



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, January 16, 2019

Time: 10:00 AM – 12:00 PM

Location: Foegen N130A

- Members Present:**
1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 2. H.D. “Toby” Bradshaw, Biology (*Plant Expert*)
 3. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 4. Garry Hamilton (*Community Member*)
 5. David Koelle, Allergy and Infectious Diseases
 6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 7. Scott Meschke, Environmental & Occupational Health Sciences
 8. Matthew R. Parsek, Microbiology
 9. Tina Rogers (*Community Member*)
 10. Jason Smith, Microbiology (*IBC Vice Chair*)
 11. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
 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 10:02 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 December 12, 2018 meeting.
 - A member made a motion to approve the December 12, 2018 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the December 12, 2018 meeting minutes. There was one abstention from a member who was not present at December's meeting.
4. **OLD BUSINESS:**
 - At the July meeting, Dr. Patel's BUA was approved pending a lab inspection.
 - At the September meeting, Dr. Greninger's BUA was approved pending a successful lab inspection.
 - At the October meeting, Dr. Stuber's BUA was approved pending a lab inspection and room changes to the BUA letter.
 - At the November meeting, Dr. Bornfeldt's BUA was approved pending additions to the BUA letter.
 - At the November meeting, Dr. Steinmetz's BUA was approved pending a successful lab inspection.
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. Muller added the use of non-human primate cells to the BUA *Andrology Research Lab / Male Fertility Lab*.
 - Dr. Muczynski renewed the BUA *Kidney Immunological Research*, using human blood, tissue, body fluids, and cell lines in vitro.
 - Dr. Fuller added a new room to the BUA *Evaluation of SIV Co-Infection on ZIKV Pathogenesis in Pigtail Macaques*.
 - Dr. Hsu renewed the BUA *Transgenic Resources Program* creating transgenic mice.
 - Dr. Kublin's BUA *Role of the microbiome in HIV vaccine induced heterogeneity* added previously approved agents in the Foegen vivarium after moving from the K-wing vivarium.
 - Dr. Brindle renewed the BUA *CSDE Biodemography Core* using human and non-human primate blood, tissue, body fluids, and cell lines in vitro.
 - Dr. Shen renewed the BUA *Bioanalytical Core for UW Obstetric-Fetal Pharmacology Unit* approving use of human blood, tissue, body fluids, and cell lines in vitro.
 - Dr. Thummel removed and added rooms for the BUA *CYP3A Regulation*.
 - Dr. Paredez removed and added rooms for the BUA *Study of the Cytoskeleton and Membrane trafficking in Giardia lamblia*.

- Dr. McLean renewed the BUA *Domestication and characterization of TM7* approving several BSL 2 agents for in vitro use.
- Dr. Yadav removed and added rooms for the BUA *Signaling in neuronal development and disease*.
- Dr. Zhang renewed the BUA *Polymeric/Ceramic Scaffolds for Tissue Engineering* approving use of human blood, tissue, body fluids, and cell lines in mice, rats, and in vitro.
- Dr. Fernandes renewed the BUA *Cartilage Collagen* approving use of human blood, tissue, body fluids, and cell lines in vitro.
- Dr. Parrish's lab for the BUA *Extrinsic signals required for maintenance of dendrite coverage* moved to a new location.
- Dr. Winkler added new rooms and use of exempt E. coli and human urine to his BUA *Winkler Lab*.
- Dr. Starita added a room to the BUA *Brotman Baty Advanced Technology Lab: General Research*.
- 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.

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

- Disis, Mary, renewal, *UW Gene and Cell Therapy Core*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project is capable of processing apheresis products, blood separation, stem cell enrichment, T cell subset selection or deletion, manufacturing gene modified cells, and ex-vivo manipulation of cells for novel gene and cell therapy products.
 - Potential exposure to human blood, blood borne pathogens, and viral vectors was listed as the greatest hazard.
 - 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. Disis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis.
- Disis, Mary, renewal, *Evaluation of Immunity to Cancer in a Rodent Model*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab designs and generates plasmid-based "naked DNA" vaccines encoding one or more antigen sequences. The goal of this research is to develop diagnostic, preventative, or treatment options to battle cancer.
 - The greatest hazard listed by the PI is the potential for blood borne pathogen exposure via human blood or tissues.
 - 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. Disis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis.
- Disis, Mary, new, *Vaccination in a modified microbiome*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project includes plasmid cloning and production in K-12 E.coli. The plasmids are used in cell culture and given to mice as part of the lab's work on DNA vaccines against cancer.
 - The greatest hazard listed by the PI is the potential for blood borne pathogen exposure via human blood or tissues.
 - 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. Disis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis, pending correction of the BUA application.
- Kojima, Yoshiko, new, *A Neuronal Process of the Error Signal That Drives Saccade Adaption*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this research is to implement optical manipulation of electrical activity in the brain by optimizing viral vectors and injection techniques in rhesus macaques.
 - The greatest risk to laboratory personnel is potential exposure to Herpes B.
 - Discussion by the committee clarified that all research in macaques must be approved at a minimum BSL 2.
 - 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. Kojima pending issues listed in recommendations.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kojima.
- Nghiem, Paul, new, *Merkel Cell Carcinoma Studies*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project investigates the T cell response to Merkel cell carcinomas. The lab will work with primary human skin and tumor cells in conjunction with lentiviral, HSV, or gamma retroviral vectors in vitro to express T cell receptor genes of interest and siRNA. EBV will transform human primary cells to lymphoblastic cell lines. African Green Monkey and mouse cell lines will also be used.
 - The use of gamma and lentiviral vectors poses the greatest risk to laboratory personnel.
 - 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. Nghiem.
 - The Committee voted unanimously to approve the draft BUA for Dr. Nghiem pending completion of the BUA application. One member left the room during the vote because of a conflict.

