



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, August 19, 2020

Time: 10:00 AM – 12:00 PM

Location: Zoom

Members Present:

1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
2. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
3. Richard Grant, Washington National Primate Research Center
4. Garry Hamilton (*Community Member*)
5. Kevin Hybiske, Allergy and Infectious Diseases
6. David Koelle, Allergy and Infectious Diseases
7. Stephen Libby, Laboratory Medicine (*IBC Chair*)
8. Scott Meschke, Environmental & Occupational Health Sciences
9. Susan Parazzoli (*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:**
 - July 15, 2020
 - The IBC Chair sought a motion to approve the minutes from the July 15, 2020 meeting.
 - A member made a motion to approve the July 15, 2020 minutes. Another member seconded the motion.
 - The committee voted to approve the July 15, 2020 meeting minutes. There were three voting abstentions.
 - August 5, 2020
 - The IBC Chair sought a motion to approve the minutes from the August 5, 2020 meeting.
 - A member made a motion to approve the August 5, 2020 minutes. Another member seconded the motion.
 - The committee voted to approve the August 5, 2020 meeting minutes. There were three voting abstentions.
4. **OLD BUSINESS:**
 - At the March 18, 2020 meeting, Dr. Jerome's BUA was approved pending completion of the BUA application. This BUA is still pending.
 - At the March 18, 2020 meeting, Dr. Lagunoff's BUA was approved pending a successful lab inspection and training completion. This BUA is still pending.
 - At the May 20, 2020 meeting, Dr. Pepper's BUA was approved pending a successful in-person lab inspection for BSL-2 work to begin. This BUA has been sent out.
 - At the June 17, 2020 meeting, Dr. Parsek's BUA was approved pending changes to the BUA application. This BUA has been sent out.
 - At the June 17, 2020 meeting, Dr. Altemeier's BUA was approved pending review of the IACUC protocol and required training. This BUA is still pending.
 - At the June 17, 2020 meeting, Dr. Kreuzer's BUA was approved pending the medical management plan. This BUA is still pending.
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. Savan added a room to the BUA *Gene regulation of immune genes and the effect on immune responses*.
 - Dr. Shendure added new imaging facility use to the BUA *Shendure: General Research*.

- Dr. Sanchez-Contreras was approved for use of human blood, tissue, body fluids, and cell lines on the BUA *Neuron-specific somatic mosaicism in brain regions susceptible to Alzheimer's Disease*.
- Dr. Gale added in vitro use of inactivated SARS-CoV-2 to the BUA *The Host Response to Virus Infection*.
- Dr. Grant added inactivated material from SARS-CoV-2 patients and plasma from macaques previously infected with SARS-CoV-2 to the BUA *Primate Diagnostic Services Laboratories*.
- Dr. Gibran added a room and use of a core facility to the BUA *Gibran Laboratory – HMC R&T Surgery Inflammation*.
- Dr. Fuller added use of inactivated SARS-CoV-2 samples (irradiated plasma and bronchial alveolar lavage from SARS-CoV-2 infected non-human primates) to the BUA *Enhanced Hepatitis B Vaccine for Immunocompromised Animals*.
- Dr. Wood renewed the BUA *Spatial ecology of schistosomiasis transmission risk*, working with *Schistosoma mansoni* in mice, snails, and crayfish and *Schistosoma haematobium* and *japonicum* in snails and crayfish.
- Dr. Eisenberg added research involving inactivated clinical samples from patients known or suspected to be infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to the BUA *Eisenberg's Anthropological Genetics Lab – Starting up lab*. No viral isolation or culturing is permitted.
- Dr. Lutz renewed the BUA *Point-of-Care Diagnostic Device*, working with non-pathogenic strains of *Escherichia coli* in vitro.
- Dr. Distillio renewed the BUA *Functional Evolution of Floral Pathway Genes in the angiosperm Thalictum and the fern Ceratopteris richardii*. This project works with transgenic *Ceratopteris richardii*, *Thalictum* species, *Agrobacterium tumefaciens*, and disarmed Tobacco rattle virus (TRV1/TRV2) in plants and in vitro.
- The IBC Chair 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

- Two projects received renewal approval for use of Botulinum neurotoxin. Neither meets the DURC definition.
- The IBC Chair sought a motion to approve this month's DURC Report.
- A member made a motion to approve this month's DURC Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's DURC Report.

7. SECTION III-D AMENDMENTS

- a. Sniadecki, Nathan, change, *Cell therapy in mice and rats*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds rats to the protocol for agents previously approved for administration to 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. Sniadecki.
- The Committee voted unanimously to approve the draft BUA for Dr. Sniadecki.

