently inspected.
 - All required training is complete.
 - A medical management plan is in place for *Coccidioides posadasii*.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Fuller. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- i. Goss, Christopher, new, *An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis*
- Section III-C
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a new application for a multicenter, industry-sponsored (4D Molecular Therapeutics), phase I/II trial of a gene therapy for Cystic Fibrosis. 4D-710 is a recombinant AAV that is replication incompetent and non-integrating and consists of a CFTR transgene and a chimeric capsid protein.
 - A discussion occurred regarding the study agent delivery method (oral nebulizer), the personnel protection for the study staff administering the drug, and study agent shedding after drug delivery. The drug delivery room is negatively pressured, and the study personnel will follow aerosol containment procedures for drug delivery. The BSO will confirm negative air flow at the lab inspection. The informed consent also addresses

precautions study participants should take to reduce incidental exposure to close contacts after drug delivery, including birth control and respiratory precautions.

- The lab inspection is scheduled for after the IBC meeting.
 - The required trainings are still pending.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Goss. Another member seconded the motion.
 - The Committee voted unanimously, with one member not voting, to approve the draft BUA for Dr. Goss, pending successful completion of the lab inspection and required training.
- j. *Hawn, Thomas, change, Innate Immunity and Susceptibility to Infectious Disease*
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Hawn lab is adding clinical isolates of drug sensitive, single-drug resistant, and multidrug resistant (MDR) strains of *Mycobacterium tuberculosis*.
 - The BSL-3 facility is inspected quarterly and not in association with BUAs/projects.
 - All required trainings are complete.
 - A medical management plan is in review for the drug-resistant TB strains.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Hawn. Another member seconded the motion.
 - The Committee voted unanimously, with one member not voting, to approve the draft BUA for Dr. Hawn.
- k. *Koelle, David, renewal, Koelle Laboratory at UW*
- Sections 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 Koelle lab aims to understand the immune responses to infectious diseases of humans.
 - This lab works with gammaretroviral vectors, lentiviral vectors, vaccinia virus, rDNA, SARS-CoV-2, and several Risk Group 2 viruses in vitro.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required training is complete.
 - Medical management plans are in place for SARS-CoV-2, *Treponema pallidum*, vaccinia virus, Zika virus, and clinical samples from monkeypox and COVID-19 patients.
 - IACUC protocol will lapse as work is no longer being done.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Koelle. Another member seconded the motion.
 - The Committee voted unanimously, with one member not voting, to approve the draft BUA for Dr. Koelle.
- l. *Sims, Amy, renewal, Testing SARS-CoV 2 Inactivation by RNA Extraction Buffers*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.

- The Sims lab aims to assess inactivation of SARS-CoV-2 infectivity following various RNA extraction protocols.
- This lab works with human source material and SARS-CoV-2 in vitro.
- BSL-3 is inspected quarterly and not in association with BUAs/projects.
- The required trainings are still pending.
- 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, with one member not voting, to approve the draft BUA for Dr. Sims.

10. FOR YOUR INFORMATION:

- The IBC Chair requested that project primary reviewers include the secondary reviewer and all subcommittee members on emails when the review is posted.

11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

- There were no issues from the floor, and no public comments.

12. MEETING ADJOURNED AT APPROXIMATELY 11:49 P.M.