

Meeting Minutes

Date: Wednesday, May 19, 2021 **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. 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. Susan Parazzoli (Community Member)

9. Jason Smith, Microbiology (IBC Vice Chair)

10. 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

<u>NIH</u>: National Institutes of Health <u>DURC</u>: Dual Use Research of Concern <u>SOP</u>: standard operating procedure

- **1. CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:00 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 April 21, 2021 meeting.
- A member made a motion to approve the April 21, 2021 minutes. Another member seconded the motion.
- The committee voted to approve the April 21, 2021 meeting minutes. There was one voting abstention.

4. OLD BUSINESS:

- At the March 18, 2020 meeting, Dr. Lagunoff's BUA was approved pending completion of training. This BUA is still pending.
- At the February 17, 2021 meeting, Dr. Thomas's BUA was approved pending a successful lab inspection. This BUA has been sent out.
- At the April 21, 2021 meeting, Dr. Bengtsson's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
- At the April 21, 2021 meeting, Dr. Ladiges' BUA was approved pending review of the IACUC protocol. This BUA is still pending.
- At the April 21, 2021 meeting, Dr. Pepper's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
- At the April 21, 2021 meeting, Dr. Scatena's BUA was approved pending review of the IACUC protocol. This BUA has been sent out.
- At the April 21, 2021 meeting, Dr. Wong's BUA was approved pending completion of a successful lab inspection. 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. Limaye was approved for the BUA A Phase 3b, open-Label, Safety and Immunogenicity Study of SARS-CoV-2-mRNA-1273 Vaccine in Adult Solid Organ Transplant Recipients and Healthy Controls.
 - Dr. Theberge added non-recombinant Staphylococccus aureus to the BUA *Studying* cell signaling and cell-microenvironment interactions with new analytical tools.
 - Dr. Rieke renewed the BUA *Biophysical Mechanisms of Photo Detection*. Work includes use of recombinant or synthetic DNA/RNA (non-viral) in vitro.
 - Dr. Schwartz added rabies virus vector, avian pseudotyped (RVdeltaG-EnvA) to the BUA Neuro-Endocrine Control of Energy Balance (Mice).
 - Dr. Gelb added a room to the BUA Analysis of Inborn Errors of Metabolism in Human Blood Samples.
 - Dr. Manookin was approved for work with non-human primate blood, tissue, body fluids, and cell lines on the BUA *Neural pathways in the retina*.

- Dr. Drury-Stewart renewed the BUA Silicon Photonic Bloody Typing.
- Dr. Mitchell added work with Shigella flexneri and Dengue virus in mice (approved by the IBC on March 3, 2021) to the BUA *Evolutionary, genetic, and molecular basis of host-pathogen interactions*.
- Dr. Koelle added HIV-1 at BSL-2 with BSL-3 practices to the BUA Koelle Laboratory at UW. The lab will be culturing patient samples containing HIV-1 with T-cell stimuli.
 While there are no plans to directly culture the virus, a higher biosafety level is required.
- Dr. Orsborn updated room numbers on the BUA Adaptive neural interfaces for treating neurological disorders and probing neural function.
- Dr. Levy added a laboratory space to the BUA Levy Research Group: ChEEP ChEEP, EcoMiD, EcoZUR, PAASIM.
- Dr. Fuller added a SARS-CoV-2 variant to the BUA DNA Vaccine Therapy.
- Dr. Starita added a laboratory space to the BUA *Brotman Baty Advanced Technology Lab: General Research.*
- Dr. Johnston was approved for a new BUA, A Phase 1/2 Study of Delayed Heterologous SARS-CoV-2 Vaccine.
- Dr. Klavins added rooms to the BUA RoL:FELS:Exploring the adaptive possibilities of 'redundancy'.
- Dr. Baker added rooms to the BUA *Institute for Protein Design and Affiliate Investigators*.
- 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. There were two voting abstentions.

6. BSL-3 INACTIVATION REPORT

- The IBC subcommittee reviewed a request to waive verification of a Trizol inactivation method of SARS-CoV-2 to remove samples out of the BSL-3 facility to be worked on at BSL-2. The subcommittee agrees Trizol is an effective method for inactivation of SARS-CoV-2. The subcommittee also agrees testing each sample may be too burdensome when processing large numbers of samples without a proportionate benefit. The subcommittee decided risk of human error cannot be discounted if no samples are tested. Therefore, the subcommittee recommends testing at least 10% of the samples or at least one sample if the sample size is less than 10.
- The IBC Chair sought a motion to approve this month's BSL-3 Inactivation Approvals Report.
- A member made a motion to approve this month's BSL-3 Inactivation Approvals Report. Another member seconded the motion.
- The Committee voted to approve this month's BSL-3 Inactivation Approvals Report. There was one voting abstention.

