



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, November 17, 2021

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. Kevin Hybiske, Allergy and Infectious Diseases
 8. David Koelle, Allergy and Infectious Diseases
 9. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 10. Scott Meschke, Environmental & Occupational Health Sciences
 11. Jason Smith, Microbiology (*IBC Vice Chair*)
 12. 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 10:03 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 20, 2021 meeting.
 - A member made a motion to approve the October 20, 2021 minutes. Another member seconded the motion.
 - The committee voted to approve the October 20, 2021 meeting minutes. There were two voting abstentions.
4. **OLD BUSINESS:**
 - At the September 15, 2021 meeting, Dr. Greninger's BUA was approved pending clarification from the PI, BUA edits, and any necessary BUA letter edits. This BUA has been sent out
 - At the September 15, 2021 meeting, Dr. Tang's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
 - At the October 20, 2021 meeting, Dr. Darnell's BUA was approved pending an additional footnote on the BUA letter. This BUA has been sent out.
 - At the October 20, 2021 meeting, Dr. Deng's BUA was approved pending completion of required trainings. This BUA has been sent out.
 - At the October 20, 2021 meeting, Dr. Gerner's BUA was approved pending additional information requested of the PI. This BUA is still pending.
 - At the October 20, 2021 meeting, Dr. Murry's BUA was approved pending review of the IACUC protocol. 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. Nilsson renewed the BUA *Microbial Lipid Extraction* working with various BSL-2 organisms in vitro.
 - Dr. Scatena added a new room and core facility to the BUA *Endothelial cells for tissue engineering and osteoprotegerin in atherosclerosis*.
 - Dr. Soge renewed the BUA *Surveillance of antimicrobial resistance in Neisseria gonorrhoeae and molecular detection of sexually transmitted pathogens* working with non-viral recombinant or synthetic DNA/RNA.
 - Dr. Andrews was approved for work with human blood, tissue, body fluids, and cell lines on the BUA *COPE Study- COVID19 Outcomes in Physical Health*.
 - Dr. Wurfel renewed the BUA *Human Innate Immune Variation* working with non-viral recombinant or synthetic DNA/RNA.
 - Dr. Sancak added the use of cell sorting facilities to the BUA *Role of mitochondrial calcium uptake in health and disease*.
 - Dr. Johnson Erickson added the use of human cells in rats to the BUA *Predicting Therapy Response*.

- Dr. Shendure added the use of exempt human iPS cells (III-F), human embryonic stem cells, recDNA with enhanced gene delivery methods, and new gene inserts for third generation lentiviral vectors to the BUA *Shendure: General Research*.
- Dr. Neitz took over as PI of the BUA *Assessment of Visual Capacities in Primates* working with adenovirus free adeno-associated viral vectors in macaques.
- Dr. Adams Waldorf added a new room the BUAs *Experimental Model for Chorioamnionitis and Preterm Labor*, *Experimental Model of Viral-Induced Brain Injury*, and *Influenza and Coronavirus Model of Immunity in Pregnancy*.
- Dr. Dunham added the use of recombinant and wildtype *Geotrichum candidum* for use at BSL-1 to the BUA *Genome Evolution in Yeast*.
- Dr. Poolos added a new room to the BUA *Epilepsy and Dendritic Excitability*.
- Dr. Stetson added the use of *Listeria monocytogenes* and Sendai virus (non-recombinant) in vitro and in mice to the BUA *Mechanisms and Consequences of Innate Immune Detection of Nucleic Acids*.
- Dr. Vavilala was approved for work with human blood, tissue, body fluids, and cell lines on the BUA *Mechanisms and Clinical Implications of Myocardial Injury Following Traumatic Brain Injury*.
- Dr. Wander was approved for work with non-viral recombinant or synthetic DNA/RNA on the BUA *Circulating miRNA signatures of beta-cell response in youth validation study*.
- 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. BSL-3 INACTIVATION REPORT

- There were no applications to review this month.

