



# INSTITUTIONAL BIOSAFETY COMMITTEE

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UNIVERSITY *of* WASHINGTON

## Meeting Minutes

**Date:** Wednesday, May 15, 2024

**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. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
  7. Richard Grant, Washington National Primate Research Center
  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*)

### 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 10:00 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 April 17, 2024 meeting.
  - A member made a motion to approve the April 17, 2024 minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the April 17, 2024 meeting minutes, with two abstentions.
4. **OLD BUSINESS:**
  - At the April 17, 2024 meeting, Dr. Guo's BUA was approved pending successful completion of the lab inspection response. This BUA has been sent.
  - At the April 17, 2024 meeting, Dr. Scatena's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
  - At the April 17, 2024 meeting, Wayne's BUA was approved pending successful completion of the lab inspection. 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. Phillips registered work with new gene inserts for previously approved viral vectors to the BUA *Phasic Dopamine Release during Motivated Behavior in Rats*.
    - Dr. Erasmus added in vivo use of Rift Valley virus vaccine strain MP-12 at ABSL-2 to the BUA *RNA vaccines*.
    - Dr. Disis registered in vivo work with no change in biohazards to the BUA *Evaluation of Immunity to Cancer in a Rodent Model*.
    - Dr. Gordon registered work already covered in the BUA *Mechanisms of TRP Channel Modulation*.
    - Dr. Lin renewed in vitro work with human source material on the BUA *Biomarkers of drug metabolism and transport*.
    - Dr. Martins renewed in vitro core facility work on the BUA *High Throughput Screening* (Section III-D).
    - Dr. Kiem registered work with new gene inserts for previously approved viral vectors on the BUA *Strategies to Improve Hematopoietic Stem Cell Transduction*.
    - Dr. Manookin renewed in vitro work with NHP source material on the BUA *Neural pathways in the retina*.
    - Dr. Sweetwyne added a room for in vitro work with previously approved agents to the BUA *Renal progenitor cells from human urine*.
    - Dr. Sakiyama-Elbert added rooms for in vitro work with previously approved agents to the BUA *Developing New Tools to Understand the Role of Interneurons in Rewiring After SCI*.

- Dr. Beliveau renewed in vitro work with non-pathogenic strains of E. coli, non-viral rDNA with enhanced gene delivery methods, and human source material on the BUA *Probing the dynamics of chromosome organization in single cells* (Sections III-E and III-F).
- Dr. Basso registered work with in vivo work with human fibrils to the BUA *Changes across the lifespan in the use of heuristics to guide decision-making (NHPs)*.
- Dr. Gale removed the use of JEV Nakayama strain and replaced it with JEV inactivated vaccine at A/BSL-2 on the BUA *The Host Response to Virus Infection*.
- Dr. Van Voorhis removed Giardia, Shigella, and Plasmodium species in mice from the BUA *1. Immune Response: Chagas 2. Biochemistry of Protein Prenylation 3. Plasmodium falciparum Protein Farnesyltransferase Inhibitors 4. Drugs for Toxoplasma and Cryptosporidium 5. Giardia 6. Shigella Inhibitors*.
- 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.

## 6. INDIVIDUAL PROJECT REVIEWS

- a. Baker, David, renewal, *Institute for Protein Design and Affiliate Investigators*
  - Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Baker lab aims to use computational design of new proteins for which synthetic genes (DNA sequences) are ordered or manufactured from oligonucleotide building blocks in the lab's Institute for Protein Design.
  - This lab works with lentiviral vectors at BSL-2 and rDNA with enhanced gene delivery, Saccharomyces species, and non-pathogenic strains of E. coli 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. Baker.
  - The Committee voted unanimously to approve the draft BUA for Dr. Baker, pending successful completion of the lab inspection.
  
- b. Bumgarner, Roger, renewal, *Bumgarner Lab Genomic Research Projects*
  - Sections III-D and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Bumgarner lab aims to characterize sequence variation that may be associated with phenotypic differences in bacteria.
  - This lab works with non-viral rDNA at BSL-1 and Cutibacterium species at BSL-2.
  - 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. Bumgarner.
  - The Committee voted unanimously to approve the draft BUA for Dr. Bumgarner.

