



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, October 19, 2016

Time: 10:00 AM – 12:00 PM

Location: Foegle N-130A

- Members Present:**
1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 2. Richard Grant, Washington National Primate Research Center
 3. Garry Hamilton (*Community Member*)
 4. Kevin Hybiske, Allergy and Infectious Diseases
 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. Jason Smith, Microbiology
 10. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)

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 am. 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 September 21, 2016 meeting.
 - A member made a motion to approve the September 21, 2016 minutes. Another member seconded the motion.
 - The committee voted unanimously, with three abstentions, to approve the September 21, 2016 meeting minutes.
4. **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

- The IBC Chair sought a motion to approve this month's Biosafety Officer Report.
- Dr. Fields renewed a BUA involving bacteriophages.
- Dr. Bryers and Dr. Doherty each added a new imaging suite to their respective BUA letter.
- Dr. Miller added *Dickeya zeae* EC1, a plant pathogen, to his BUA letter. The required APHIS permits have been obtained.
- Dr. Kurath renewed a BUA involving infectious hematopoietic necrosis virus. This is a fish pathogen. The work is conducted at Western Fisheries Research Center.
- Dr. Raftery renewed a BUA involving human tissue, blood, and cells.
- Dr. Schmechel renewed a BUA involving baculovirus, human cells and tissue, and plasmid DNA.
- Dr. Byers added two new rooms to his BUA letter.
- Dr. Kaufman renewed a BUA involving human cells.
- Dr. Vojtech received a new BUA letter for human and non-human primate cells and wild-type Zika virus.
- 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.

5. INDIVIDUAL PROJECT REVIEWS

1. Clark, Edward, change, *Lymphocyte Activation (Role of CD22 & Syk Kinase)*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change to add Zika virus used in vitro and in mice.
 - The Zika virus is not recombinant, but is used in a transgenic mouse model, so this work falls under section III-D.

- The employees who work with Zika virus will receive in-person medical counseling as outlined in the Zika Medical Management Policy.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Clark. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Clark.
2. Chao, Jennifer, renewal, *In vitro models of retinal degenerative diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the project is to establish in vitro models of retinal degenerative diseases and to use the models to screen for pro-survival drug compounds.
 - Lentiviral vectors and adeno-associated viral vectors (AAV) are used on the project, as well as human cells. These agents are used in vitro. This project previously involved animals, but that research has been completed.
 - The draft BUA letter was shown.
 - The required trainings have been completed and the lab has been inspected with no remaining deficiencies.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chao. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chao.
3. Doherty, Dan, renewal, *Joubert Syndrome and related disorders*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the project is to identify genetic causes of human brain malformations and to study the molecular mechanisms underlying these disorders.
 - Epstein-Barr virus, gammaretroviral vectors, and lentiviral vectors are used on the project.
 - The draft BUA letter was shown.
 - The required trainings have been completed and the lab has been inspected with no remaining deficiencies.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Doherty. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Doherty.
4. Fink, Susan, new, *Host-Pathogen Interactions During Viral Infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the project is to understand cellular pathways used by viruses to promote infection and host defense mechanisms that prevent or alleviate infection.
 - Zika virus, herpes simplex virus, and lentiviral vectors are used on the project. The vesicular stomatitis virus (Indiana strain) is also used.
 - The draft BUA letter was shown.
 - The required trainings have been completed and the lab has been inspected with no remaining deficiencies.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Fink. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fink.
5. Dodd, Michael, renewal, *ARG Disinfection*