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. SECTION III-D REPORT

- a. Disis, Mary, renewal, *UW Gene and Cell Core Therapy*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This BUA covers the UW Gene and Cell Therapy core facility that provides services for UW investigators and industry sponsored studies.
 - A lab inspection has been successfully completed with no findings.
 - 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. Disis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis.

9. INDIVIDUAL PROJECT REVIEWS

- b. Bosma, Martha, renewal, *A characterization of Hydra Gap Junctions*

- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project aims to characterize the proteins that mediate electrical connections between cell sin Hydra, a freshwater jellyfish.
 - A lab inspection is scheduled but has yet to be completed.
 - 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. Bosma pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Bosma pending completion of a successful lab inspection.
- c. Fujise, Ken, change, *Study of Fortilin*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds the use of ecotropic gammaretroviral vectors with oncogenic inserts, for in vitro use.
 - The lab was recently inspected, so one is 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. Fujise.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fujise.
- d. Horwitz, Greg, change, *Neurology of Vision*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change add recombinant Sindbis viral vector for in-vitro uses.
 - The lab was recently inspected, so one is 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. Horwitz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Horwitz.
- e. Hotchkiss, Charlotte, new, *CNS Injections in NHP*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to utilize adeno-associated viral vector (adenovirus free) CNS injections to increase knowledge of anatomical pathways of macaques within the brain.
 - The WaNPRC Vivarium locations are inspected on a regular basis so a lab inspection was not required for this project.
 - 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. Hotchkiss.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hotchkiss.
- f. Neitz, Maureen, renewal, *Assessment of Visual Capacities in Primates*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies retinal circuitry for vision by using adeno-associated viral vectors (adenovirus free) in macaques.
 - The lab had been recently inspected 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. Neitz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Neitz.
- g. Nghiem, Paul, renewal, *Merkel Cell Carcinoma Studies*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab conducts in vitro work to investigate Merkel Cell Carcinoma.
 - A lab inspection has been successfully completed with one minor finding resolved.
 - 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. Nghiem.
 - The Committee voted to approve the draft BUA for Dr. Nghiem. There was one voting abstention.
- h. Phillips, James, new, *Safety and efficacy of intracochlear delivery of AAV in the non-human primate*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to utilize adeno-associated viral vectors (adenovirus free) to restore hearing function to patients with congenital deafness due to biallelic mutations of the otoferlin gene.
 - The WaNPRC Vivarium locations are inspected on a regular basis so a lab inspection was not required for this project.
 - 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. Phillips.
 - The Committee voted unanimously to approve the draft BUA for Dr. Phillips.
- i. Pun, Suzie, renewal, *Biomaterials for biomedical applications*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research goal is to develop drug delivery vehicles and biomaterials for biomedical applications.
 - A lab inspection is scheduled but has yet to be completed.
 - All of the required trainings have been completed.
 - The IACUC protocol has yet to be submitted and will require review before approval.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Pun pending completion of a successful lab inspection and review of the IACUC protocol.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pun pending the items stated above.
- j. Regnier, Michael, renewal, *Rodent Striated Muscle*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies muscle cell function, including stem cell and gene therapy approaches to treat diseased cardiac and skeletal muscle.
 - After discussion, the Committee requests clarification regarding the nature of the iPS cells for use.
 - Issues identified during a lab inspection require correction before approval.

