INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, August 18, 2021
Time: 10:00 AM – 12:00 PM

Location: Zoom

Members Present:
1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
2. Thea Brabb, Comparative Medicine *(Animal Containment Expert)*
3. Jason Cantera *(Community Member)*
4. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
5. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
6. Richard Grant, Washington National Primate Research Center
7. David Koelle, Allergy and Infectious Diseases
8. Stephen Libby, Laboratory Medicine (*IBC Chair*)
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. **EH&S BIOTOXIN REVIEW PROCESS:** EH&S presented an overview of updates to the biotoxin review process.

4. **APPROVAL OF MINUTES:**
   - July 21, 2021
     - The IBC Chair sought a motion to approve the minutes from the July 21, 2021 meeting.
     - A member made a motion to approve the July 21, 2021 minutes. Another member seconded the motion.
     - The committee voted unanimously to approve the July 21, 2021 meeting minutes.
   - July 29, 2021
     - The IBC Chair sought a motion to approve the minutes from the July 29, 2021 meeting.
     - A member made a motion to approve the July 29, 2021 minutes. Another member seconded the motion.
     - The committee voted to approve the July 29, 2021 meeting minutes. There were three voting abstentions.

5. **OLD BUSINESS:**
   - At the June 16, 2021 meeting, Dr. Baker's BUA was approved pending completion of a successful lab inspection. This BUA is still pending.
   - At the June 16, 2021 meeting, Dr. Lee's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
   - At the July 21, 2021 meeting, Dr. Cirulli's BUA was approved pending BUAA edits and a successful lab inspection. This BUA has been sent out.
   - At the July 21, 2021 meeting, Dr. Freedman's BUA was approved pending a successful lab inspection. This BUA has been sent out.
   - At the July 21, 2021 meeting, Dr. Rasmussen's BUA was approved pending BUAA edits. This BUA is still pending.
   - At the July 21, 2021 meeting, Dr. Wills's BUA was approved pending training completion. This BUA is still pending.

6. **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. Koelle added three wild type human coronaviruses to existing rooms on the BUA *Koelle Laboratory at UW.*
      - Dr. Kennedy added a room and recombinant risk group 1 agents to the BUA *Somatic mutagenesis in aging and diseases.*

- Dr. Telfer renewed the BUA *Robotic system to study injuries and surgical treatments of the knee, the ankle, and the foot.* Work involves in vitro use of human blood, tissue, body fluids, and cell lines.
- Dr. Lutz added in vitro use of HIV-1 at BSL-2 w/3 practices to the BUA *Point-of-Care Diagnostic Device.*
- Dr. Wood added new rooms to the BUA *Multiple projects involving sexually transmitted bacterial pathogens.*
- Dr. Andrews added new rooms to the BUA *SHAPE - Sarcopenia as a predictor of Hospital-Associated ADL Disability in Older Adults.*
- 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.

7. BSL-3 INACTIVATION REPORT

- Dr. Fuller requested approval for inactivation of formalin-fixed mouse tissues infected with SARS-CoV-2 as well as DNA/RNA shield inactivation of SARS-CoV-2 cell supernatant.
- Dr. Hyde requested approval for RIPA buffer inactivation of SARS-CoV-2 cells and Glutaraldehyde inactivation of SARS-CoV-2 cells on coverslips.
- The subcommittee reviewed procedure and inactivation data provided by the labs and approved all requests.
- The IBC Chair a motion to approve this month's BSL-3 Inactivation Report.
- A member made a motion to approve this month's BSL-3 Inactivation Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's BSL-3 Inactivation Report.

8. 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.

9. INDIVIDUAL PROJECT REVIEWS

a. Brenowitz, Eliot, renewal, *Comparative Studies of Vocal Control*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goals of this project are to understand recovery from brain injuries by understanding the neurologic pathways involved in auditory processing and song motor control in white crown sparrows.
- Work includes use of: adeno-associated viral vectors (adenovirus free); foamy viral vectors, replication defective (RCV free packaging system); and, lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient in white-crowned sparrows.
- A lab inspection is scheduled and requires successful completion prior to BUA 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. Brenowitz pending completion of a successful lab inspection.