- The assigned IBC Primary Reviewer presented the Primary Review.
 - One member declared a conflict of interest.
 - Several species of bacteria are used, including *Cryptosporidium parvum*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.
 - The experiments involve dosing water samples with known concentrations of each pathogen, and then treating them with various combinations of chlorine and UV light.
 - An IBC reviewer raised a question about how the liquid waste is decontaminated. The biosafety officer responded that bleach is added until the concentration reaches 10%, and then sufficient contact time is allowed before the waste is disposed. The IBC reviewer requested an opportunity to review the SOPs. The biosafety officer will send the IBC reviewer the waste disposal SOPs.
 - The draft BUA letter was shown.
 - Question 21 on the BUA application needs to be completed.
 - The required trainings have been completed and the lab has been inspected with no remaining deficiencies.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Dodd. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Dodd, pending IBC review of the waste SOPs and correction of the BUA application.
6. Oganessian, Anush, renewal, *Subcellular Distribution and regulation of Alpha-1-adrenoceptors*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the project is to elucidate molecular mechanisms of alpha-1-adrenergic receptors in health and various cardiovascular diseases such as hypertension.
 - Adenoviral vectors and lentiviral vectors are used on the project.
 - The lab still needs to be inspected, and some parts of the BUA application need to be edited.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Oganessian. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Oganessian, pending biosafety officer review of the BUA application and the lab inspection.
7. Ong, Shao-En, renewal, *Characterizing muscle regulatory elements with mass spectrometry-based proteomics*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The Ong lab studies proteins interacting with DNA sequences in cells that control transcriptional programs in muscle differentiation.
 - Adenoviral vectors and lentiviral vectors are used on the project.
 - None of the inserts to be studied are oncogenic.
 - The draft BUA letter was shown.
 - The required trainings have been completed and the lab has been inspected with no remaining deficiencies.

- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Ong. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ong.
8. Seshadri, Chetan, renewal, *Human Immunity to Mycobacterial Diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The Seshadri lab studies the genetic, molecular, cellular, and immunologic mechanisms of mycobacterial disease pathogenesis with an emphasis on human studies. The overall goal of the research is to understand why people have varying susceptibility to infections like tuberculosis with the hope that these insights will improve treatment strategies.
 - Human and non-human primate cells are used on the project. Lentiviral vectors are also used.
 - Several strains of *Mycobacterium* are used on the project; *M. avium*, *M. bovis*, *M. leprae*, and *M. tuberculosis*, H37Ra strain. The IBC reviewer stressed that the wildtype virulent strain of *Mycobacterium tuberculosis* is not used. The strain used on the project is avirulent. BSL-2 containment is appropriate for the *Mycobacterium* strains used on this project.
 - The draft BUA letter was shown.
 - The required trainings have been completed and the lab has been inspected with no remaining deficiencies.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Seshadri. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Seshadri.
9. Sniadecki, Nathan, renewal, *Studying Cellular Mechanics and Mechanotransduction with Microsystems*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the research is to better understand the mechanics of biological cells, using nanofabricated tools to measure their mechanical properties.
 - Human cells are used on this project. Lentiviral vectors are used to introduce a fluorescent protein.
 - The draft BUA letter was shown.
 - The required trainings have been completed and the lab has been inspected with no remaining deficiencies.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Sniadecki. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sniadecki.
10. Stamatatos, Leonidas, new, *Eliciting VRC01-like bNAbs by specifically designed Env Immunogens*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the research is to understand the host immune response to vaccination with soluble HIV-1 envelope immunogens in non-human primates, with the aim of developing envelope-based vaccines that can elicit broadly neutralizing antibodies.
 - A plasmid DNA vaccine is used in macaques. The animal work is conducted at UW, while the immunogen production, vaccine formulation, and sample processing and

analysis occurs at Fred Hutchinson Cancer Research Center (under approved FHCRC IBC protocols).

- A question was raised about a herpes B virus exposure kit. These kits are readily available in areas where primates or primate source material is used.
- The draft BUA letter was shown.
- The investigator has not yet submitted the associated IACUC protocol. The final approval will be pending the biosafety officer review of the IACUC protocol.
- The required trainings have been completed and the lab has been inspected with no remaining deficiencies.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Stamatatos. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Stamatatos, pending the biosafety officer review of the IACUC protocol.

