



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, March 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. Richard Grant, Washington National Primate Research Center
 5. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 6. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 7. David Koelle, Allergy and Infectious Diseases
 8. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 9. Scott Meschke, Environmental & Occupational Health Sciences
 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*)

Commonly Used Abbreviations

BSL: Biosafety level

BSO: Biosafety officer

BUA: Biological Use Authorization

DURC: Dual Use Research of Concern

IACUC: Institutional Animal Care and Use Committee

IBC: Institutional Biosafety Committee

NHP: Non-human primate

NIH: National Institutes of Health

PI: Principal Investigator

rDNA: Recombinant or synthetic DNA/RNA

RG: Risk Group

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 February 15, 2023, meeting.
 - A member made a motion to approve the February 15, 2023, minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the February 15, 2023, meeting minutes with two members abstaining and one member not voting.
4. **OLD BUSINESS:**
 - At the February 15, 2023, meeting, Dr. Bryant's BUA was approved pending successful completion of the lab inspection and development of a medical management plan. This BUA has been sent.
 - At the February 15, 2023, meeting, Dr. Folch's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the February 15, 2023, meeting, Dr. Groat Carmona's BUA was approved pending clarification of the use of Dengue virus and if the plasmodium is recombinant. This BUA has been sent.
 - At the February 15, 2023, meeting, Dr. Jordan's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the February 15, 2023, meeting, Dr. Lagunoff's BUA was approved pending clarification of a Vaccinia strain. This BUA has been sent.
 - At the February 15, 2023, meeting, Dr. Stella's BUA was approved pending a biosafety level update to the BUA application. This BUA has been sent.
 - At the February 15, 2023, meeting, Dr. Fuller's BUA was approved pending occupational health review of vaccine strains of *Coccidioides posadasii*. 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. Van Gelder was approved for in vitro work with rDNA with and without enhanced gene delivery methods and non-pathogenic strains of *E. coli* on the BUA *Biome Representational in Silico Karyotyping (BRISK), cell and tissue culture, the study of circadian properties of mouse retina and SCN, NDC of the optical control of biological function* (Sections III-E and III-F).
 - Dr. Baneyx renewed the BUA *Baneyx Laboratory* for work with rDNA with enhanced gene delivery methods and non-pathogenic *E. coli* (Sections III-E and III-F).
 - Dr. Hsu renewed the BUA *Murine Norovirus and Helicobacter infections* working in vitro with non-viral rDNA, non-pathogenic *E. coli*, and wildtype RG 1 agents. (Section III-F)

- Dr. Nivala was approved for in vitro work with non-viral rDNA and non-pathogenic E. coli on the BUA *Molecular Information Systems and Nanopore Technology*. (Sections III-E and III-F)
- Dr. Green registered the BUA *Alpha-Emitter Targeting HIV Infected Cells* for work with non-human primate blood within primate center spaces. This work is covered by the primate center core BUA.
- Dr. Gelb renewed the BUA *Analysis of Inborn Errors of Metabolism in Human Blood Samples* working with human blood, tissue, body fluids, and cell lines in vitro .
- Dr. Temkin added new rooms for work with previously approved agents to the BUA *Clinical Evaluation of the i-STAT TBI Test*.
- Dr. Ting registered work adding new gene inserts for previously approved adeno-associated viral vectors.
- Dr. Lieberman was approved for in vitro work with non-pathogenic E. coli and wildtype RG 2 bacteria and viruses on the BUA *Development of rapid POC assays for infections and whole genome sequencing of leishmania*. (Section III-F)
- Dr. Carothers renewed the BUA *RNA Synthetic Biology* working with non-viral rDNA and recombinant RG 1 bacteria in vitro. (Sections III-E and III-F)
- Dr. Regnier updated rooms for use with previously approved agents on the BUA *Rodent Striated Muscle*.
- Dr. Moreno updated rooms for use with previously approved agents on the BUA *Calcium signaling in the aging pacemaker*.
- Dr. Lai was approved for in vitro work with human feces on the BUA *Household-scale bioprocess toilet system*.
- Dr. Mitchell added the use of wildtype Citrobacter rodentium in vitro and in mice to the BUA *Evolutionary, genetic, and molecular basis of host-pathogen interactions*.
- Dr. Meschke added the use of lesion and non-lesion samples suspected to be infected with monkeypox virus. This change also added the use of monkeypox nucleic acids to the BUA *Detection and Characterization of Pathogens in Environmental Media*. All work is in vitro. (Section III-F)
- Dr. Duthie was approved for in vivo work with non-viral rDNA with enhanced gene delivery methods on the BUA *RNA immunization strategies to protect against viral infections*. This research was reviewed by the IBC in September 2022. (Section III-D)
- Dr. Ruohola-Baker added animal research that was approved at the July 2022 IBC meeting to the BUA *microRNA Function in Human Embryonic Stem Cells*. (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 voted unanimously (with one member abstaining and one member not voting) to approve this month's Biosafety Officer Report.

