



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, August 21, 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. David Koelle, Allergy and Infectious Diseases
4. Stephen Libby, Laboratory Medicine (*IBC Chair*)
5. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
6. 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 10:05 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 July 17, 2019 meeting.
 - A member made a motion to approve the July 17, 2019 minutes pending one change to the attendance list. Another member seconded the motion.
 - The committee voted unanimously to approve the July 17, 2019 meeting minutes pending the change above. There was one abstention from a member who was not present at the July IBC meeting.
4. **OLD BUSINESS:**
 - At the July 2018 meeting, Dr. Patel's BUA was approved pending a lab inspection. This is still pending.
 - At the October 2018 meeting, Dr. Stuber's BUA was approved pending a lab inspection and room changes to the BUA letter. This is still pending.
 - At the November 2018 meeting, Dr. Bornfeldt's BUA was approved pending additions to the BUA letter. This is still pending.
 - At the February 2019 meeting, Dr. Nahmani's BUA was approved pending a lab inspection and verification of third generation lentiviral vectors. This BUA has been sent out.
 - At the March 2019 meeting, Dr. Bajjalieh's BUA was approved pending additional information to the BUA. This BUA has been sent out.
 - At the July 2019 meeting, Dr. Bornfeldt's BUA was approved pending a BUA application change. This BUA has been sent out.
 - At the July 2019 meeting, Dr. Darvas' BUA was approved pending review of the IACUC protocol. This BUA has been sent out.
 - At the July 2019 meeting, Dr. Dhaka's BUA was approved pending a successful lab inspection, review of the IACUC protocol, and BUA application changes. This BUA has been sent out.
 - At the July 2019 meeting, Dr. Hybiske's BUA was approved pending a successful lab inspection. 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. Ho renewed the BUA *Mechanisms of Targeting Drugs to the Lymphatics* using human blood, tissue, body fluids, and cell lines in mice and in vitro.
 - Dr. Nghiem added a new room for in vitro work with previously approved agents to the BUA *Merkel Cell Carcinoma Studies*.
 - Dr. Isoherranen added the Pathology Flow Cytometry Core Facility to their BUA *Mechanisms of Regulation of Retinoic acid homeostasis*.

- Dr. Lieber added the Foege vivarium to their BUA *Stem Cell and Gene Therapy of Cancer and Hematological Diseases*.
- Dr. Grady renewed the BUA *Gastrointestinal Cancer Resource (GICaRes) Biorepository* using human blood, tissue, body fluids, and cell lines in vitro.
- Dr. Doulatov added rooms for in vitro work with previously approved agents to the BUA *Hematopoiesis from cord blood and pluripotent stem cells*.
- Dr. Vojtech renewed the BUA *Mechanisms of sexual virus transmission* using Herpes simplex virus 2, Zika virus, and human and non-human primate blood, tissue, body fluids, and cell lines in vitro.
- Dr. Greninger added a room for in vitro work with previously approved agents to the BUA *Discovery and Characterization of Virus-Host Interactions*.
- Dr. Kim was approved to work with human blood, tissue, body fluids, and cell lines in vitro on the new BUA *ctDNA Next Generation Sequencing Development*.
- Dr. Davis added a new animal surgery room to the BUA *The cellular and molecular mechanism of cardiac wound healing and fibrotic remodeling*.
- Dr. Ho renewed the BUA *Targeting Drug to HIV Sanctuary in Lymphatics* using non-human primate blood, tissue, body fluids, and cell lines in vitro.
- Dr. Oberst added the use of *Chromobacterium violaceum* in mice in previously approved rooms on the BUA *Programmed Cell Death and Immunity*.
- Dr. Bakker was approved to work with non-pathogenic Bacterial endophyte isolates, *Achillea millefolium*, and *Castilleja levisecta* in plants on the new BUA *Bacterial endophytes and hemiparasites*.
- Dr. Paik took over the BUA *Linking Innate and Adaptive Immunity* from Dr. Meeker. This BUA works with various BSL1 and 2 agents in mice and in vitro.
- Dr. Adams Waldorf was approved to work with Influenza A virus strains and human and non-human primate blood, tissue, body fluids, and cell lines in vitro and in macaques on the new BUA *Influenza Virus Model of Immunity in Pregnancy*.
- Dr. Stella's lab for the BUA *ST in PD-GBM* changed locations. Their work involves human blood, tissue, body fluids, and cell lines in vitro and in mice.
- Dr. Hsu took over the BUA *Inflammatory Bowel Disease, Colon Cancer, Diet and the Microbiome* from Dr. Meeker. This BUA works with various BSL 1 and 2 agents in vitro and in mice.
- Dr. Veesler was approved to work with human blood, tissue, body fluids, and cell lines in vitro on the new BUA *Expression of recombinant proteins using mammalian cell lines*.
- Dr. Sen renewed the BUA *Identification and characterization of E. coli, Campylobacter and Salmonella present in wetland water and crow feces within the Bothell Campus* working with various BSL2 agents in vitro.
- Dr. Lood renewed the BUA *Neutrophil contribution to inflammation and autoimmunity in rheumatic diseases* working with human blood, tissue, body fluids, and cell lines and enhanced gene delivery methods in vitro.
- Dr. Limaye renewed the BUA *Limaye Clinical Research* working with human blood, tissue, body fluids, and cell lines in vitro.
- Dr. Davis added the Immunology Cell Analysis Facility to the BUA *Investigating the role of GBA in the propagation of Lewy bodies in Parkinson's disease (PD)*.
- Dr. Furlan took over the BUA *Transplant Tolerance in Non-Human Primates* from Dr. Kiem. This BUA works with non-human primate cells transduced with lentiviral vectors.