8. INDIVIDUAL PROJECT REVIEWS

- b.** Fields, Stanley, renewal, *Functional analysis of human genes*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project is developing methods to introduced mutations into human genes in order to test the effect these mutations have on the function the mutations in vivo. The work will be done in model organisms E. coli and yeast S. cerevisiae. The mutations will then be transferred to human cells 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. Fields.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fields.
- c.** Gordon, Sharona, renewal, *Mechanism of protein modulation*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to study the molecular basis for inflammatory pain-related hypersensitivity in order to identify appropriate targets for future drug developments; and to also develop methods for measuring conformational dynamics in proteins in order to develop novel and improved therapeutics.
 - Work involves in vitro use of Baculoviral vectors.
 - A successful lab inspection is 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. Gordon pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gordon pending a successful lab inspection.
- d.** Hawn, Thomas, change, *Innate immunity and Susceptibility to infectious Disease*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change is to add in vitro use of wild type and recombinant strains of Mycobacterium marinum.
 - 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. Hawn.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hawn.
- e.** Hotchkiss, Charlotte, renewal, *WaNPRC Colonies*
- The assigned IBC Primary Reviewer presented the Primary Review.

- This application is for a holding project for non-human primates that are not assigned to specific research projects. There is a potential that any non-human primate previously administered ABSL-1 or ABSL-2 biological agents on another project could be transferred to this holding protocol. Use of these biological agents would have been previously reviewed and approved by the IBC. No laboratory procedures will be performed on this project. Health monitoring of animals will be performed in accordance with the research protocol involving the biological agent previously administered.
 - A lab inspection is not required for this approval since it is a holding protocol only.
 - 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. Hotchkiss.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hotchkiss.
- f. Keel, Sioban, renewal, *Mechanisms of marrow failure and anemia*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies hematologic malignancies and inherited bone marrow failure syndromes.
 - Work includes in vitro use of Gammaretroviral vectors, replication deficient, ecotropic, oncogenic inserts, Lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient, oncogenic inserts, and Recombinant or synthetic DNA/RNA (non-viral), oncogenic inserts - enhanced gene delivery methods.
 - 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. Keel.
 - The Committee voted unanimously to approve the draft BUA for Dr. Keel.
- g. Kwon, Ronald, renewal, *Genetic Regulation of Bone in Zebrafish*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to identify new pathways underlying skeletal disease, development, and regeneration, as well as therapeutic strategies for intervention.
 - Work includes use of replication deficient Herpes simplex viral vector and recombinant or synthetic DNA/RNA (non-viral) enhanced gene delivery methods in vitro and in transgenic zebrafish.
 - A successful lab inspection is 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. Kwon pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kwon pending a successful lab inspection.
- h. Mathieu, Julie, renewal, *Human ES Core*
- The assigned IBC Primary Reviewer presented the Primary Review.

- The goal of this research is for the core facility to foster cell culture of pluripotent stem cells and their derivatives including through creation of pluripotent stem cells through embryo culture and inducing pluripotency from somatic cells.
 - Work involves various viral vectors in vitro and use of human cells transduced with viral vectors and cells transfected with recombinant or synthetic DNA for work in mice.
 - The Committee discussed use of oncogenes requiring BSL-2 w/3 practices. Suggestions made were that the PI drop this work from the BUA, change to use of third generation, or provide additional information to the IBC.
 - The lab was inspected and all deficiencies were corrected.
 - All of the required trainings have been completed.
 - The IACUC protocol has not been submitted yet and will require review.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Mathieu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mathieu.
- i. Murry, Charles, renewal, *NHP iPSC Derived Cardiomyocyte Grafts*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this research is to develop a clinical therapy for cardiovascular diseases and heart failure using heart muscle cells derived from non-human primate pluripotent stem cells.
 - Work involves various viral vectors in vitro and use of non-human primate cells transduced with viral vectors and cells transfected with recombinant or synthetic DNA for work in macaques.
 - A lab inspection was not required; the Murry lab is inspected when another BUA renews.
 - 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. Murry.
 - The Committee voted unanimously to approve the draft BUA for Dr. Murry.
- j. Muster, Jeanot, renewal, *Wnt Genes and Signaling (Zebrafish)*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this lab is to understand how a class of proteins, called Wnts, function to regulate communication between cells in both embryonic development and adults. This communication regulates regenerative functions in zebrafish with the goal of small molecule therapies.
 - Work includes use of human induced pluripotent stem (iPS) cells and replication deficient Herpes simplex viral vectors in transgenic zebrafish. In vitro work includes use of various 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. Muster.
 - The Committee voted unanimously to approve the draft BUA for Dr. Muster.
- k. Salipante, Stephen, renewal, *Next-generation sequencing for clinical translation*
- The assigned IBC Primary Reviewer presented the Primary Review.

