INSTITUTIONAL BIOSAFETY COMMITTEE UNIVERSITY of WASHINGTON

Meeting Minutes

| Date: | Wednesday, March 20, 2019 |
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| Time: | 10:00 AM – 12:00 PM |

Location: Foege N130A

Members Present:

- **mbers** 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. Richard Grant, Washington National Primate Research Center
 - 5. David Koelle, Allergy and Infectious Diseases
 - 6. Stephen Libby, Laboratory Medicine (IBC Chair)
 - 7. Jason Smith, Microbiology (IBC Vice Chair)
 - 8. Eric Stefansson, Environmental Health & Safety (Biosafety Officer, Animal Containment Expert)
 - 9. 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 February 20, 2019 meeting.
- A member made a motion to approve the February 20, 2019 minutes. Another member seconded the motion.
- The committee voted unanimously to approve the February 20, 2019 meeting minutes.

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 November 2018 meeting, Dr. Steinmetz's BUA was approved pending a successful lab inspection. This is still pending.
- At the January 2019 meeting, Dr. Noss's BUA was approved pending verification of third generation lentiviral vectors. This is still pending.
- At the February 2019 meeting, Dr. Berg's BUA was approved pending correction of deficiencies identified in a lab inspection. This is still pending.
- At the February 2019 meeting, Dr. Liao's BUA was approved pending a lab inspection and changes to the BUA. This is still pending.
- At the February 2019 meeting, Dr. Lieber's BUA was approved pending a lab inspection and changes to the BUA. 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 is still pending.
- 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. Disis received approval for a new BUA titled *Ongoing Research at UWMC Translational Research Unit (TRU).* This BUA approves in vitro use of human blood, tissue, body fluids, and cell lines.
 - Dr. Jarvik renewed the BUA *Pacific Northwest Undiagnosed Disease Network* allowing in vitro use of human blood, tissue, body fluids, and cell lines.
 - Dr. Fu renewed the BUA *Multimodal optical microscope* allowing in vitro use of human blood, tissue, body fluids, and cell lines.
 - Dr. Daggett renewed the BUA *Peptide-Based Diagnostics and Inhibitors for Amyloid Diseases* permitting in vitro use of various microorganisms at BSL2, as well as human blood, tissue, body fluids, and cell lines.

- Dr. Hawn added a new room to the BUA *Innate Immunity and Susceptibility to Infection Disease* where in vitro work with various BSL 2 agents takes place.
- Dr. Juul renewed the BUA *Neonatal Neuroprotection* allowing in vitro use of nonhuman primate and human blood tissue, body fluids, and cell lines.
- Dr. Hladik added a new lab space for work with previously approved agents to the BUA Mechanisms of HIV-1 Transmission in Genital Mucosa of Women and the Role of Exosomes in Semen for HIV Infection in the Genital Mucosa of Women.
- Dr. Frevert added a new space for work with previously approved agents in mice to the BUA *Proteoglycans and Influenza Infection: Gene-targeted mouse models to study versican.*
- Dr. Eisenberg renewed the BUA *Eisenberg's Anthropological Genetics Lab Starting up lab* for work with human and non-human primate blood, tissue, body fluids, and cell lines.
- Dr. Parikh received approval for a new BUA titled *Exosome derived from induced neural stem cell as neuroprotective agent in in-vitro model of neonatal brain injury.* This includes work with human and non-human primate blood, tissue, body fluids, and cell lines. It also permits in vitro work with human iPS cells.
- Dr. Vojtech added a new lab space for work with previously approved agents on the BUA *Mechanisms of sexual Zika virus transmission.*
- Dr. Cao added use of a new space for work with previously approved agents on the BUA *Predicting Therapy Response*.
- 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.
- <u>The Committee unanimously voted to approve this month's Biosafety Officer</u> <u>Report.</u>
- 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. Bajjalieh, Sandra, renewal, Cell Biology of the Neuron
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project focuses on how the composition of the synaptic vesicle membrane modulates the release of neurotransmitter from neurons, as well as how lipid modifying enzymes contribute to vesicle fusion and intracellular signaling. Work involves modifying MuLK and recombinant lentiviral vectors expressing GFP.
 - The committee discussed how freestanding RNA is not a concern and the possibility of MuLK as an oncogene.
 - The lab was inspected, and no deficiencies were identified.
 - All 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. Bajjalieh pending specification of various mammalian proteins cited in the BUA application.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Bajjalieh</u> pending the additional information the BUA.