- 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 with the removal of Dr. Tait Wojno's BUA that has yet to be sent out. Another member seconded the motion.
 - The Committee unanimously voted to approve this month's Biosafety Officer Report pending the change above. One member abstained from the vote because of a conflict of interest.
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. **BIOSAFETY MANUAL AND BIOHAZARDOUS WASTE MANAGEMENT PLAN EDITS:** Due to changes in Oregon State sharps regulations, EH&S and the UW Infectious Waste Committee have decided to update the University's sharps definition. "Syringes without needles" are no longer considered sharps. They will instead be collected as laboratory glass/plastic waste, either biohazardous or non-hazardous depending on what materials they were used with. The Biosafety Manual and Biohazardous Waste Management Plan have been updated accordingly. Holding times for waste in each resource have also been updated.

8. INDIVIDUAL PROJECT REVIEWS

- a. Bair, Wyeth, renewal, *Functional circuitry in the macaque visual system*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab aims to develop and refine novel methods to record signals from multiple neurons simultaneously in macaques to understand how populations of neurons in the visual cortex process and represent information. Work involves adeno-associated virus –GCaMP injections into the visual cortex of macaques.
 - 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. Bair.
 - The Committee voted unanimously to approve the draft BUA for Dr. Bair.
- b. Berger, Alice, new, *Mechanism and therapeutic targeting of lung cancer*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab seeks to understand how genetic mutations promote or suppress lung cancer development. Mice injected with adenovirus, gutless, $2/3^{\text{rd}}$ of genome at Fred Hutch Cancer Research Center will be transported to UW for imaging months later after testing negative for RCV.
 - A lab inspection is not required since only imaging of mice is taking place at UW.
 - 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. Berger.
 - The Committee voted unanimously to approve the draft BUA for Dr. Berger.
- c. Chatterjee, Champak, renewal, *Histone SUMOylation*
- The assigned IBC Primary Reviewer presented the Primary Review.

