



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, February 19, 2020

Time: 10:00 AM – 12:00 PM

Location: Foege N130A

- Members Present:**
1. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 2. Richard Grant, Washington National Primate Research Center
 3. David Koelle, Allergy and Infectious Diseases
 4. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 5. Scott Meschke, Environmental & Occupational Health Sciences
 6. Susan Parazzoli (Community Member)
 7. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
 8. 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 January 15, 2020 meeting.
 - A member made a motion to approve the January 15, 2020 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the January 15, 2020 meeting minutes. One member abstained from the vote because they were not present.
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. Wood's BUA was approved pending a successful lab inspection. This is still pending.
 - At the January 2020 meeting, Dr. Ailion'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. Kublin added four new bacterial strains to the BUA *Role of the microbiome in HIV vaccine induced heterogeneity*.
 - Dr. Shendure renewed the *Foege Flow Lab* core facility BUA.
 - Dr. Kelly added a new lab room to the BUA *In Vivo Function of CYP4BI; Generation of Induced Pluripotent Stem Cells*.
 - Dr. Gale added the use of various wild type BSL1 and BSL2 bacterial agents in previously approved BSL2 w/3 practices rooms to the BUA *The Host Response to Virus Infection*.
 - Dr. Oshima added use of a core facility for sorting of human cells to the BUA *International Registry of Werner Syndrome*.
 - Dr. Carothers renewed the BUA *RNA Synthetic Biology*. This BUA approves in vitro work with various BSL1 bacteria.
 - 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

- a. Berndt, Andre, new, *Screening and engineering of fluorescent biosensors*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab engineers fluorescent proteins and sensors that detect the activity of ions, neurotransmitters, neuromodulators, hormones and intracellular signaling molecules in real time and in living animals and tissue.
 - Work includes in vitro use of adeno-associated viral vectors in human and non-human primate 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. Berndt.
 - The Committee voted unanimously to approve the draft BUA for Dr. Berndt.
- b. Campos, Carlos, new, *Viscerosensory contributions to behavior*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research goal is to dissect genetically defined viscerosensory pathways involved in controlling food intake and affective behavior.
 - Work includes use of viral vectors in vitro and in transgenic 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. Campos.
 - The Committee voted unanimously to approve the draft BUA for Dr. Campos.
- c. Fuller, Deborah, renewal, *DNA Vaccine Therapy*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab is developing nucleic acid vaccines (DNA and non-infectious RNA) for various viral pathogens in mouse models.
 - Work includes in vivo use of WT dengue and Zika viruses, recombinant VSV, and a variety of influenza A viruses.
 - For most of the IAVs, the viruses should not be cultured concurrently with other viruses to minimize the risk of co-infection and reassortment. Lab personnel who have received FluMist or who suffered a flu-like illness must refrain from working with these viruses for 7 days. Personnel should avoid contact with avian species or their housing when away from the workplace.
 - 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. Fuller.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- d. Hansen, John, new, *IL-26 Immunity*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project assesses the role of IL-26 Zebrafish immunity to fish pathogens. *Edwardsiella ictalurid*, *Vibrio anguillarum*, and *Streptococcus iniae* are not known
 - Human pathogens, and the bacterial strains will not be genetically modified.

- This work is performed at the Western Fisheries Research Center.
 - 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. Hansen.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hansen.
- e. Horwitz, Marshall, renewal, *Genetics of Hematopoietic Malignancy: 1) Cyclic and Severe Congenital Neutropenia; 2) Familial Hodgkin Lymphoma*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This research investigates the molecular genetic basis for the genetic predisposition to developing bone marrow failure or bone marrow cancers. This is done by identifying mutations in relevant genes, determining if cell-cell communication is disrupted, and determining if the steps to blood cell differentiation are normal.
 - Work involves use of viral vectors and culturing of 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. Horwitz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Horwitz.
- f. Hyde, Jennifer, renewal, *Contribution of virus-host interactions to viral pathogenesis*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab works to identify the molecular mechanism of action of interferon stimulated genes (ISGs) that impact viral pathogenesis, and identify mechanisms which viruses have evolved to inhibit the IFN response. One key aspect this project will focus on is the role of viral RNA in the modulation of these responses.
 - The greatest biohazard identified is infection of cells in culture with wild type and recombinant viruses, as well as the use of 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. Hyde.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hyde.
- g. Jayadev, Suman, renewal, *Inflammatory Mediators of Neurodegeneration*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project aims to characterize the inflammatory or neurodegenerative mechanisms that contribute to dementia. It uses directed molecular biology to understand the genetic pathways of human dementia.
 - Work includes use of viral vectors and human and mouse cell lines.
 - 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. Jayadev.
 - The Committee voted unanimously to approve the draft BUA for Dr. Jayadev.
- h. Mullins, James, renewal, *HIV-1 and Host Cell Changes in Disease Progression*
- The assigned IBC Primary Reviewer presented the Primary Review.