- b. Fang, Ferric, renewal, Salmonella Pathogenesis and Immunity
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - Various bacterial species are used with mice in vivo and with murine and human immune system cells in vitro to try and understand how they interact in these cells with an ultimate goal of preventing and treating disease.
 - This lab is making lentiviral vectors. Antibiotic resistance is involved in the engineering of recombinant strains.
 - The handling of Risk Group 2 bacterial pathogens and the possibility of pathogens in primary human macrophages present a risk to laboratory personnel.
 - Edits to IACUC submission are required.
 - The lab was inspected, and no deficiencies were identified.
 - All 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. Fang pending edits to the IACUC submission.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Fang pending</u> <u>edits to the IACUC submission.</u>
- **c.** Fuller, Deborah, change, DNA Vaccine Therapy
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - Recombinant vesicular stomatitis virus is being added as a vaccine vector to immunize mice against influenza antigens.
 - The rVSV is being obtained from a collaborator.
 - The lab was inspected, and no deficiencies were identified.
 - All 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 pending changes to the BUA.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Fuller pending</u> <u>changes to BUA.</u>
- **d.** Fuller, Deborah, change, *Immunogenicity and efficacy of universal influenza DNA vaccine in nonhuman primates*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - Recombinant vesicular stomatitis virus is being added as a vaccine vector to immunize non-human primates against influenza antigens.
 - The rVSV is being obtained from a collaborator.
 - A USDA permit is needed for use of rVSV (Indiana strain) since it is coming from out of state.
 - The lab was inspected, and no deficiencies were identified.
 - All 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 pending changes to the BUA application and BUA letter.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Fuller pending</u> <u>changes to the BUA application and BUA letter.</u>