6. INDIVIDUAL PROJECT REVIEWS

- a. Catterall, William, renewal, *Catterall Biohazards*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Catterall lab aims to understand the pathophysiological mechanisms that cause severe pain, epilepsy, autism, cognitive impairment, and heart failure.
 - This lab works with baculoviral vectors and adeno-associated viral vectors, non-viral rDNA, and non-pathogenic strains of *E. coli*.
 - 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. Catterall.
 - The Committee voted unanimously to approve the draft BUA for Dr. Catterall with one member not voting pending successful completion of the lab inspection.
- b. Cui, Yue, renewal, *Regulation of drug metabolism by developmental exposure to environmental chemicals and gut microbiome*
- *NIH Guidelines* Sections III-D and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Cui lab aims to understand the impact of environmental chemicals on host cell metabolism and genetic perturbations.
 - This lab works with human cell lines, human feces, and RG 1 bacteria in vitro and in mice.
 - 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. Cui.
 - The Committee voted unanimously (with one member not voting) to approve the draft BUA for Dr. Cui pending successful completion of the lab inspection.
- c. DeForest, Cole, renewal, *Protein Engineering in E. coli*
- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The DeForest lab aims to produce recombinant proteins using genetically engineered *E. coli* to direct mammalian cell function in a polymer scaffold.
 - This lab does in vitro work with adenoviral vectors and lentiviral vectors with oncogenic inserts and non-viral 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. DeForest.
 - The Committee voted unanimously to approve the draft BUA for Dr. DeForest.
- d. Hyde, Jenny, new, *Establishment of NHP model of VEEV infection*
- *NIH Guidelines* Section III-D applies.

- The assigned IBC Primary Reviewer presented the Primary Review.
 - The Hyde lab aims to establish a non-human primate model of natural Venezuelan equine encephalitis virus (VEEV) infection in pigtail macaques to define early infection events that impact pathogenesis and define the role of viral RNA structure in modulating these responses.
 - This lab works with recombinant Venezuelan equine encephalitis virus (VEEV) TC-83 strain (exempt from select agent regulations) both in vitro and in vivo.
 - 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. Hyde.
 - The Committee voted unanimously (with one member not voting) to approve the draft BUA for Dr. Hyde.
- e. *Perlmutter, Steve, renewal, Neural Plasticity for Learning and Rehabilitation*
- *NIH Guidelines* Section III-D applies.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Perlmutter lab aims to investigate the neural mechanisms underlying motor learning and recovery of motor function after central nervous system damage and to develop therapies to improve recovery.
 - This lab works with adeno-associated viral vectors in rat.
 - A lab inspection has been performed and is still pending a response.
 - All required trainings are complete.
 - The IACUC protocol has not yet been submitted.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Perlmutter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Perlmutter pending successful completion of the lab inspection and submission and review of the IACUC protocol.

7. SUBCOMMITTEE REPORTS:

- f. *Maloney, David, new, An Adaptive Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of Axicabtagene Ciloleucel versus Standard of Care Therapy as First-Line Therapy in Subjects with High-Risk Large B-Cell Lymphoma*
- *NIH Guidelines* Section III-C applies.
 - 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 (Kite), open-label multicenter phase III clinical trial to determine the benefit of axicabtagene ciloleucel as first-line therapy compared with standard chemoimmunotherapy in a high-risk large B-cell lymphoma population.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Maloney. Another member seconded the motion.

- The Committee voted unanimously (with one member not voting) to approve the draft BUA for Dr. Maloney.

- g. Shadman, Mazyar, new, *Allogeneic Natural Killer T-Cells Expressing CD19 Specific Chimeric Antigen Receptor and Interleukin-15 in Relapsed or Refractory B-Cell Malignancies 2 (ANCHOR2)*
 - *NIH Guidelines* Section III-C applies.
 - 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 multi-center phase I dose-escalation study of a KUR-502, an allogeneic CAR NK T cell product for patients with B cell lymphomas or acute lymphocytic leukemia.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Shadman. Another member seconded the motion.
 - The Committee voted unanimously (with one member recusing themselves and another member not voting) to approve the draft BUA for Dr. Shadman.

10. FOR YOUR INFORMATION:

- The BUA application is currently being updated. If any of the members have ideas to improve the application, please email them to Lesley Decker and cc Jennifer Cabarrus.

11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

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

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