



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, December 18, 2019

Time: 10:00 AM – 12:00 PM

Location: Foege N130A

Members Present:

1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
2. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
3. Richard Grant, Washington National Primate Research Center
4. Garry Hamilton (*Community Member*)
5. Kevin Hybiske, Allergy and Infectious Diseases
6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
7. Scott Meschke, Environmental & Occupational Health Sciences
8. Susan Parazzoli (*Community Member*)
9. Jason Smith, Microbiology (*IBC Vice Chair*)
10. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
11. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)

Commonly Used Abbreviations

IBC: Institutional Biosafety Committee

BSO: Biological Safety Officer

BUA: Biological Use Authorization

BSL: biosafety level

PI: Principal Investigator

IACUC: Institutional Animal Care and Use Committee

NIH: National Institutes of Health

DURC: Dual Use Research of Concern

SOP: standard operating procedure

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. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the November 20, 2019 meeting.
 - A member made a motion to approve the November 20, 2019 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the November 20, 2019 meeting minutes. There were four abstentions from members who were absent at the November 20, 2019 meeting.
4. **OLD BUSINESS:**
 - At the August 2019 meeting, Dr. Zhang's BUA was approved pending a successful lab inspection pending. This is still pending.
 - At the September 2019 meeting, Dr. Horwitz's BUA was approved pending IACUC review, testing HSV for resistance, and occupational health recommendations. This is still pending.
 - At the September 2019 meeting, Dr. Wood's BUA was approved pending a successful lab inspection. This is still pending.
 - At the November 2019 meeting, Dr. Fink's BUA was approved pending subcommittee review of Flavivirus use and combinations. This BUA has been sent out.
 - At the November 2019 meeting, Dr. Miller's BUA was approved pending a correction to a room on the BUA letter. This BUA has been sent out.
 - At the November 2019 meeting, Dr. Pepple's BUA was approved pending a successful lab inspection. This BUA has been sent out.
5. **BIOSAFETY UNIT'S TRANSITION TO EHSA:** A Biosafety Officer from EH&S presented on new software being used for electronic lab inspections and to produce BUA letters and reports.
6. **BIOSAFETY OFFICER (BSO) REPORT:** The Biosafety Officer Report includes (1) projects involving recombinant or synthetic nucleic acids covered under section III-E and III-F of the *NIH Guidelines*, (2) proposals involving non-recombinant biohazardous agents requiring BSL-1 and BSL-2 containment, and (3) administrative updates, such as room additions.
 - a. Biosafety Officer Report
 - Dr. Gale added a room to the BUA *The Host Response to Virus Infection*.
 - Dr. Sally Thompson-Iritani was approved for the BUA *Operation of WaNPRC Animal Housing and Support Facilities – ARCF, RR & I-wing*. This BUA renews and combines three separate BUAs that allow for non-human primate housing and/or procedures in these facilities.
 - Dr. Steinbrenner was approved for work with various BSL1 agents in vitro and in plants on the BUA *Function and Evolution of Plant Immune Receptors*.
 - The IBC Chair sought 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. **DURC REPORT:** The Dual Use Research of Concern Institutional Review Entity (DURC IRE) did not meet this month because there were no applications to review.

8. INDIVIDUAL PROJECT REVIEWS

a. Bruchas, Michael, change, *Neuromodulation in Affective Behavior*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The change to this BUA is to add vivarium locations and the use of rabies viral vectors in mice to facilitate neural tracing to identify monosynaptic projections.
- The lab was recently inspected, so a new lab inspection was not required for this change.
- All of the required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Bruchas.
- The Committee voted unanimously to approve the draft BUA for Dr. Bruchas.

b. Gerner, Michael, change, *Organization of Immunity*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The change to this BUA is to add the use of mouse tumor cells transduced with replication deficient lentiviral and gammaretroviral vectors containing OVA and fluorescent reporters for use in mice.
- The lab was recently inspected, so a new lab inspection was not required for this change.
- All of the required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gerner.
- The Committee voted unanimously to approve the draft BUA for Dr. Gerner.

c. Green, Damian, new, *Alpha-Emitter Targeting HIV Infected Cells*

- The assigned IBC Primary Reviewer presented the Primary Review.
- Macaques will be infected with SHIV and then treated with anti-retroviral agents. Blood samples will be collected and sent to PIs at Fred Hutch Cancer Research Center.
- The most significant biohazard is the SHIV infected animals and bodily fluids.
- An SOP for the facility regarding cage washing is in place in consultation with Radiation Safety. The IACUC protocol approves these procedures before initiation of work with animals.
- The lab was recently inspected under a core BUA, so a lab inspection was not required.
- All of the required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Green.
- The Committee voted unanimously to approve the draft BUA for Dr. Green.