- **e.** Giacani, Lorenzo, renewal, *Studies on the pathogenesis of syphilis and human treponematoses*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this research is to better understand the pathogenesis, infection, dissemination, and evasion and persistence of human treponematoses infections in infected individuals. Work involves putting T. pallidum antigens into Borrella sp. To present the antigens to immune cells, and incubating cells infected with T. pallidum with DNA to attempt to genetically modify the T. pallidum.
 - Non-pathogenic recombinant Borelia strains, if transformed, fall under Section III.D.2.A, and can be conducted under BSL1.
 - All infected rabbit carcasses used in this research must be incinerated.
 - The lab was inspected, and no deficiencies were identified.
 - All 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. Giacani pending a change to the BUA letter.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Giacani pending</u> <u>a change to BUA letter.</u>
- f. Greenberg, Everett Peter, renewal, Quorum Sensing in Burkholderia mallei
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This work studies the molecular mechanism and evolution of quorum sensing and response in Risk Group 1 and Risk Group 2 bacteria, allowing bacteria to monitor their population densities and activate sets of genes when a sufficient population density has been achieved.
 - The greatest biohazard risk to lab personnel is work with Risk Group 2 organisms and recombinant DNA with antibiotic resistance markers.
 - The lab was inspected, and no deficiencies were identified.
 - All 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. Greenberg.
 - The Committee voted unanimously to approve the draft BUA for Dr. Greenberg.
- **g.** Hladik, Florian, change, *Mechanisms of HIV-1 Transmission in Genital Mucosa of Women and the Role of Exosomes in Semen for HIV Infection in the Genital Mucosa of Women*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change application is to add the following: 1) macaque blood samples and vero cell (AGM); 2) several non-human cell lines, CHO, and other mouse cell lines; 3) several non-recombinant infectious agents (Herpes simplex virus 1 and 2, Cytomegalovirus, Epstein-Barr virus, and Zika virus); 4) recombinant microorganisms (HIV infectious molecular clone expressing Nano-luciferase-encoding, replication deficient Amphotropic gammaretrovirus expressing HPV E6 and E7 oncogenes, and lentivirus).
 - Gammaretrovirus with lentivirus at BSL 2 w/3 practices is adequate.
 - Once a cell is transformed with E6 or E7 the resulting cell should not be RCV.
 - The lab was inspected, and deficiencies identified are being addressed.
 - All 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. Hladik pending changes to the BUA application and a successful lab inspection.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Hladik pending</u> <u>changes to the BUA application and a successful lab inspection. One member</u> <u>abstained because they were not in the room at the time of the vote.</u>
- h. Horwitz, Greg, renewal, Neurophysiology of Vision
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This goal of this research is to understand the relationship between vision and electrical activity in the brain. Work involves genetic engineering of plasmids in E. coli (K-12 strains) to transfect cells and production of the following: adeno-associated viral vectors (adenovirus free); Herpes simplex viral vector, replication deficient; and, lentiviral vectors, non-HIV pseudotyped, replication deficient. Viral vectors are used in vivo with Rhesus macaques.
 - The greatest risk to lab personnel declared by the PI is potential Herpes B exposure from non-human primates and work with lentiviruses.
 - The lab was inspected, and no deficiencies were identified.
 - All 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.
- i. Iritani, Brian, change, Gene Function in Lymphopoiesis and Cancer
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change is to add use of wild type Streptococcus pneumoniae, cultured and administered to transgenic mice.
 - It will be noted on the BUA letter that this agent requires occupational health review.
 - A lab inspection was recently successfully completed, so no additional inspection is needed for this change.
 - All 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. Iritani.
 - The Committee voted unanimously to approve the draft BUA for Dr. Iritani.
- **j.** Kavanagh, Terrance, renewal, *Predictive Toxicology Center for Organotypic Cultures and Assessment of AOPs for Engineered Nanomaterials*
 - The assigned IBC Secondary Reviewer presented the Primary Review.
 - This project uses human and murine cells transduced with lentiviral vectors to determine responses to a variety of toxic chemicals.
 - The greatest biohazard is exposure to the 3rd generation replication deficient lentivirus.
 - A lab inspection is pending.
 - The required trainings still need to be completed.
 - The draft BUA letter was shown.

- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kavanagh pending a successful lab inspection, completion of training, and changes to the BUA letter.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Kavanagh</u> <u>pending a successful lab inspection, completion of training, and changes to the BUA</u> <u>letter. One member abstained from voting due to a conflict of interest.</u>
- k. Merz, Alexey, new, Bacterial interactions with mammalian cells
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to understand how bacterial cells (Neisseria sp.) adhere to human cells as part of the infection process, and how human cells respond to bacterial attachment. Neisseria gonorrhoeae and N. meningitidis will be propagated, genetically manipulated to mutate adhesion factors, and used to infect cultured mammalian cells.
 - The lab was inspected, and deficiencies identified are being addressed.
 - Occupational health will direct the PI to contact the Employee Health Center in regard to the N. Meningitides vaccine.
 - All 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. Merz pending a successful lab inspection.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Merz pending a</u> <u>successful lab inspection.</u>
- I. Moreno, Claudia, new, *Calcium signaling in the aging pacemaker*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the effects of aging on calcium signaling and the functions of the pacemaker of the heart. Work involves use of adenoviral vectors, lentiviral vectors and plasmid/liposome to express calcium-signaling genes in human cell lines. Adeno-associated viral vectors will be used to express calcium-signaling genes in mice.
 - This approval is pending verification of the IACUC protocol.
 - The lab has not yet been set up. The investigator will be arriving within the next few months. The biosafety officer will inspect the lab once the investigator arrives at UW and the lab is ready.
 - The required trainings still need to be completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Moreno pending a successful lab inspection and training completion.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Moreno</u> pending a successful lab inspection and training completion.
- m. Neumaier, John, renewal, Regulation of Serotonin Receptors
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the serotoninergic system in the CNS using rodents, including creating transgenic mice. Viruses and plasmids are used to change gene expression in rodents by intracranial injection. Routine plasmid engineering in E. coli is performed.