- All of the required trainings have been completed.
 - The IACUC protocol has yet to be submitted and will require review before approval.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Regnier pending clarification of iPS cells, completion of a successful lab inspection, and review of the IACUC protocol.
 - The Committee voted unanimously to approve the draft BUA for Dr. Regnier pending the items stated above.
- k. Starita, Lea, change, *Brotman Baty Advanced Technology Lab: General Research*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds a new human iPS cell line that was made with lentiviral vectors expressing oncogenes.
 - The cells are approved at BSL-2 with BSL-3 practices prior to RCV testing, but they can be used at BSL-2 if RCV testing shows no replication competent virus is present.
 - SOPs for BSL-2 with BSL-3 practices work is still needed prior to approval.
 - A successful lab inspection still needs to be conducted.
 - 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. Starita pending SOPs for BSL-2 with BSL-3 practices work and completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Starita pending the items stated above.
- l. Wang, Wang, renewal, *Role of mitochondria in cardiac physiology and disease*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the role of mitochondrial functions such as respiration, calcium, reactive oxygen species and dynamics in the heart under normal and disease conditions. Work includes use of various viral vectors and human cell lines.
 - After discussion, the Committee requests that the lab include information to the BUA application regarding possible oncogenes and use of E. coli strains.
 - A lab inspection has been successfully completed with no findings.
 - 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. Wang pending the additional information requested.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wang pending the additional information requested.
- m. Yang, Xiaoming, renewal, *Interventional Oncology (Rabbits)*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The purpose of this work is to develop new technologies of radiofrequency (RFA) heating enhanced gene therapy or chemotherapy for human pancreaticobiliary, hepatic, and esophageal malignancies.
 - A lab inspection has been successfully completed with no findings.
 - 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. Yang.
- The Committee voted unanimously to approve the draft BUA for Dr. Yang.

10. SUBCOMMITTEE REPORTS:

- n. Cowan, Andrew, new, *AN EXPLORATORY PHASE 1/2 TRIAL TO DETERMINE RECOMMENDED PHASE 2 DOSE(RP2D), SAFETY AND PRELIMINARY EFFICACY OF BB2121 (IDE-CEL) COMBINATIONS IN SUBJECTSWITH RELAPSED/REFRACTORY MULTIPLE MYELOMA - (KARMMA-7)*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - Multiple Myeloma (MM) has inadequate treatment. This is an autologous CART adoptive immunotherapy trial in which persons with relapsed or refractory (R/R) MM will be infused with their own T cells genetically modified to kill their MM cells.
 - The greatest risk to staff is percutaneous exposure of the cell product.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Cowan. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Cowan.
- o. Maloney, David, new, *A Phase 1, First-In-Human, Open-Label, Multicenter, Multicohort Study of CD4 Targeted Chimeric Antigen Receptor T-Cells (CD4-CAR-T) in Subjects with Relapsed or Refractory T-cell lymphoma (TCL)*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is an industry-sponsored, multi-center, open-labeled, first-in-human phase 1 clinical trial of CD4 targeted CAR-T cells to treat patients with relapsed/refractory T cell lymphoma. The overall objective is to establish safety and determine the optimal dose for a future phase 2 study.
 - The greatest risk to staff is percutaneous exposure of the cell product.
 - 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 to approve the draft BUA for Dr. Maloney.
- p. Shadman, Mazyar, new, *A Phase 1/2, Open Label, Multicenter Study to Assess the Safety, Tolerability and Efficacy of MB-106 in Patients with Relapsed or Refractory CD20+ B-Cell Non-Hodgkin Lymphoma or Chronic Lymphocytic Leukemia*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is an industry-sponsored, phase 1/2, multi-center, open-label study of a CD20 targeting CAR-T product to treat patients with relapsed/refractory CD20+ B-cell NHL and CLL.
 - The greatest risk to staff is percutaneous exposure of the cell product.
 - 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 to approve the draft BUA for Dr. Shadman. There was one voting abstention.

10. FOR YOUR INFORMATION:

- **NIH Incident Report:** A research assistant (RA) was working along with a PhD student in a BL-1 laboratory room inoculating plants with a recombinant *Agrobacterium tumefaciens* (disarmed strain GV3101) using a 1 mL plastic syringe without a needle. Pressure built up while the RA was trying to inject the liquid culture into the interstitial space of a plant leaf. The pressure caused the culture of *Agrobacterium* to squirt into the RA's left eye. There is no eye wash in this room, so one will be installed. And while a BUA is in place for this project, the room where the incident took place is not listed and must be added.
- **Occupational Health Update for *Listeria Monocytogenes***

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:41 A.M.