- Noss, Erika, renewal, *Understanding Fibroblasts Role in Autoimmune Diseases*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab works on fibroblasts in inflammation. Biohazards include human cells and cell lines and lentiviral vectors in cell culture. Additional recombinant DNA work includes cloning in K-12 E.coli and the use of siRNA and plasmids in cell lines.
 - The committee clarified that 1st and 2nd generation lentiviral vectors must be used at BSL2 w/3 practices.
 - 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. Noss.
 - The Committee voted unanimously to approve the draft BUA for Dr. Noss pending the lab sends verification that third generation lentiviral vectors are indeed being used.

- Orsborn, Amy, new, *Adaptive neural interfaces for treating neurological disorders and probing neural function*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project develops neural interfaces to restore sensorimotor function using a non-human primate model. Viral vectors are used to delivery promoters and genes that lead to expression of light-sensitive and/or light-emitting proteins within neurons, allowing measurement and manipulation of their activity.
 - The greatest risks are exposure to Herpes B virus and lentiviral vectors.
 - 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. Orsborn.
 - The Committee voted unanimously to approve the draft BUA for Dr. Orsborn.

- Perlmutter, Steve, new, *Neural Plasticity for Learning and Rehabilitation*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project investigates the mechanism underlying motor learning and recovery of motor function after central nervous system damage, as well as developing therapies that will improve recovery through activation of the neural pathways.
 - The greatest biohazard is the stereotactic injection of adeno-associated viral vectors into rats.
 - The lab was inspected and no deficiencies were identified.
 - All of the required trainings have been completed.
 - An occupational health referral was recommended for lab personnel. Occupational Health will discuss this with the nurse practitioner to gain more information about the tetanus toxin.
 - The IACUC protocol amendment has yet to be 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 to approve the draft BUA for Dr. Perlmutter pending occupational health consultation and IACUC submission.

- The approval of this project is being held until additional significant concerns raised by IBC members are sufficiently addressed by the PI.

- Queitsch, Christine, change, *Tandem repeats as a source of phenotypic variation*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project uses transgenic plants, worms, and yeast as model organisms to try to understand how repetitive DNA elements contribute to heritable phenotypic variation within and among species.
 - 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. Queitsch.
 - The Committee voted unanimously to approve the draft BUA for Dr. Queitsch.

- Ruohola-Baker, Hannele, renewal, *microRNA Function in Human Embryonic Stem Cells*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this research is to understand the function of microRNAs in the generation of human and murine embryonic stem cells. Methods include transduction of cell lines with lentiviruses, genetic engineering of plasmids in laboratory strain E.coli, microRNA work and delivery by lentiviral vectors or by RNA transfection, and teratoma work with iPSCs.
 - 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. Ruohola-Baker.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ruohola-Baker. The biosafety officer will verify any additional laboratory staff and have oncogenes checked on the BUA application.

- Woodward, Joshua, renewal, *Staphylococcus aureus and Pseudomonas aeruginosa pathogenesis and host response*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to study the molecular mechanisms that allow Staphylococcus aureus and Pseudomonas aeruginosa to infect and cause tissue damage to eukaryotic hosts.
 - The greatest biohazardous risk to laboratory personnel is working with Staphylococcus aureus and Pseudomonas aeruginosa.
 - Vague portions regarding genes and drug markers in the BUA application require additional information.
 - 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. Woodward.
 - The Committee voted unanimously to approve the draft BUA for Dr. Woodward pending changes to the BUA application.

8. SUBCOMMITTEE REPORTS:

- Krakow, Elizabeth, new, *Phase I trial with “off-the-shelf” third-party BPX-501 donor lymphocyte immunotherapy to treat persistence or relapse of hematologic malignancies after allogeneic stem cell transplantation*
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This research strives to harness an additional anti tumor effect by infusing donor T cells into patients with relapse after HSCT, but also to provide a safety switch to be able to eliminate these cells if they become too aggressive in the patient and cause graft versus host disease. Donor lymphocytes are genetically modified with a retrovirus encoding a potentially cell auto-destructive protein that can be activated by oral administration of a small molecule drug.
 - The possibility of RCR exposure to medical staff, if RCR is present in the cell product, is the greatest risk.
 - The lab was inspected and no deficiencies were identified.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Krakow. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Krakow.
- Mougous, Joseph, change, *Type VI secretion-dependent interbacterial interactions*
 - Three members of the IBC served as the Subcommittee Reviewers. They were assisted by three ad hoc reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This BUA change application adds recombinant Mycobacterium abscesses in vitro.
 - The subcommittee recommends that all work with M. abscesses be performed at BSL2 and in a manner which minimizes aerosol generation of the pathogen. If possible, the manipulation of the pathogen should be performed in the biosafety cabinet. An appropriate surface decontaminant is to be identified to clean work spaces. All personnel working with or near this pathogen require occupational health screening and consultation.
 - The lab was recently inspected, so no inspection is required for this change.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Mougous. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mougous. The comment field will be revised to reference the medical management plan, which will also be sent along with the BUA letter.

10. FOR YOUR INFORMATION:

- **Biosafety Manual Updates:** Updates to the Biosafety Manual for 2019 were presented. The committee voted to approve all changes made.
- **2018 Metrics:** A presentation was given regarding biological use authorizations in 2018.

- **Clinical Trial Application Edits:** Updates to the clinical trial application were presented. The committee voted to approve all changes made.
- **EH&S Annual Report:** The EH&S FY2018 Annual Report was provided to committee members.

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

12. MEETING ADJOURNED AT APPROXIMATELY 12:00 P.M.