- This lab aims to understand post-translation modification effects of the small protein SUMO on histones. They are specifically interested in looking at how SUMO and other enzymes effect chromatin compaction.
 - Work involves E. coli and human cells in cultures, as well as amphotropic gamma retroviral 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. Chatterjee.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chatterjee.
- d. Darveau, Richard, renewal, *Healthy Homeostasis / P. gingivalis Virulence / Neutrophil Migration*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab's research goal is to determine the bacterial mechanisms involved in promoting the development of periodontal disease using a human cell line based model system. Work involves use of recombinant P. gingivalis and B. thetaiotaomicron.
 - 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. Darveau.
 - The Committee voted unanimously to approve the draft BUA for Dr. Darveau.
- e. Furlan, Scott, new, *Persistence of eTregs*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project will focus on whether a chemically-induced signaling complex tethered to the IL2 receptor can enhance gene-modified cells capable of mediating an immunosuppressive effect.
 - This BUA covers the transport of previously genetically modified autologous T cells generated at Seattle Children's Research Institute to the WaNPRC research facility and subsequent infusion of these cells into non-human primates. No vectors are used at the WaNPRC. The infused cells were generated using replication incompetent viral 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. Furlan.
 - The Committee voted unanimously to approve the draft BUA for Dr. Furlan.
- f. Hu, Shiu-lok, renewal, *Glycan modification, CD4 independence, and Env Immunogenicity*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab aims to examine novel concepts in HIV vaccine design and immunization methods. Work involves primate lentivirus in macaques at BSL2 w/3 practices.
 - Transportation from Fred Hutch Cancer Research Center (FHCRC) follows FHCRC policies.
 - 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. Hu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hu.
- g.** Kiem, Hans-Peter, renewal, *Strategies to Improve Hematopoietic Stem Cell Transduction*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to use SIV or SHIV infected macaques to discover new technologies to improve low stem cell gene transfer efficiencies in human stem cell gene therapy trials, improve stem cell engraftment once the recipient receives their transplant, and refine in vivo selection to more effectively target genes of interest.
 - Primate lentivirus, adeno-associated viral vectors, human cells and non-human primate cells transduced with lentiviral vectors and adeno-associated viral vectors are used in macaques.
 - The greatest biohazard risk to laboratory personnel is the work with SIV and SHIV.
 - The lab was recently inspected, so a new lab inspection was not 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. Kiem.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kiem.
- h.** Kiem, Hans-Peter, renewal, *T-Cell Therapy for HIV*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to use gene therapy as a potential treatment modality for HIV/AIDS. Primate lentivirus and non-human primate cells transduced with lentiviral vectors are used in macaques.
 - The greatest biohazard risk to laboratory personnel is the work with SIV and SHIV.
 - The lab was recently inspected, so a new lab inspection was not 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. Kiem.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kiem.
- i.** Kublin, James, renewal, *Role of the microbiome in HIV vaccine induced heterogeneity*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab is interested in how the gut microbiome shapes immune responses to HIV vaccines and contributes to vaccine response heterogeneity. Vaccines will be given to mice that are nearly identical with the exception of their gut bacterial communities. They will rear mice in the gnotobiotic facility at UW where they remain clear of any bacteria in their guts until the lab re-introduces bacteria. Mouse tissue and blood to analyze the immune response of the mice. All in vitro work is done at Fred Hutch Cancer Research Center, and all animal work is being conducted at UW.
 - 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. Kublin.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kublin.
- j. Neitz, Maureen, new, *Regeneration M opsin KO*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab develops new AAV vectors for opsin gene replacement therapy. They will use a transgenic mouse model to compare the efficacy of five different AAV2 capsid variants (compared to wild type) to increase the virus's ability to penetrate the outer retina from an intra-vitreous injection.
 - 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. Neitz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Neitz.
- k. Neitz, Maureen, renewal, *Gene therapy and retinal circuits*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to characterize the retinal circuits responsible for different aspects of visual experience and to develop therapeutic approaches to restore light sensitivity to the eye. The lab is developing adeno-associated virus-mediated gene therapy vectors that are capable of penetrating photoreceptors when injected into the vitreous. This is performed in a macaque model. Work also include blood or saliva from human subjects for DNA extraction and other human cell lines. Human iPSC's are generated using non-viral techniques (episomal vectors) or lentiviral vectors or Sendai virus kit.
 - 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. Neitz pending a change to the BUA letter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Neitz pending a change to the BUA letter.
- l. Pepple, Kathryn, change, *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 change is to add use of adeno-associated viral vectors 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. Pepple.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pepple.
- m. Phillips, Paul Edward, renewal, *Phasic Dopamine Release during Motivated Behavior in Rats*
- The assigned IBC Primary Reviewer presented the Primary Review.

