



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, September 16, 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. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 4. Richard Grant, Washington National Primate Research Center
 5. Garry Hamilton (*Community Member*)
 6. Kevin Hybiske, 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. 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 August 19, 2020 meeting.
 - A member made a motion to approve the August 19, 2020 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the August 19, 2020 meeting minutes.
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 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 has been sent out.
 - At the August 19, 2020 meeting, Dr. Gordon's BUA was approved pending a successful lab inspection.
 - At the August 19, 2020 meeting, Dr. Kwon's BUA was approved pending a successful lab inspection. This BUA has been sent out.
 - At the August 19, 2020 meeting, Dr. Mathieu's BUA was approved pending review of the IACUC submission. This BUA has been sent out.
 - At the August 19, 2020 meeting, Dr. Salipante's BUA was approved pending a successful lab inspection. This BUA is still pending.
 - At the August 19, 2020 meeting, Dr. Hyde's BUA was approved pending review of the IACUC submission. This BUA is still pending.
 - At the August 19, 2020 meeting, Dr. Voigt's BUA was approved pending a medical management plan, Occupational Health consultations, training, and edits to the BUA application. 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. Bammler added a room to the BUA *Generating data for large-scale molecular epidemiology studies using genotyping capabilities and gene expression profiling*.
 - Dr. Cangelosi added non-recombinant human coronavirus strains 229E and OC43 to the BUA *Novel Detection of Bacterial, Viral, and Parasitic Pathogens in Clinical and Environmental Samples*.

- Dr. Abuzeid was approved for work with *Pseudomonas aeruginosa* in vitro and in rabbits for the new BUA *Disruption of Pseudomonas aeruginosa biofilms in a rabbit sinusitis model using a nitric-oxide releasing nanoparticle*.
- Dr. Mourad was approved for in vitro work with human blood, tissue, body fluids, and cell lines for the new BUA *Catheter Clearing*.
- Dr. Chiu renewed the BUA *Development of technologies for early detection and stratification of breast Cancer* to continue in vitro work with human blood, tissue, body fluids, and cell lines.
- Dr. Dey renewed the BUA *Gut microbial bile acid metabolism and effects on host physiology/pathophysiology* to continue work with various agents in mice at BSL-1 and -2.
- Dr. Perkel updated their location for the BUA *Neural circuits for auditory and vocal processing*.
- Dr. Giacani added a lab space for work with previously approved agents to the BUA *Studies on the pathogenesis of syphilis and human treponematoses*.
- Dr. Adams Waldorf added two new in vitro rooms for work with previously approved agents to the BUAs *Experimental Model of Viral-Induced Brain Injury*, *Experimental Model for Chorioamnionitis and Preterm Labor*, and *Influenza and Coronavirus Model of Immunity in Pregnancy*.
- Dr. Baker added new locations to the BUA *Institute for Protein Design and Affiliate Investigators*.
- Dr. Ladiges added two mouse cell lines requiring BSL-2 containment to the BUA *Aging Intervention*.
- Dr. Fujise added a new room for animal use to the BUA *Study of Fortilin*.
- Dr. Rabinovitch added the use of human iPS cells generated by episomal reprogramming and new gene inserts for adenoviral vectors to the BUA *Biology of Aging*.
- Dr. James took over as PI for the BUA *Persistence of immune cells* for work with non-human primate cells transduced with adeno-associated viral vectors (adenovirus-free) in macaques.
- Dr. Heinecke renewed the BUA *Studies of HDL Function* to continue in vitro work with human and non-human primate blood, tissue, body fluids, and cell lines.
- Dr. Imaizumi renewed the BUA *Molecular Mechanisms in Seasonal Time Management* to continue work in plants.
- Dr. Bomszyk renewed the BUA *Epigenetics and Disease Pathways* to continue in vitro work with human blood, tissue, body fluids, and cell lines.
- 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 voted to approve this month's Biosafety Officer Report. There was one voting abstention.

6. BSL-3 INACTIVATION REPORT

- Two projects received inactivation approval for BSL-3 agents.
- Dr. Murry was approved to conduct SARS-CoV-2 inactivation (Human pluripotent stem cell-derived and VERO cell-derived organoids) WITH 4%PFA (paraformaldehyde) and with Trizol.
- Dr. Hyde was approved to conduct SARS-CoV-2 inactivation with Trizol/TRI reagent/Acid phenol.

- The IBC Chair sought a motion to approve this month's BSL-3 Inactivation 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 BSL-3 Inactivation Report.

