



# INSTITUTIONAL BIOSAFETY COMMITTEE

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## UNIVERSITY *of* WASHINGTON

### Meeting Minutes

**Date:** Wednesday, June 21, 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. Jennifer Nemhauser, Department of 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*)
  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 10:02 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 May 17, 2023, meeting.
  - A member made a motion to approve the May 17, 2023, minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the May 17, 2023, meeting minutes.
4. **OLD BUSINESS:**
  - At the May 17, 2023, meeting, Dr. Fowler's BUA was approved pending successful completion of the lab inspection response. This BUA is still pending.
  - At the May 17, 2023, meeting, Dr. Hoffman's BUA was approved pending completion of a successful lab inspection and clarification on the antibiotic resistance used in recombinant *P. aeruginosa* and *S. aureus* and pending successful completion of the lab inspection. This BUA is still pending.
  - At the May 17, 2023, meeting, Dr. Hoppin's BUA was approved pending successful completion of the required training and lab inspection response. This BUA has been sent out.
  - At the May 17, 2023, meeting, Dr. Kollman's BUA was approved pending successful completion of the lab inspection and completion of training. This BUA has been sent out.
  - At the May 17, 2023, meeting, Dr. Moussavi-Harami's BUA was approved pending successful completion of the lab inspection response. This BUA has been sent out.
  - At the May 17, 2023, meeting, Dr. Parsek's BUA was approved pending successful completion of the lab inspection response and an update to the BUA letter. 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. Mougous added rooms for previously approved work to the BUA *Type VI secretion-dependent interbacterial interactions*.
    - Dr. Gao renewed in vivo and in vitro work with rDNA, non-pathogenic strains of *E. coli*, and human source material on the BUA *Systemic Delivery of siRNA Drugs and Nanoparticle-based Tumor Detection* (Sections III-E).
    - Dr. Wood renewed in vivo work with *Schistosoma* spp. on the BUA *Spatial ecology of schistosomiasis transmission risk*.
    - Dr. Greninger added the use of pathogenic *E. coli* to new lab space and contemporary influenza strains to previously approved spaces to the BUA *Discovery and Characterization of Virus-Host Interactions and Determination of Antiviral Drug Resistance*.

- Dr. Sniadecki added new rooms to work with previously approved agents to the BUA *Cell therapy in mice and rats*.
- Dr. Sniadecki added new rooms to work with previously approved agents to the BUA *Cell therapy in NHPs*.
- Dr. Sniadecki added new rooms to work with previously approved agents to the BUA *Swine Model of Heart Disease and Novel Therapies*.
- Dr. Brentnall renewed in vitro work with non-pathogenic strains of E. coli, rDNA, and human and NHP source material to the BUA *Early Detection of Pancreatic Cancer* (III-E and III-F).
- Dr. Johnsen added a room to work with previously approved agents to the BUA *Studies of variation impacting traits and disease in classical hematology*.
- Dr. Byers renewed in vitro work with rDNA and human source material to the BUA *Collagen Diagnostic Laboratory and Research Repository for Heritable Disorders of Bone, Blood Vessels and Skin* (III-F).
- Dr. Derdeyn added rooms for work with previously approved agents to the BUA *Virus neutralization, diversity, and B cell immunology*.
- Dr. Smith registered work adding an imaging room with no open manipulation to the BUA *Antiviral Mechanisms of Defensins*.
- Dr. Derdeyn added the use of a core facility with previously approved agents to the BUA *Virus neutralization, diversity, and B cell immunology*.
- Dr. Sakiyama-Elbert added rooms for work with previously approved agents to the BUA *Developing New Tools to Understand the Role of Interneurons in Rewiring After SCI*.
- Dr. Emerson was approved for in vitro work with human source material on the BUA *Modeling of Malignant Brain Tumors with Cerebral Organoids*.
- Dr. Koelle added new rooms for use with human source material to the BUA *Koelle Laboratory at UW*.
- Dr. An renewed in vitro work with rDNA and human and NHP source material to the BUA *Aging Oral Tissue Repository and Testing* (III-F).
- Dr. Lutz renewed in vitro work with bacteriophage, cytomegalovirus, influenza virus strains, SARS-CoV-2 nucleic acid and SARS-CoV-2 clinical samples, and rDNA to the BUA *Pathogen Diagnostic Development* (III-E and III-F).
- Dr. Sims renewed in vitro work with lentiviral vectors and human and NHP source material to the BUA *Propagation of mammalian cells in tissue culture and preparation of frozen stocks* (III-D). The lentiviral vector research was previously reviewed at the May 17, 2023, IBC meeting.
- Dr. Scott registered the addition of non-biohazardous work to the BUA *AKAP structure and Function*.
- Dr. Cammarata was approved for in vitro work with Pichia pastoris and non-pathogenic strains of E. coli on the BUA *Arzeda Strain and DNA Design Cell Sorting* (III-E and III-F).
- Dr. Seibel registered work with mouse tissue on the BUA *CoreView ION development*.
- 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 with three recusals.