- The goal of this research is to understand how genes control brain function and behavior in order to explain how alterations in gene function can result in neurological and psychiatric disorders such as substance abuse disorder.
 - Work involves use of adeno-associated virus in mice and rats.
 - 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. Phillips.
 - The Committee voted unanimously to approve the draft BUA for Dr. Phillips.
- n. Savan, Ram, change, *Gene regulation of immune genes and the effect on immune responses*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab is requesting use of three additional influenza strains for in vitro work.
 - 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. Savan.
 - The Committee voted unanimously to approve the draft BUA for Dr. Savan.
- o. Van Voorhis, Wesley, change, *1. Immune Response: Chagas 2. Biochemistry of Protein Prenylation 3. Plasmodium falciparum Protein Farnesyltransferase Inhibitors 4. Drugs for Toxoplasma and Cryptosporidium 5. Giardia 6. Shigella Inhibitors*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change is to add Klebsiella pneumonia and Shigella sonnei for use in vitro.
 - 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. Van Voorhis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Van Voorhis.
- p. Xia, Zhengui, renewal, *Neurogenesis*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This research uses mouse models to study the role of gene-environment interactions in maintenance of the central nervous system. Work includes adeno-associated viral vectors in mice, as well as work with lentiviral and gammaretroviral vectors in vitro.
 - 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. Xia pending clarification of rat involvement.
 - The Committee voted unanimously to approve the draft BUA for Dr. Xia pending the clarification requested above.

q. **Zhang**, Jing, renewal, *Jing Zhang's Laboratory Animal Use & Zhang Post Mortem Tissue Research*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of this research is to explain cellular and molecular mechanisms underlying neurodegeneration particularly in human diseases such as Parkinson's disease and Alzheimer's disease. Work includes human blood, tissue, body fluids, and cell lines in mice, as well as adeno-associated viral vectors, non-pathogenic E. coli, lentiviral vectors, and enhanced gene delivery methods in vitro.
- Work with MPTP is not new to this lab. An occupational health specialist is checking with lab to verify that work is not being done with MPTP during the temporary Harborview Research & Training building closure.
- A lab inspection will be conducted once temporary lab spaces are set up for this group. Their permanent spaces are in the temporarily closed Harborview Research & Training building.
- 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. Zhang pending successful lab inspection.
- The Committee voted unanimously to approve the draft BUA for Dr. Zhang pending a successful lab inspection.

9. SUBCOMMITTEE REPORTS:

r. **Hawn, Thomas**, renewal, *Innate Immunity and Susceptibility to Infectious Disease*

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This lab examines the genetics of innate resistance to bacterial and viral pathogens. Work includes use of Mycobacterium bovis, BCG strain, and Mycobacterium tuberculosis in vitro at BSL3.
- Mycobacterium leprae is listed for work at BSL2 because it cannot replicate.
- 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. Hawn. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Hawn.

s. **Lee, Silvia**, new, *A PHASE 1/2 SINGLE ARM OPEN-LABEL CLINICAL TRIAL OF TC-210 T CELLS IN PATIENTS WITH ADVANCED MESOTHELIN-EXPRESSING CANCER*

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a passive T cell immunotherapy trial in which patients with solid tumors that express the non-mutated protein mesothelin will be intravenously infused with autologous T cells that are engineered to express a targeting molecule called TC-210. TC-210 has specificity for a mesothelin peptide and delivers a positive signal to T cells via fusion to the CD3epsilon transmembrane and intracellular domains.
- The draft BUA letter was shown.

- A member made a motion to approve the draft BUA letter for Dr. Lee. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lee.
- t. Shah, Javeed A., renewal, *Immunology and Genetics of Infectious Diseases and Vaccines*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This lab examines the genetics of innate resistance to bacterial and viral pathogens. Work involves use of Mycobacterium tuberculosis in mice and in vitro at BSL3.
 - 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. Shah. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Shah.

10. FOR YOUR INFORMATION:

- **Online Autoclave Training:** This training will be developed by EH&S for researchers working specifically with biohazardous waste.
- **NIH Incident Report:** A researcher poked their finger while disposing of a bone marrow needle into a sharps container. The bone marrow needle had been used on a non-human primate that had been inoculated with SHIV. This incident was reported to the NIH. The NIH OSP stated that the University's response was appropriate, and that no further action was required.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:51 A.M.