- c. Carrol, Jeff, change, *ATN1-lowering Studies in a Novel Mouse Model of DRPLA*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Carrol lab is adding in vitro work with mouse cells transduced with gammaretroviral vectors with oncogenic inserts at BSL-2.
  - 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. Carrol.
  - The Committee voted unanimously to approve the draft BUA for Dr. Carrol.
- d. Crudele, Julie, renewal, *Gene therapy in mice*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Crudele lab aims to develop a treatment or cure for GNE myopathy by delivering new, therapeutic genes to muscles by way of the bloodstream or intramuscular injection.
  - This lab works with AAV in mice and in vitro. They also do in vitro work with non-pathogenic strains of E. coli and rDNA with enhanced gene delivery methods.
  - 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. Crudele.
  - The Committee voted unanimously to approve the draft BUA for Dr. Crudele, pending successful completion of the lab inspection.
- e. Kelly, Edward, renewal *Microphysiological Systems-Based Research*
- Sections III-D and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Kelly lab aims to develop micro-physiological systems of kidneys, intestines, and other organs to replace animal models, receive living organ tissue to create cell lines for research, and use intestinal organoids to understand drug disposition.
  - This lab works with lentiviral vectors, non-viral 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. Kelly.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kelly.
- f. Hamazaki, Nobuhiko, change, *Hamazaki: General Research*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Hamazaki lab is adding third generation lentiviral vectors for in vitro work.
  - 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. Hamazaki.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hamazaki.
- g. Lee, Kelly, renewal, *Structural studies of enveloped viruses and plasmodia*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Lee lab aims to develop vaccine design and anti-influenza virus inhibitors to understand how neutralizing antibodies target viral surface proteins and how better vaccines and antiviral therapeutics can be developed.
  - This lab does in vitro work with influenza viruses, gammaretroviral and lentiviral vectors, and Risk Group 2 Plasmodium species at BSL-2. They also work with Risk Group 1 Plasmodium species and non-viral rDNA at BSL-1.
  - 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. Lee.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lee, pending successful completion of the lab inspection.
- h. McGuire, Andrew, renewal, *Proof of Concept for an EBV Vaccine*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The McGuire lab aims to evaluate whether the presence of a neutralizing antibody can block experimental Epstein-Barr virus (EBV) infection and to evaluate whether sub-unit vaccines derived from proteins encoded by EBV can elicit antibodies that protect against viral infection.
  - This lab works with non-viral rDNA with enhanced gene delivery methods and wildtype Rhesus lymphocryptovirus at ABSL-2 in NHPs.
  - 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. McGuire.
  - The Committee voted unanimously to approve the draft BUA for Dr. McGuire.
- i. Singh, Pradeep, renewal, *Determinants of virulence and antimicrobial tolerance in biofilm and acute infections*
- Sections III-D and III-E
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Singh lab aims to examine how *Pseudomonas aeruginosa* and other bacteria interact with their host and with each other.
  - This lab does in vitro work with several species of Risk Group 2 bacteria at BSL-2, including *Klebsiella pneumoniae*, *Acinetobacter baumannii*, and *Staphylococcus aureus*.
  - 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. Singh.
  - The Committee voted unanimously to approve the draft BUA for Dr. Singh, pending successful completion of the lab inspection.
- j. Woodward, Joshua, renewal, *Targeted bacterial eradication using designed chimeric molecules*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Woodward lab aims to use rational design methods to create and test macrocycles and miniproteins to target bacterial pathogens for degradation by the host immune response.
  - This lab does works with several species of Risk Group 2 bacteria in vitro at BSL-2. They administer bacteria to mice at ABSL-2 including *Francisella novicida* and *Klebsiella pneumoniae*. They also work with non-pathogenic strains of *E. coli*, non-viral rDNA with enhanced gene delivery methods, and human source material in vitro.
  - A discussion occurred regarding occupational health requirements for the antibiotic resistant strains of bacteria. The Employee Health Center does not have medical management requirements, but they do want the lab personnel to be aware of which strains they are working with in case of an exposure.
  - 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. Woodward.
  - The Committee voted unanimously to approve the draft BUA for Dr. Woodward, pending a BUA application edit to include murine cells transduced with an ecotropic gammaretroviral vectors with oncogenic inserts.

## 7. SUBCOMMITTEE REPORTS:

- k. Banerjee, Ruhul, new, *A Phase 2, Open-Label, Multicenter Study of BMS-986393, a GPRC5D-directed CAR T Cell Therapy in Adult Participants with Relapsed or Refractory Multiple Myeloma (QUINTESSENTIAL)*
- 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, open-label, single-arm, multi-center phase 2 trial to evaluate safety and efficacy of a CAR-T cell therapy targeting GPRC5D for relapsed/refractory multiple myeloma.
  - Human cells transduced with third generation lentiviral vectors are administered to 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. Banerjee. Another member seconded the motion.

- The Committee voted unanimously to approve the draft BUA for Dr. Banerjee.
- I. Fertrin, Kleber, new, *A Phase 1/2 Study Evaluating The Safety And Efficacy Of A Single Dose Of Autologous Cd34+ Base Edited Hematopoietic Stem Cells (Beam-101) In Patients With Sickle Cell Disease And Severe Vaso-Occlusive Crises (Beacon Trial)*
- 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 phase 1, industry-sponsored, multi-site trial to evaluate the safety and efficacy of ex-vivo base edited hematopoietic stem and progenitor cells in patients with Sickle Cell Disease and severe vascular-occlusive crisis.
  - Human cells transfected with rDNA are administered to human subjects.
  - 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. Fertrin. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fertrin.

#### 10. FOR YOUR INFORMATION:

- **NIH Incident Response:**
  - The NIH has responded that no further information or action was required for a recent reportable rDNA incident involving a needlestick used while handling a non-human primate that had been inoculated with rDNA-modified cells.
  - A new NIH reportable rDNA incident is being investigated involving a scratch from a non-human primate that had been previously exposed to recombinant simian-human immunodeficiency virus (SHIV). The employee washed the injury for 15 minutes with a herpes B scrub kit containing a chlorhexidine solution and then reported to the emergency department for treatment. They have consulted with the UW Employee Health Center (EHC) for follow up care and monitoring.

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:20 A.M.**