11. Stetson, Dan, change, *Mechanisms and Consequences of Innate Immune Detection of Nucleic Acids*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change request to add two viruses, herpes simplex virus 1 and murine encephalomyocarditis virus, for administration to human and mouse cells and transgenic mice. The viruses are non-recombinant.
- The lab has been inspected and all 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. Stetson. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Stetson.

SUBCOMMITTEE REPORTS:

12. Maloney, David, new, *A Phase 1, Multicenter, Open-Label Study of JCAR017, CD19-targeted Chimeric Antigen Receptor (CAR) T Cells, for Relapsed and Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL)*

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This clinical trial involves autologous T-cell therapy for non-Hodgkins lymphoma. Peripheral blood mononuclear cells (PBMCs) will be transduced with a third-generation lentiviral vector, which is designed to express a transmembrane protein that recognizes CD19 on cancer cells, and then infused back into the participant. No adverse events have been reported to be associated with this vector.
- The subcommittee reviewed the consent form documents. The documents appropriately convey the risks and benefits of participating in the study.
- The draft BUA letter was shown.
- The investigator still needs to complete the biosafety training.
- 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, pending completion of the biosafety training.

- 13.** Wald, Anna, renewal, *A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Trial to Evaluate the Safety and Efficacy of Herpes Simplex Virus, Type 2 (HSV-2) Therapeutic DNA Vaccine in Adults with Symptomatic Genital HSV-2 Infection*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - One member declared a conflict of interest.
 - This is a renewal for a clinical trial involving a therapeutic DNA vaccine (VCL-HB01) for herpes simplex virus 2. The vaccine will be administered to recipients four times throughout the study, and swabs will be collected at various times following each dose. Each participant will be enrolled in the study for approximately 16 months.
 - The subcommittee reviewed the consent forms, which clearly and thoroughly state the risks and benefits to the participants and clearly outline all procedures that will be conducted as part of the study.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Wald. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wald.
- 14.** Gale, Michael, new, *Host Response to BSL-3 Pathogens*
- Three members of the IBC served as the Subcommittee Reviewers. Two additional ad-hoc reviewers participated in the review of this project. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This proposal is to study adjuvants as a way to improve vaccines against highly pathogenic avian influenza viruses. In particular, the principal investigator wants to use H5N1 influenza viral strains to immunize mice and determine the immunological response to the viral challenge.
 - The application that was originally submitted back in 2014 included proposed work with 1918 H1N1 influenza virus. This proposed work has been removed from the application. No work with 1918 influenza virus will occur.
 - The CDC Select Agent program approved the proposal to work with H5N1 in June 2016.
 - The work with H5N1 strains of influenza falls under the Select Agent regulations and the research will be conducted at BSL-3/ABSL-3. Detailed SOPs have been provided and reviewed by numerous parties, including the CDC, NIH, USDA, the King County Public Health Officer, and the responsible officials of the UW Select Agent Program.
 - The IBC reviewer discussed the medical management plan for employees who will be involved with the research on this project. Every day, they complete an online survey and note if they have any influenza symptoms, such as a fever. A doctor from the Employee Health Center follows up if any concerns are noted. Personnel with any potential flu-like illnesses are restricted from working in the BSL-3 facility.
 - All researchers must receive the seasonal influenza vaccine.
 - Only one strain of influenza may be worked with at a time, to minimize the risk of reassortment. An IBC member asked if this meant one strain at a time in the specific room, or one strain at a time throughout the entire BSL-3/ABSL-3 facility. The subcommittee reviewer clarified that only one strain of influenza may be worked on at a time throughout the entire BSL-3/ABSL-3 facility.
 - A question was raised about conflicts of interest. None of the subcommittee reviewers share a grant with Dr. Gale.
 - 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.

FOR YOUR INFORMATION:

- October is National Biosafety Month.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

There were no issues from the floor, and no public comments.

MEETING ADJOURNED AT APPROXIMATELY 11:58 a.m.