## 6. INDIVIDUAL PROJECT REVIEWS

- a. Gale (004), Michael, renewal, *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 aims to understand the host immune response to emerging viruses, including influenza viruses and flaviviruses, and to develop therapeutics and vaccines to modulate the innate immune response.
  - This lab works with nanomaterial enhanced gene delivery systems, rDNA and Zika virus in NHP and in vitro and contemporary, circulating strains of influenza viruses in vitro.
  - 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. Gale.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gale, with one recusal.
- b. Gale (001), Michael, change, *The Host Response to Virus Infection*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Gale lab is adding a nanomaterial enhanced gene delivery system in mice, the use of West Nile Virus infected cells at their confocal microscope, and the removal of poliovirus work from their BUA (all stocks have been destroyed).
  - 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. Gale.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gale, with one recusal and one member not voting.
- c. Jayadev, Suman, change, *Inflammatory mediators of neurodegeneration*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Jayadev lab is adding use of AAV in mice and in vitro, as well as NHP tissue processing.
  - 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. Jayadev.
  - The Committee voted unanimously to approve the draft BUA for Dr. Jayadev.
- d. Lam, Hung-Ming, renewal, *Identification of the biology and novel treatment target for advanced urological cancers*

- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Lam lab aims to characterize the biology underlying advanced urological cancers including the prostate and the bladder, and to identify and test novel treatment targets focusing on both tumor and its tumor microenvironment.
  - This lab works with human cells transduced with lentiviral vectors and rDNA in mice and 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. Lam.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lam, pending an update to the IBC primary review.
- e. Maly, Dustin, renewal, *Study of Intracellular Protein Kinases*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Maly lab aims to better understand how structure of protein kinases and cellular signaling influence function in cellular systems.
  - This lab does in vitro work with lentiviral vectors with and without oncogenic inserts. They also work with human and NHP source material 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. Maly.
  - The Committee voted unanimously to approve the draft BUA for Dr. Maly pending successful completion of the lab inspection.
- f. Mathieu, Julie, renewal, *Human ES Core*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Mathieu lab is an Institute for Stem Cells and Regenerative Medicine (ISCRM) core facility. The core facility provides training in the culture and generation of induced pluripotent stem cells, gene editing services, and assistance with pilot studies for laboratories new to the expertise within the core.
  - This lab does in vivo work in mice using human and NHP cells transduced with foamy viral vectors and Sendai virus vectors, and human, NHP, and murine cells transfected with rDNA. They also do in vitro work with AAV.
  - 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. Mathieu.
  - The Committee voted unanimously to approve the draft BUA for Dr. Mathieu.
- g. Mougous, Joseph, renewal, *Type VI secretion-dependent interbacterial interactions*
- Sections III-D and III-E
  - The assigned IBC Primary Reviewer presented the Primary Review.