- The Committee voted unanimously to approve the draft BUA for Dr. Brenowitz pending completion of a successful lab inspection.

b. Davis, Jennifer, renewal, *The cellular and molecular mechanism of cardiac wound healing and fibrotic remodeling*
- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies extracellular matrix deposition in muscle and skin and cardiac repair.
- Work includes use of gammaretroviral vectors, replication deficient, amphotropic, oncogenic inserts in mice and in vitro. Various other viral vectors and human induced pluripotent stem (iPS) cells are also used in rats, mice, and in vitro.
- A successful lab inspection has been completed.
- 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. Davis.
- The Committee voted unanimously to approve the draft BUA for Dr. Davis.

c. de la Iglesia, Horacio, renewal, *Neural control of circadian rhythms*
- The assigned IBC Primary Reviewer presented the Primary Review.
- This project aims to understand how rhythmic processes (sleep-wake cycle, release of hormones and mood) are modulated by biological clocks, and how these clocks are affected by environmental challenges and other temporal disruptions.
- Work includes use of adeno-associated viral vectors (adenovirus free) in vitro and in mice.
- A lab inspection is scheduled and requires successful completion prior to BUA approval.
- Training completion is still required.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. de la Iglesia pending completion of training and a successful lab inspection.
- The Committee voted unanimously to approve the draft BUA for Dr. de la Iglesia pending completion of training and a successful lab inspection.

d. del Alamo, Juan, new, *Biomechanics of amoeboid cell migration*
- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall research goals are to understand how amoeboid cells such as leukocytes migrate and how multiple cells can act in concert biomechanically.
- Work includes use of human cells transduced with Sendai virus vectors, replication deficient, oncogenic inserts and lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient in vitro.
- A lab inspection is scheduled and requires successful completion prior to BUA 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. del Alamo pending a successful lab inspection.
- The Committee voted unanimously to approve the draft BUA for Dr. del Alamo pending a successful lab inspection.

e. Escobar, Thelma, new, *Chromatin dynamics in stem cells and immune cell function*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of this project is to study the mechanisms of chromatin dynamics in human hematopoietic stem cells and mouse embryonic stem cells in order to understand and model development of disease.
- Work includes use of: baculoviral vectors; gammaretroviral vectors, replication deficient, ecotropic; Sendai viral vector, oncogenic inserts; and, lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient, both with and without oncogenic inserts. All work is done in vitro.
- A successful lab inspection has been completed.
- 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. Escobar.
- The Committee voted unanimously to approve the draft BUA for Dr. Escobar.

f. Papayannopoulou, Thalia, renewal, *Gene therapy for hemoglobinopathies: bone marrow conditioning*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies the regulation of erythropoiesis and conditions leading to terminal maturation and fetal glob in expression.
- Work includes use of human cells transduced with lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient in mice.
- A lab inspection is scheduled and requires successful completion prior to BUA 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. Papayannopoulou pending completion of a successful lab inspection.
- The Committee voted unanimously to approve the draft BUA for Dr. Papayannopoulou pending completion of a successful lab inspection.

g. Weil, Ana, change, *Isolation of gut microbes from human stool/vomitus, testing bacteria for pathogen interactions*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This study investigates the functional relationships between gut microbial communities and enteric diseases, including identification of gut species that may protect against infection, relationships between gut microbial species and mucosal immune responses, and defining how the gut microbiota may influence immune responses to V. cholerae infection and vaccination.
- This change adds in vitro use of several bacterial microbes including recombinant L. monocytogenes.
- A successful lab inspection has been completed.
- 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. Weil.
- The Committee voted unanimously to approve the draft BUA for Dr. Weil.