- Manufacture of amplicons can remain at BSL1 (as it was approved by the IBC in 2016) because of checks and RCV testing.
- The viruses come from Switzerland.
- This approval is pending submission of the IACUC protocol.
- Occupational health review for possible post-exposure prophylaxis for HSV infection was suggested by the IBC.
- The lab was inspected, and no deficiencies were identified.
- All 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. Neumaier pending IACUC submission.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Neumaier</u> pending IACUC submission.
- n. Skerrett, Shawn, change, Host Defense Against Bacterial Pneumonia
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change is to add the vaccine strain BCG, a highly attenuated strain of Mycobacterium bovis, for use in vitro and in mice.
 - This will be given by aerosol in a biosafety cabinet, using BSL2 practices.
 - Immunosuppressed lab personnel may want to consult with Occupational Health.
 - The lab was inspected, and no deficiencies were identified.
 - All 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. Skerrett.
 - The Committee voted unanimously to approve the draft BUA for Dr. Skerrett.
- o. Woodrow, Kim, renewal, Primate Models to Evaluate HIV Preventions and Strategies
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This project uses RT-SHIV infected macaques and cells to test antiretroviral drugs loaded into nanoparticles and nanofiber delivery vehicles, used to test a drug's ability to stop or inhibit viral infection across mucosal surfaces.
 - Work using recombinant lentiviruses in vivo with non-human primates, blood and tissue collection, use of sharps, and culturing viruses in non-human primates and human cells present the most hazards to lab personnel.
 - This approval is pending submission of the IACUC protocol.
 - The lab was inspected, and no deficiencies were identified.
 - All 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. Woodrow pending submission of the IACUC protocol.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Woodrow</u> pending submission of the IACUC protocol.

8. SUBCOMMITTEE REPORTS:

p. BSL 3 Inactivation

- Three members of the IBC served as the subcommittee reviewers. One of the subcommittee reviewers presented the subcommittee report.
- The subcommittee believes that there should be a verification process that is decided on a case by case basis for non-select agents.
- Committee members discussed the possibility of rechecking processes at some frequency and placing a time frame on these inactivation processes.
- More precise recommendations for particular select agents are to be presented at the April 17 IBC, along with the subcommittee's final recommendations.
- q. Japanese Encephalitis Virus (JEV) and West Nile Virus (WNV) Review
 - This report is being deferred to the April 17 IBC meeting.

10. FOR YOUR INFORMATION:

- **2019 UW Biohazardous Waste Management Plan:** The IBC voted to approve annual edits to the UW Biohazardous Waste Management Plan that were also approved by the UW Infectious Waste Committee.
- NIH Incident Reports:
 - An individual accidently stuck their thumb with a needle that was used to administer fluids to a non-human primate (NHP) that had been inoculated with HSIV. The individual was wearing appropriate personal protective equipment (PPE) and post exposure procedures were correctly followed. The incident was investigated and the SOP for administering fluids will be revised to include additional procedures to reduce the potential risk of a sharps injury. 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.
 - A NHP scratched an employee on the hand through their gloves while the person was transferring NHPs from individual cages to shared caging. The NHPs had been inoculated with SHIV. The person was wearing appropriate PPE. Post exposure procedures were correctly followed. The employee is undergoing additional training. 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.
- **NWABR IBC Conference:** One committee member and one biosafety officer will be presenting at the Northwest Association for Biomedical Research (NWABR) conference on April 4.
- **11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:** There were no issues from the floor, and no public comments.
- 12. MEETING ADJOURNED AT APPROXIMATELY 12:01 P.M.