- The Mougous lab aims to understand the mechanisms and consequences of bacterial interactions.
  - This lab works with a large list of wildtype and recombinant Risk Group 1 and 2 bacteria both in vivo and in vitro.
  - A lab inspection has been performed and is still pending a response.
  - All required trainings are complete.
  - There are occupational health requirements for work with of *S. pneumoniae* and *H. influenzae*.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Mougous.
  - The Committee voted unanimously to approve the draft BUA for Dr. Mougous, pending successful completion of the lab inspection and follow up with the lab to clarify if there is potential for enzyme conferring resistance to gentamycin or other aminoglycoside antibiotics.
- h. Murphy (001), Sean, change, *Immunity to malaria infection*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Murphy lab is adding an adenoviral vector in mice and in vitro.
  - 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.
- i. Murphy (002), Sean, change, *NHP study*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Murphy lab is adding an adenoviral vector in NHPs and the use of NHP-derived samples from those exposed NHPs.
  - 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.
- j. Shi, Min, renewal, *The Shi Laboratory Animal Use and Other Research*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Shi lab aims to elucidate the cellular and molecular mechanisms underlying neurodegeneration, especially in diseases like Parkinson's and Alzheimer's.
  - This lab works with human source materials in mice. They also work with AAV, non-pathogenic *E. coli*, lentiviral vectors, and rDNA 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. Shi.
- The Committee voted unanimously to approve the draft BUA for Dr. Shi.

## 7. SUBCOMMITTEE REPORTS:

- k. Distad, Jane, new, *A two-part multicenter study: a randomized, double-blind, placebo-controlled dose-escalation safety phase (Part 1) followed by double-blind, placebo-controlled, adaptive phase (Part 2) study to evaluate the safety and efficacy of LION-101 in adult subjects with LGMD21/R9 mutations in the gene encoding Fukutin Related Protein (FKRP)*
- Sections 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 an industry-sponsored (AskBio), multi-center, phase I clinical trial of LION-101 AAV gene therapy for the treatment of Limb-Girdle Muscular Dystrophy 21/R9 (LGMD21/R9).
  - This lab works with AAV in vitro and in 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. Distad. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Distad.
- I. Gale (002), Michael, change, *The Host Response to BSL-3 Pathogens*
- Sections III-D and III-E
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Gale lab is adding a nanomaterial enhanced gene delivery system in mice, and adding new wild type strains of SARS-CoV-2, and one recombinant strain expressing a reporter gene.
  - A lab inspection was not performed because the BSL-3 facility is inspected quarterly.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Gale. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gale, with one recusal.
- m. Hirayama, Alex, renewal, *A Phase 2, Open-Label, Single Arm, Multicohort, Multicenter Trial To Evaluate The Efficacy And Safety Of Jcar017 In Adult Subjects With Relapsed Or Refractory Indolent B-Cell Non-Hodgkin Lymphoma (Nhl) (Transcend FI)*
- 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 renewal of an industry-sponsored, multi-center, open-label, phase 2 study to evaluate the efficacy of JCAR017 for relapsed/refractory follicular and marginal zone lymphomas.
  - This lab works with human cells transduced with third generation, non-HIV pseudotyped, replication deficient lentiviral vectors.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Hirayama. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hirayama.
- n. Safyan, Rachael, new, *A Phase 2 Clinical Trial Investigating Oncolytic Immunotherapy in Combination with Atezolizumab and Bevacizumab for the Treatment of Patients with Advanced Microsatellite Stable and Mismatch Repair Proficient Colorectal Carcinoma*
- Section III-C
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is a new application for an industry-sponsored , multi-center, phase 2 study to improve outcomes in patients with Colorectal cancer (CRC) using RP2 and RP3, selectively replication competent herpes simplex viruses 1 (HSV-1) that express exogenous genes and are intended for direct injection into suitable non-neurological solid tumors.
  - All required trainings are complete.
  - An updated medical management plan has been completed.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Safyan. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Safyan pending completion of the medical management plan.

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

**11. MEETING ADJOURNED AT APPROXIMATELY 11:39 A.M.**