d. Kenagy, Richard, renewal, *Kenagy Lab*

- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to define the regulation of the vascular response to injury. Work involves in vitro use of adeno-associated viral vectors and human cells.
 - The lab was inspected and no deficiencies were identified.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kenagy.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kenagy.
- e. Koelle, David, change, *Immune Response and Pathogenesis of Viral Infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The change to this BUA is to add the use of an RNA replicon for cell culture and in vivo experiments in mice by lipofection.
 - The lab was recently inspected under a core BUA, so a new lab inspection was not required.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Koelle.
 - The Committee voted unanimously to approve the draft BUA for Dr. Koelle.
- f. Mougous, Joseph, change, *Type VI secretion-dependent interbacterial interactions*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The change to this BUA is to add several bacteria for ongoing bacterial studies. These include the following: *Faecalibacterium prausnitzii*, *Blautia hydrogenotrophica*, *Eubacterium rectale*, *Collinsella aerofaciens*, *Eggerthella lenta*, *Desulfovibrio piger*, *Clostridium sordellii*, *Fusobacterium nucleatum*, *Francisella hispaniensis*, *Francisella philomiragia* and *Legionella pneumophila*.
 - Treatment methods for two bacterium were discussed to ensure that they are appropriate.
 - The lab inspection is scheduled to take place in January 2020.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Mougous pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mougous pending a successful lab inspection.
- g. Perlmutter, Steve, new, *Cellular Properties of NHP Cortical Neurons*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this application is to identify subpopulations of cortical neurons and characterize their cellular properties. Non-human primates will be injected with adeno-associated viruses expressing recombinant DNA that encodes a fluorescent protein prior to euthanasia and tissue extraction.
 - No lab inspection is required since all work takes place at the WaNPRC.
 - All of the required trainings have been completed.
 - 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.
- h. Rea, Shane, new, *Maintaining Mitochondrial Health into Old Age*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to define molecular mechanisms that can be used to counter mitochondrial dysfunction into old age. Work involves use of CRISPR and lentiviral vectors in human cells and *C. elegans*.
 - The lab was inspected and no deficiencies were identified.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Rea pending clarification of plasmid constructs and lentiviral vector gene inserts being used.
 - The Committee voted unanimously to approve the draft BUA for Dr. Rea pending clarification of plasmid constructs and lentiviral vector gene inserts being used.
- i. Shendure, Jay, renewal, *Shendure: General Research*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This BUA change is to use next generation sequencing to advance understanding of genetics in human illnesses, functional genomics, single-cell analysis and genome editing. This change is to include use of lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient and human cells transduced with lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient.
 - The lab was inspected and no deficiencies were identified.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Shendure.
 - The Committee voted unanimously to approve the draft BUA for Dr. Shendure.
- j. West, Timothy, change, *Host genetics and response to infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This BUA change adds bacteria for use in human, murine, and hamster cells and for use in mice. It also includes work with mouse and human macrophages transduced with lentiviral vectors, which are produced by another lab. Human and murine transduced cells will be used in vitro to evaluate bacterial killing.
 - The secondary reviewer clarified use of lentiviral vectors on the BUA letter. The lab is only working with cells transduced with lentiviral vectors from another lab, so lentiviral vector work will be removed from the BUA letter.
 - The lab was recently inspected, so a new lab inspection was not required for this change.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. West pending the removal of lentiviral vector work from the BUA letter.
 - The Committee voted unanimously to approve the draft BUA for Dr. West pending the removal of lentiviral vector work from the BUA letter.

9. SUBCOMMITTEE REPORTS:

- k. Turtle, Cameron, renewal, *A two-stage Phase 1 open-label study of huJCAR014, CD19-targeted chimeric antigen receptor (CAR)-modified T cells bearing a human binding domain, in adult patients with relapsed or refractory B-cell non-Hodgkin lymphoma and acute lymphocytic leukemia*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is an ongoing clinical trial to evaluate preliminary safety of huJCAR014 in adult patients with CD19+ relapsed/refractory (R/R) aggressive B-cell Non-Hodgkin lymphoma (NHL) and acute lymphoblastic leukemia (ALL). Study patients undergo leukapheresis to enable huJCAR014 product generation. Patients then enter the treatment phase and receive one cycle of huJCAR014 treatment. Patients will be followed for one year after their last dose of huJCAR014 for safety, disease status, and survival followed by a 15 year long-term follow up phase.
 - The main biosafety concern for lab personnel is percutaneous exposure to the product, but the product is expected to be rejected without adverse effects to the exposed individual.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Turtle. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Turtle.

10. FOR YOUR INFORMATION

11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:30 A.M.