7. 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.

8. INDIVIDUAL PROJECT REVIEWS

a. Fuller, Deborah, renewal, *Influenza DNA Vaccine*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of this project is to develop a vaccine that can protect against both seasonal strains of influenza and provide an additional level of protection against pandemic strains emerging from avian and swine sources.
- Work includes use of the FluMist Influenza vaccine in 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. Fuller.
- The Committee voted unanimously to approve the draft BUA for Dr. Fuller.

b. Gire, David, renewal, *Neural circuit mechanisms of odor localization*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall research goal is to study the mechanisms through which the brain integrates and processes information across the cerebral cortex. The lab studies brain activity focused on the olfactory system during sensory-guided behaviors such as finding food, communicating with each other, and avoiding predators.
- Work includes use of Adeno-associated viral vectors (adenovirus free) in mice and rats.
- A successful lab inspection is still required.
- 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. Gire pending a successful lab inspection.
- The Committee voted unanimously to approve the draft BUA for Dr. Gire pending a successful lab inspection.

c. Goverman, Joan, renewal, *Animal Models of Autoimmunity*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies multiple sclerosis using transgenic and knockout mice.
- Work involves use of Adenoviral vector (E1a deleted), >2/3 adenovirus genome and Vaccinia virus in mice.
- The lab was inspected and any deficiencies identified were corrected.
- 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. Goverman.
 - The Committee voted unanimously to approve the draft BUA for Dr. Goverman.
- d. Hellstrom, Karl Erik, renewal, *Tumor Vaccines*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to develop more effective immunotherapy, including immunomodulatory monoclonal antibodies and therapeutic vaccines for several tumors such as melanoma and ovarian carcinoma in mouse models for later translation to humans.
 - Work includes in vitro use of viral vectors and use of human, mouse, and murine cells in mice.
 - A successful lab inspection is still required.
 - 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. Hellstrom pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hellstrom pending a successful lab inspection.
- e. Kennedy, Scott, renewal, *Somatic mutagenesis in aging and diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal is to understand the role of mutations in mitochondrial and nuclear DNA that affect lifespan and the propensity to develop common diseases of aging, cancer and neurodegenerative diseases.
 - Work includes breeding and use of transgenic *Drosophila*.
 - A successful lab inspection is still required.
 - 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. Kennedy pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kennedy pending a successful lab inspection.
- f. Moritz, Chet, change, *Combined Stem Cell Transplantation and Targeted Microstimulation to Direct the Formation of Functional Connections and Neural Repair in Rats*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change is to add a recombinant, replication competent HSV-1 (strain H129) containing the Brainbow cassette for use in vivo in rats. No viral genes have been deleted, and the vector is therefore acyclovir sensitive.
 - 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. Moritz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Moritz.
- g. Mougous, Joseph, renewal, *Type VI secretion-dependent interbacterial interaction*
- The assigned IBC Primary Reviewer presented the Primary Review.

- The goal of this renewal is to understand the mechanisms and consequences of bacterial interactions, and the mechanisms by which the pathogen *Francisella tularensis* causes disease.
 - Work includes in vitro use of several BSL-1 and -2 agents.
 - 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. Mougous.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mougous.
- h. Rabinovitch, Peter, change, *Biology of Aging*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds in vitro use of Adeno-associated viral vectors to previously approved rooms.
 - The lab was recently inspected, so no inspection was 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. Rabinovitch.
 - The Committee voted unanimously to approve the draft BUA for Dr. Rabinovitch.
- i. Ruohola-Baker, Hannele, change, *microRNA function in Human Embryonic Stem Cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds the breeding, creation, and/or use of transgenic zebrafish.
 - 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. Ruohola-Baker.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ruohola-Baker.
- j. Servetnick, Marc, renewal, *Role of vertebrate 'mesoderm genes' in development of the sea anemone Nematostella vectensis*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the roles of specific genes in the development of embryos of the sea anemone *Nematostella vectensis*, which have many of the genes found in vertebrates but lack vertebrate structures and organs. This research may yield insights into the role of these genes in animals that existed prior to the evolution of more complex vertebrates.
 - The lab is approved for creation, breeding, and/or use of transgenic *Nematostella vectensis*.
 - A successful lab inspection is still required.
 - 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. Servetnick pending a successful lab inspection.

