



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, November 20, 2019

Time: 10:00 AM – 12:00 PM

Location: Foege N130A

Members Present:

1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
2. Garry Hamilton (*Community Member*)
3. Kevin Hybiske, Allergy and Infectious Diseases
4. David Koelle, Allergy and Infectious Diseases
5. Stephen Libby, Laboratory Medicine (*IBC Chair*)
6. Jason Smith, Microbiology (*IBC Vice Chair*)
7. 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 October 16, 2019 meeting.
 - A member made a motion to approve the October 16, 2019 minutes with the exception of a project from Dr. Nair that still requires review. Another member seconded the motion. Three members abstained from the vote.
 - The committee voted unanimously to approve the October 16, 2019 meeting minutes with the exception noted above.
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 October 2019 meeting, Dr. Nair's BUA was approved with the following conditions: 1) Approve HSV-1 at BSL-2 with the possibility of lowering containment to BSL-1 if data for RCV testing is provided; 2) Approve CAV and AAV as written conditional on providing a list of transgenes (If oncogenes are listed then this application must go back for full IBC review in November). This is still pending.
 - At the October 2019 meeting, Dr. Waterston's BUA was approved pending corrections to the BUA application. This BUA has been sent out.
 - At the October 2019 meeting, Dr. Green's BUA was approved pending PI response to IBC reviewer questions and additional subcommittee review. This BUA has been sent out.
5. **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. Adams Waldorf added in vitro use of *Staphylococcus aureus* to the BUA *Experimental Model for Chorioamnionitis and Preterm Labor*.
 - Dr. Heath's new BUA *Sorting the antigen specific T-cells for TCR sequencing* was approved. This projects works with human blood, tissue, body fluids, and cell lines in vitro.
 - Dr. Palmiter added new rooms for use of previously approved agents in mice to the BUA *Genetics of Mouse Behavior*.
 - Dr. Gale added use of RNA/single cell isolation from uninfected human and non-human primate tissues to the BUA *The Host Response to Virus Infection*.
 - Dr. Lidstrom renewed the BUA *Lidstrom Lab* using non-pathogenic strains of *Escherichia coli* and *Methylobacterium* in vitro.

- Dr. Arbabi was approved for use of human blood, tissue, body fluids, and cell lines in vitro for the BUA *Sample Processing for Clinical Research Studies*.
- Dr. Bryers added in vitro use of Klebsiella pneumonia and new rooms to the BUA *Periodontal Biomaterials with BITE (NIDCR) GRANT 1 Now Adding Biomaterials that Promote Infection Immunity (NIAID) GRANT 2*.
- Dr. Muller renewed the BUA *Andrology Research Lab / Male Fertility Lab*. This includes in vitro work with human and non-human primate blood, tissue, body fluids, and cell lines.
- Dr. Thompson-Iritani combined previously approved BUAs for non-human primate housing and procedures onto the BUA *Operation of WaNPRC Animal Housing and Support Facilities - ARCF, RR & I-wing*.
- Dr. Nakamura added in vitro use of non-human primate tissue to the BUA *NR2E3 Signaling to treat inherited retinal disease*.
- Dr. Andrews was approved for in vitro use of human blood, tissue, body fluids, and cell lines on the BUA *SHAPE - Sarcopenia as a predictor of Hospital-Associated ADL Disability in Older Adults*.
- 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 pending a change to the BSL listed on the Arbabi BUA. Another member seconded the motion.
- The Committee unanimously voted to approve this month's Biosafety Officer Report pending the change above.

6. 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.