- This lab works to expand the capabilities of next-generation DNA sequencing for clinical applications in order to advance the understanding of genetics in various areas of human health, including cancer and infectious disease.
 - Work involves in vitro use of *Pseudomonas aeruginosa* and *Staphylococcus aureus*.
 - A successful lab inspection is 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. Salipante pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Salipante pending a successful lab inspection.
- I. Schweppe, Devin, new, *Spatiotemporal regulation of host-pathogen interactions*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab investigates the changes in protein expression in human cells when they are infected with various gram negative pathogens.
 - Work includes in vitro use of *Acinetobacter baumannii*, *Klebsiella pneumonia*, and *Pseudomonas aeruginosa*.
 - 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. Schweppe.
 - The Committee voted unanimously to approve the draft BUA for Dr. Schweppe.
- m. Stempien-Otero, April, change, *Macrophages in Cardiac Fibrosis*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research goal is to understand how macrophages direct repair in the heart by modulating macrophage function to decrease the accumulation of excess collagen (fibrosis) which impairs cardiac function in patients with congestive heart failure.
 - Work includes use of mouse cells transduced with lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient in mice as well as in vitro work with lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient.
 - 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. Stempien-Otero.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stempien-Otero.
- n. Zalatan, Jesse, renewal, *Physical organizing principles of biological signaling protein networks*
- The assigned IBC Primary Reviewer presented the Primary Review.

- This lab studies cell signaling pathways such as molecular disruptions, purified protein biochemistry, and kinase scaffolding.
 - Work includes in vitro use of Baculovirus 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. Zalatan.
 - The Committee voted unanimously to approve the draft BUA for Dr. Zalatan.
- o. Zheng, Ying, renewal, *Microfluidic control of vascular growth and remodeling*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab strives to create functioning vascularized tissue, which can be used to recapitulate different organ environments to model organ-specific vascular diseases and regenerate lost tissue.
 - Work includes in vitro use of Gammaretroviral vectors, replication deficient, amphotropic with oncogenic inserts and Lentiviral vectors, non-HIV pseudotyped, replication deficient.
 - 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. Zheng.
 - The Committee voted unanimously to approve the draft BUA for Dr. Zheng.

9. SUBCOMMITTEE REPORTS:

- p. Green, Damian, renewal, *A phase I study of adoptive immunotherapy for advanced B-cell maturation antigen (BCMA)+ multiple myeloma with autologous CD4+ and CD8+ T cells engineered to express a BCMA-specific chimeric antigen receptor*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This clinical trial aims to address unmet medical needs to treat patients with relapsed or refractory Multiple Myeloma. Patients will be infused intravenously with CD4 and CD8 T cells transduced with a CAR construct at UW.
 - Possible percutaneous exposure of pharmacy or nursing staff is listed as the greatest biohazard.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Green. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Green.
- q. Hyde, Jennifer, change, *Contribution of virus-host interactions to viral pathogenesis (BLS3, non-select)*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This change adds several previously approved risk group 3 viruses for use in mice.
 - A lab inspection is not required because all work takes place in either the BSL-3 facility.
 - All of the required trainings have been completed.
 - The IACUC protocol has not been submitted, and requires review.

- The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Hyde. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hyde.
- r. Voigt, Emily, new, *Immunogenicity and efficacy testing of an RNA vaccine against yellow fever virus*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This lab will investigate the immunogenicity of a novel RNA-based vaccine against Yellow Fever Virus and Zika Virus.
 - A lab inspection is not required because all work takes place in either the BSL-3 facility or a vivarium, covered under other BUA approvals.
 - This approval is pending a medical management plan, Occupational Health consultations, training, and edits to the BUA application.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Voigt. Another member seconded the motion pending the items listed above.
 - The Committee voted unanimously to approve the draft BUA for Dr. Voigt pending the items listed above.
- s. McClelland, Scott, new, *A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This application was reviewed at a special IBC convened meeting on August 5, 2020 (meeting minutes are also available). Several conditions were made by the IBC, and have since been addressed.
 - Replication incompetence was confirmed and documentation was provided regarding the mobile clinics, PPE use, and biohazardous waste processes.
 - Occupational Health will work on recommendations for universal precautions.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. McClelland. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. McClelland.

10. FOR YOUR INFORMATION:

- The IBC requested guidance from the NIH regarding work proposed by Dr. Jennifer Hyde. Based on the information received back from the NIH, Dr. Hyde has chosen not to proceed with the proposed work.
- NIH Incident Report: A veterinary technician had a splash of buffer in the eye that had contained tissue from a non-human primate that had been infected with the recombinant virus SHIV-1157ipd3N4. The employee went to the Emergency Room for medical attention and is being monitored by the University Employee Health Clinic. This incident has been reported and is awaiting response from NIH.

- An update was provided on non-human primate SHIV waste protocols that the IBC has been asked to review. Information is still being collected.
- UW EH&S is working to produce a webinar for the IBC and UW IRB regarding oversight of human gene transfer work. The tentative date for this webinar is October 2020.
- Eric Stefansson was thanked for his many years of service on the IBC Committee.

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

12. MEETING ADJOURNED AT APPROXIMATELY 12:11 P.M.