- The Committee voted unanimously to approve the draft BUA for Dr. Servetnick pending a successful lab inspection.
- k. Trapnell, Cole, renewal, *Trapnell Lab General Operations*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab aims to discover novel regulators that govern cellular transitions (i.e. cell differentiation, reprogramming, etc.) by utilizing single-cell genomics. They will analyze large scale measurements of cellular transitions, build gene regulatory networks that govern them, and validate these networks with perturbations in the lab.
 - Work includes in vitro use of Lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient and oncogenic inserts.
 - A successful lab inspection is still required.
 - 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. Trapnell pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Trapnell pending a successful lab inspection.
- l. Xu, Haodong, renewal, *Regulation of Cardiac Na⁺ Channel*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - Ischemic heart disease (IHD), where blood supply to the heart is reduced, is a common health problem, and cardiac arrhythmias are often associated with it. Studies have associated these arrhythmias with problems of ion channels, such as sodium channel through heart cell membranes. This study investigates the role of Wnt/beta-catenin, FoxO1, Meis1 and Brg1 signaling pathways usually altered in IHD in the regulation of sodium channel, with the hope that our studies of these molecular signaling regulating the sodium channels may provide the basis for the development of new therapeutic agents.
 - 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. Xu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Xu.

9. SUBCOMMITTEE REPORTS:

- m. Lee, Sylvia, new, *A Phase 1 Open-Label, Multi-Center First in Human Study of TnMUC1-Targeted Genetically-Modified Chimeric Antigen Receptor T Cells in Patients with Advanced TnMUC1-Positive Solid Tumors and Multiple Myeloma*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The purpose of this study is to evaluate the safety, tolerability, feasibility, and preliminary efficacy of the administration of genetically modified autologous T cells (CAR-TnMUC1 cells) engineered to express a chimeric antigen receptor (CAR) capable of recognizing the tumor antigen, TnMUC1, and activating the T cell. Approximately 40 patients will be treated in the dose escalation phase followed by an additional 72 patients in the expansion phase. Patients will undergo lymphodepletion (LD)

chemotherapy at Day -6 to -4 (with an LD chemotherapy window of -1 day) and CART-TnMUC1 cell infusion on Day 0. Follow-up visits will commence per protocol following the CART infusion to monitor disease status and safety. After disease progression, patients will continue to be followed for long-term safety assessments and finally for the survival endpoint.

- The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Lee pending an edit to the BUA letter. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lee pending an edit to the BUA letter.
- n. West, T. Eoin, change, Host genetics and response to infection
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This change request adds antibiotic resistant and isolates and recombinant strains of *Burkholderia pseudomallei* at BSL-3. All strains are provided by a collaborator from Mahidol University in Bangkok. All strains will be used in vitro and in vivo (mice).
 - Many of the proposed strains have natural or engineered mutations at the *hcp1* allele, which is implicated as a virulence factor, and *penA* (ceftazidime, first line). *Hcp1* null strains have been shown to carry growth defects and are proposed as possible vaccine strains. The primary concerns surround a handful of isolates which are resistant to one or more first- and second-line antibiotics used to treat melioidosis: ceftazidime (CAZ), sulfamethoxazole (SXT), amoxicillin/clavulanate (AMC), and meropenem (MEM).
 - CDC approval is pending.
 - It is recommended that additional antibiotic sensitivity testing be performed prior to approval of the medical management plan.
 - The draft BUA letter was shown.
 - The Committee agreed to hold this as a conditional approval while the items above are addressed.

10. FOR YOUR INFORMATION:

- EH&S has launched a new viral vector website for PI use.
- The FBI informed EH&S that COVID-19 researchers on the East coast have received suspicious packages. A notice has been sent out to UW PIs by EH&S. No activity has been reported at UW or other universities along the West coast.
- NIH Incident Reports:
 - 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. The NIH OSP stated that the University's response was appropriate, and that no further action was required.
 - A recent incident is being followed up on to report to the NIH. A technician was injured with a scalpel during the dissection of a non-human primate.
- An updated was provided by a committee reviewer regarding the AstraZenica COVID-19 Vaccine Trial. The reviewer shared his knowledge regarding the current pause in the study due to an adverse event.

- A subcommittee will be formed to review UW processes around receiving BSL-3 agents from other PIs outside of the UW. This subcommittee will report back by the November IBC meeting.
- Lesley Decker, a Biosafety Officer with EH&S, was welcomed as a new IBC member.

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

12. MEETING ADJOURNED AT APPROXIMATELY 12:00 P.M.