- This lab's research goal is to design more effective therapeutic strategies and vaccines through study of virus-host interactions during HIV-1, SIV, or SHIV infection.
 - Work involves use of primate lentivirus and human and non-human primate blood, tissue, body fluids, and cell lines.
 - 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. Mullins pending completion of page one of the BUA application.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mullins pending completion of page one of the BUA application.
- i. Reniere, Michelle, renewal, *Redox regulation and virulence in bacterial pathogens*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to investigate the regulation of virulence factors in *Listeria monocytogenes* and *Staphylococcus aureus* in response to changing conditions.
 - Work involves use of lentiviral vectors and human and murine 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. Reniere.
 - The Committee voted unanimously to approve the draft BUA for Dr. Reniere.
- j. Sellers, Drew, renewal, *Stem Cells and Regeneration of the Spinal Cord*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab is working to understand the genes involved in neuron regeneration after injury.
 - Viral vectors will be used in vitro in human and rat cells and in vivo 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. Sellers pending an addition of nanoparticles to the BUA letter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sellers pending an addition of nanoparticles to the BUA letter.
- k. Soge, Olusegun, renewal, *Horizontal Gene Transfer in Chlamydia*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab conducts lateral gene transfer of the tetC gene from tetracycline resistant strains of *Chlamydia suis* to strains of *Chlamydia trachomatis* through recombination techniques. This is a collaborative research project with Dr. Scott Hefty (University of Kansas), Dr. Daniel Rockey (Oregon State University), and Dr. Kevin Hybiske (University of Washington).
 - The greatest biohazardous risk is the introduction of tetracycline resistance and beta-lactamase genes into *Chlamydia trachomatis*. An SOP in place addresses these biosafety issues, and there are alternative effective antimicrobials available for chlamydia treatment.

- 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. Soge.
- The Committee voted unanimously to approve the draft BUA for Dr. Soge.

8. SUBCOMMITTEE REPORTS:

- i.** Disis, Mary, new, *Phase 1/2 expansion cohorts trial of intravenous administration of TAEK-VAC-HerBy vaccine alone and in combination with HER2- and PD-1/PD-L1 antibodies in patients with advanced HER2-expressing cancer*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The primary objective of this industry sponsored study is to assess safety and tolerability of IV administration of TVH vaccine alone and in combination with HER2 antibodies as well as with HER2- and PD-1/PD-L1 antibodies in patients with locally advanced unresectable and metastatic tumors with HER2-expressing tumors. Secondary objectives are to determine the pharmacokinetic (PK) profile of TVH in patients' sera by measurement of viral load after IV administration of TVH.
 - The vaccine will be administered in the Translational Research Unit on 7 South at UW Medical Center. There is a possibility of non-participant exposure through a needle stick during preparation or administration.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Disis. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis.
- m.** Gwin, William, new, *A Phase II Study of Concurrent WOKVAC Vaccination with Neoadjuvant Chemotherapy and HER2-Targeted Monoclonal Antibody Therapy*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The trial will administer three doses of a DNA vaccine encoding a fusion of portions of three non mutated human oncodriver proteins, HER2, IGFBP-2 and IGF-1R, together with FDA-licensed therapies as neoadjuvant therapy to persons with breast cancer.
 - The main risk is sharp needle accidental inoculation of a health care worker. Theoretically, this might lead to an immune response against normal self proteins in the health care worker and the remote possibility of an autoimmune reaction.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Gwin. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gwin.
- n.** Krakow, Elizabeth, renewal, *Phase I study of adoptive immunotherapy with CD8+ and CD4+ memory T cells transduced to express an HA-1-specific T cell receptor (TCR) for children and adults with recurrent acute leukemia after allogeneic hematopoietic stem cell transplantation (HCT)*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.