7. INDIVIDUAL PROJECT REVIEWS

- a. Cabernard, Clemens, renewal, *Cellular and molecular mechanisms of asymmetric cell division*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project uses recombinant DNA with enhanced gene delivery methods to create transgenic fruit flies for investigation of how their cells position the molecular machinery used for cell division.
 - 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. Cabernard.
 - The Committee voted unanimously to approve the draft BUA for Dr. Cabernard.
- b. Doulatov, Sergei, renewal, *Hematopoiesis from cord blood and pluripotent stem cells*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project studies the biology of hematopoietic stem cells isolated from umbilical cord blood and generates hematopoietic cells from induced pluripotent stem cells in order to understand and model development and disease.
 - This work involves viral vectors in vitro and transfer of transfected cells in mice.
 - 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. Doulatov.
 - The Committee voted unanimously to approve the draft BUA for Dr. Doulatov.
- c. Ennis, Jeanette, new, *RGD siRNA carriers in vivo assessment*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab is developing carriers to deliver siRNA and human cells with recombinant DNA to tumors in mice.
 - 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. Ennis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ennis.
- d. Fink, Susan, renewal, *Host-Pathogen Interactions During Viral Infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies viral pathogenesis using human and non-human primate cell lines and mouse cells with lentiviral vectors, Zika, VSV (Indiana), HSV1 (KOS), E. coli, Salmonella Typhimurium, Y. pseudotuberculosis, Yellow fever (vax strain 17D), replication-deficient pseudotyped Flaviviruses, and gammaretroviral vectors in mice.
 - The IBC requests that the PI send a list of Flavivirus use and combinations for subcommittee review.
 - 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. Fink pending subcommittee review of Flavivirus use and combinations.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fink pending the condition stated above.
- e. Miller, Samuel I., renewal, *Role of the phoP Regulon and Salmonella Virulence/Regulation of Salmonella Invasion of Epithelia/SPI2*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The focus of the research is on the Salmonella invasion, the role of the phoP regulon and invasion, and the role of several pathogenicity islands on invasion and virulence.
 - Work involves human and murine cells and Salmonella, Pseudomonas, Acinetobacter, Yersinia, pathogenic E.coli, and BCG.
 - 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. Miller pending a correction to a room on the BUA letter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Miller pending the above change to the BUA letter.
- f. Pepple, Kathryn, renewal, *The role of the innate and adaptive immune system in a novel model of uveitis*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This project works to better understand the mechanisms of uveitis or ocular inflammation and develop new treatments for patients.
- The lab uses adeno-associated viral vectors (adenovirus free) and human blood, tissue, body fluids, and cell lines in mice.
- A lab inspection is still required for this approval.
- 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. Pepple pending a successful lab inspection.
- The Committee voted unanimously to approve the draft BUA for Dr. Pepple pending a successful lab inspection.

8. SUBCOMMITTEE REPORTS:

- g. Schweizer, Michael, new, *CART-PSMA-TGF β RDN-02 A Phase 1 Open-Label, Multi-Center Study of PSMA Targeted Genetically Modified Chimeric Antigen Receptor T Cells in Patients with Metastatic Castration Resistant Prostate Cancer*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a CART therapy trial for metastatic castration resistant prostate cancer (mCRPC). This is not a first in humans trial. In a prior trial with the same CAR molecule there was dose limiting toxicity especially with chemotherapy, so the goal of this study is to find the best dose of CART cells and accompanying lymphodepletion (LD) chemotherapy for future studies.
 - The greatest biosafety issue to personnel is percutaneous exposure to the cell infusion product.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Schweizer. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Schweizer.

9. UNIVERSITY POLICY FOR CHEMICAL AND PHYSICAL SAFETY IN LABS INCLUDING THE NEW INSTITUTIONAL CHEMICAL AND PHYSICAL SAFETY COMMITTEE

- The Director of EH&S presented on a new university policy and committee being formed to support safety and compliance in research and academic labs and other research environments. The Chemical and Physical Hazards in Research Safety Committee is an independent committee led by faculty, administered by EH&S, and overseen by Health Sciences Administration. The Committee will identify deficiencies, form an escalation policy, and provide outreach, education, and engagement to the University.

10. FOR YOUR INFORMATION:

- **NIH Incident Report:** A biohazard bag that contained biohazardous waste was not intact and was placed into a secondary bag by a researcher. At the time of contact between the two bags, a liquid aerosol formed and dispersed mist and droplets that got on the face of the researcher. The researcher was only wearing nitrile gloves, no laboratory coat or eye protection. Laboratory procedures have been evaluated and

updated. This incident was reported to the NIH as the biohazardous waste contained recombinant viruses. The NIH OSP stated that the University's response was appropriate, and that no further action was required.

- The IBC discussed established human cell lines that have been tested for known pathogens being downgraded from BSL2 to BSL1 by other institutions. These requests will continue to be reviewed on a case-by-case basis by the UW IBC.
- Registration is open for the 2020 Northwest Association for Biomedical Research (NWABR) conference on February 26. Committee members were encouraged to attend.

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.