10. SUBCOMMITTEE REPORTS:

h. Johnston, Christine, change, *A Phase 1/2 Study of Delayed Heterologous SARS-CoV-2 Vaccine Dosing (Boost) after Receipt of EUA Vaccines*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a NIH-sponsored, multi-site, phase 1/2 study of two different COVID-19 vaccine platforms. This study originally involved vaccines with FDA EUAs and did not require IBC review. This application is a modification in a which spike protein coding sequences are changed to reflect currently circulating SARS-CoV-2 variants.
- This will be administered intramuscularly as a booster to recipients of the Johnson & Johnson, Pfizer, or Moderna vaccines at least 12 weeks from their last dose. Safety and immunogenicity are the primary endpoints.
- Percutaneous exposure to staff administering the booster is the greatest risk.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Johnston. Another member seconded the motion.
- <u>The Committee voted to approve the draft BUA for Dr. Johnston. There was one voting abstention.</u>

i. Liao, John, new, *Phase I study evaluating benefit of PRGN-3005 (autologous CAR T cells) delivered by intraperitoneal infusion (IP) or intravenous infusion (IV) in advanced stage platinum resistant ovarian cancer patients*

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is an industry-sponsored, multi-site, phase I study of intraperitoneal and intravenous infusion of autologous CAR T cells for advanced stage platinum resistant ovarian cancer.
- The study is broken up into two phases: a dose escalation phase followed by a dose expansion phase. The primary objective is to characterize dose-toxicity and to estimate the maximum tolerated dose. The dose expansion phase will further characterize safety and efficacy at the maximum tolerated dose. Currently, the study is in the dose escalation phase with over 15 patients enrolled and treated without any experiencing dose-limiting toxicity.
- Percutaneous exposure to staff is the greatest risk.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Liao. Another member seconded the motion.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Liao.</u>

j. Oberst, Andrew, renewal, *Programmed cell death and immunity*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The goal of the research is to understand the mechanisms that control the cellular suicide programs collectively called "programmed cell death," and the immunological consequences of different types of programmed cell death in vivo.
- Work includes use of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in vitro and in mice.

- A lab inspection is scheduled and requires successful completion prior to BUA approval.
- All of the required trainings have been completed.
- Revisions are required to the IACUC protocol prior to BUA approval.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Oberst. Another member seconded the motion pending a successful lab inspection and edits to the IACUC protocol.
- The Committee voted unanimously to approve the draft BUA for Dr. Oberst pending the conditions state above.

k. Olmos de Koo, Lisa, new, *GT005-02 (EXPLORE): A PHASE 2, OUTCOMES ASSESSOR-MASKED, MULTICENTRE, RANDOMISED STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TWO DOSES OF GT005 ADMINISTERED AS A SINGLE SUBRETINAL INJECTION IN SUBJECTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is an industry sponsored, multi-site, not-first-in-humans, one eye, two-dose-level, placebo-controlled trial of eye injection of a gene therapy for specific type of age-related macular degeneration (AMD).
- Percutaneous exposure to staff is the greatest risk.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Olmos de Koo. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Olmos de Koo.

l. Olmos de Koo, Lisa, new, *GT005-03 (HORIZON): A PHASE II, OPEN-LABEL, OUTCOMES-ASSESSOR MASKED, MULTICENTRE, RANDOMISED, CONTROLLED STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TWO DOSES OF GT005 ADMINISTERED AS A SINGLE SUBRETINAL INJECTION IN SUBJECTS WITH GEOGRAPHIC ATROPHY SECONDARY TO DRY AGE-RELATED MACULAR DEGENERATION*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is an industry sponsored, multi-site, not-first-in-humans, one eye, two-dose-level, placebo-controlled trial of eye injection of a gene therapy for specific type of age-related macular degeneration (AMD).
- Percutaneous exposure to staff is the greatest risk.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Olmos de Koo. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Olmos de Koo.

10. FY2021 BUA METRICS: EH&S presented an overview of BUA metrics over the course of fiscal year 2021.

11. FOR YOUR INFORMATION:

- There was an inactivation failure discovered in the BSL-3 facility. The failure involved one positive sample of Trizol inactivation, most likely due to human error. All work was contained.

The Trizol inactivation was redone, and an inactivation failure SOP was created in response to the event. EH&S will continue to follow up on the exact cause and will report their findings back to the IBC at an upcoming meeting.

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

13. **MEETING ADJOURNED AT APPROXIMATELY 12:04 P.M.**