- The primary objectives of this investigator initiated, first in human study are to assess the feasibility, safety, and efficacy of administration of a single dose of allogeneic HA-1 TCR T cells to patients with persistent or recurrent leukemia after allogeneic hematopoietic stem cell transplantation (HCT).
 - Manufacturing will take place in the Fred Hutch cell processing facility. Infusion will occur at UW Medical Center. There is a possibility of non-participant exposure through a needle stick during preparation or administration.
 - 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.
- o. *Shadman, Mazyar, renewal, A Phase I/II Study to Evaluate the Safety of Cellular Immunotherapy Using Autologous T cells Engineered to Express a CD20-Specific Chimeric Antigen Receptor for Patients with Relapsed or Refractory B-cell Non-Hodgkin Lymphomas*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - CD20 is expressed on the surface of many B-cell Non-Hodgkin Lymphomas. CAR-T re-targeted T cells directed against CD19 are FDA-approved for several B cell malignancies; CD19 is a similar B-cell specific surface protein. In the trial, autologous T cells will be lentivirally modified to express a CD20-specific CAR molecule and re infused in the patients to promote killing of tumor cells by the CAR-modified T cells.
 - There is the possibility of accidental sharp inoculation of the health care worker.
 - 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 unanimously to approve the draft BUA for Dr. Shadman.
- p. **Wuhan Coronavirus**
- Three members and three ad hoc reviewers of the IBC served as the Subcommittee Reviewers for the four projects below. One of the Subcommittee Reviewers presented each Subcommittee Report.
 - *Starita, Lea, change, Brotman Baty Advanced Technology Lab: General Research*
 - This change adds research involving clinical samples from patients known or suspected to be infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The work will involve biobanking and nucleic acid extraction from samples from infection individuals. No viral isolation or culturing is permitted.
 - The CDC's current recommendation for this work is that it be performed at BSL-2.
 - The lab was inspected and no deficiencies were identified. Additional conditions regarding signage and limited access to the lab have been mandated by the IBC.
 - All of the required trainings have been completed.
 - Medical counseling must be offered to researchers who handle potential coronavirus samples.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Starita. Another member seconded the motion.

- The Committee voted unanimously to approve the draft BUA for Dr. Starita.
- Chu, Helen, change, *Seattle Flu Study*
 - This change adds research involving clinical samples from patients known or suspected to be infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). No viral isolation or culturing is permitted. This change also adds four Risk Group 2 human coronaviruses (229E, HKU1, NL63, OC43).
 - The CDC's current recommendation for this work is that it be performed at BSL-2.
 - The lab was inspected and no deficiencies were identified. Additional conditions regarding signage and limited access to the lab have been mandated by the IBC.
 - All of the required trainings have been completed.
 - Medical counseling must be offered to researchers who handle potential coronavirus samples.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Chu. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chu.
- Gale, Michael, change
 - Serum, plasma, peripheral blood, and sputum specimens from the Everett patient known to have been infected with the Wuhan 2019-nCoV Coronavirus will be sent to the Gale Lab to facilitate studies of SARS-CoV-2 aimed at understanding the virus-host cell interactions that support virus replication and that mediate viral pathogenesis.
 - The work will be performed at BSL-3 and will involve isolating SARS-CoV-2 from the Everett patient specimens and in vitro experiments (generating virus stocks, infection of cells in tissue culture using human cells). All procedures will be conducted according to EH&S and DCM approved BSL-3 protocols.
 - All of the required trainings have been completed.
 - Occupational Health recommends enhanced medical daily monitoring for personnel working with SARS-CoV-2.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Gale. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gale.
- Adams Waldorf, Kristina, change
 - Serum, plasma, peripheral blood, and sputum specimens from the Everett patient known to have been infected with the Wuhan 2019-nCoV Coronavirus will be sent to facilitate studies of the SARS-CoV-2 aimed at understanding the virus-host cell interactions that support virus replication and that mediate viral pathogenesis.
 - The work will be performed at BSL-3 and will involve isolating SARS-CoV-2 from the Everett patient specimens and in vitro experiments (generating virus stocks, infection of cells in tissue culture using human cells). All procedures will be conducted according to EH&S and DCM approved BSL-3 protocols.

- In vitro experiments performed at BSL-3 will also include infection of human placentas. Biohazardous agents will also include SARS-CoV-2 provided by the CDC or the Biodefense and Emerging Infectious Research Resources Repository.
- All of the required trainings have been completed.
- Occupational Health recommends enhanced medical daily monitoring for personnel working with SARS-CoV-2.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Adams Waldorf. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Adams Waldorf.

10. FOR YOUR INFORMATION:

- **NIH Incident Report:** A research scientist was bitten by a mouse infected with a gutless human adenovirus. The scientist was wearing standard personal protective equipment that included facility scrubs, laboratory gown, nitrile gloves (single pair), dedicated facility shoes, and hair bonnet. The scientist noticed a small amount of blood from the site of the wound. The scientist removed the gloves and washed the hands with soap and water for approximately 15 minutes. The employee followed up with the University Employee Health Clinic the following day for medical counseling and monitoring. This incident has been reported and is awaiting response from NIH.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:54 A.M.