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. Allbritton, Nancy, change, Tissue culture in Allbritton Lab

- The assigned IBC Primary Reviewer presented the Primary Review.
- This change adds the use of replication deficient lentiviral vectors in vitro.
- A lab inspection was recently completed and is 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.
 Allbritton
- The Committee voted to approve the draft BUA for Dr. Allbritton. There was one voting abstention.

b. Cabernard, Clemens, renewal, *Snail Asymmetry*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This study will apply advanced imaging methods to visualize cytoskeletal structures and dynamics in snails and snail embryos. This study will test methods to tag and express cytoskeleton proteins of interest fused with fluorescent proteins.
- 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. Cabernard.
- The Committee voted to approve the draft BUA for Dr. Cabernard. There was one voting abstention.

c. Crudele, Julie, new, *Gene therapy in mice*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall research goal is to develop a treatment or cure for GNE myopathy.
- Work includes use of adeno-associated viral vectors (adenovirus free) in mice.
- 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. Crudele.
- The Committee voted to approve the draft BUA for Dr. Crudele. There was one voting abstention.

d. Guo, Monica, new, *Chromosome organization in microbes*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab studies the chromosome organization in microbes and how that chromosome structure affects DNA replication. A major component of the lab is to describe proteins required for DNA replication or topoisomerase function in order to identify new proteins as targets for potential antimicrobial drugs.
- Work includes in vitro use of Enterococcus faecalis and Pseudomonas auruginosa.
- 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. Guo.
- The Committee voted unanimously to approve the draft BUA for Dr. Guo.

- **e.** Parrish, Jay, renewal, *Structural and functional coupling of epidermis to somatosensory neurons in Drosophila*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab studies somatosensory neuron development and function using the Drosophila model.
 - 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. Parrish.
 - The Committee voted unanimously to approve the draft BUA for Dr. Parrish.
- f. Pasupathy, Anitha, renewal, Neural basis of visual shape representation and recognition
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of the lab is to understand the relationship between brain activity and higher level cognitive functions such as visual perception, recognition, memory and decision making. In this project they use molecular tracers to map neural connections in NHPs brain in the prefrontal cortex, visual cortex, and the pulvinar and study how these regions work together.
 - Work includes use of adeno-associated viral vectors (adenovirus free) in macaques.
 - 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. Pasupathy.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pasupathy.
- g. Patel, Anoop, renewal, Heterogeneity in Glioblastoma
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - Using profiling of patient brain tumors, this lab aims to understand glioblastoma heterogeneity and how that leads to treatment resistance.
 - Work includes use of lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient, oncogenic inserts.
 - 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. Patel.
 - The Committee voted unanimously to approve the draft BUA for Dr. Patel.
- **h.** Wang, Yak-Nam, change, *Ultrasound treatment of abscesses*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change approves use of previously approved Bacteroides fragilis and pathogenic strains of Escherichia coli in pigs.
 - A successful lab inspection has been completed.
 - All of the required trainings have been completed.
 - Review of a site-specific ABSL-2 SOP is pending.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Wang pending development and review of the ABSL-2 SOP.

• The Committee voted unanimously to approve the draft BUA for Dr. Wang pending development and review of the ABSL-2 SOP.

9. SUBCOMMITTEE REPORTS:

- i. Carter, Darrick, new, HDT Bio. COVID-19 Research
 - Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The proposed studies are to infect a human kidney organ-on-a-chip device with SARS-CoV-2 in the presence or absence of anti-virals, immune stimulants, antibodies, or serum. The device is seeded with human cells. Progeny virus will be collected, and viral titers will be determined. They intend to use both WA-1 and B.1.351 isolates provided by other UW labs. This lab does not plan to culture their own inocula.
 - The draft BUA letter was shown.
 - Additional personnel need to be added to BUA application and have training completion verified
 - A member made a motion to approve the draft BUA letter for Dr. Carter pending the addition of personnel to the BUA application. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Carter pending the addition stated above.
- i. Koelle, David, change, C19 SARS-CoV-2-specific T cells in the infected nasal epithelium
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This change adds the use of SARS-CoV-2, human cells, and non-human primate cells in the BSL-3/ABSL-3 facility. Nucleic acid containing SARS-CoV-2 genes was also added.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Koelle. Another member seconded the motion.
 - The Committee voted to approve the draft BUA for Dr. Koelle. There was one voting abstention.
- **k.** Maloney, David, renewal, An Open-Label, Phase 1 Safety and Phase 2 Randomized Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (017004)
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is an autologous CAR-T clinical trial with a CD19-targeting CAR molecular for
 patients with relapsed or refractory chronic lymphocytic leukemia or a related illness,
 small lymphocytic lymphoma.
 - UWMC is a backup site if patients are sick and need hospital level care or backup at the time of cell infusion (at a local outside site).
 - The greatest biohazardous risk to personnel is possible percutaneous exposure.
 - The draft BUA letter was shown.
 - 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.

- **I.** Mitchell, Patrick, change, Evolutionary, genetic, and molecular basis of host-pathogen interactions
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This change adds the use of SARS-CoV-2 and human and non-human primate cells at BSL-3. A recombinant version of mouse hepatitis virus, wildtype human coronavirus OC43, and nucleic acid from SARS-CoV-2 were also added.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Mitchell. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mitchell.
- **m.** Oberst, Andrew, change, *Programmed cell death and immunity*
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This amendment changes the containment of West Nile Virus to BSL-2 (from BSL-2 with BSL-3 practices) in response to new regulatory guidelines.
 - 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.
 - The Committee voted unanimously to approve the draft BUA for Dr. Oberst.
- **n.** Biosafety Manual Updates, policy
 - Biosafety Manual updates were presented to the committee.
 - A member made a motion to approve the updates to the Biosafety Manual. Another member seconded the motion.
 - The Committee voted unanimously to approve the updates to the Biosafety Manual.

10. FOR YOUR INFORMATION:

- NIH Incident Report: In a BSL-2 laboratory, a research assistant poked their right thumb with a pair of sharp forceps. The forceps had been used to transfer a coverslip that contained human induced pluripotent cardiomyocytes that were transfected with recombinant DNA via lipofectamine transfection. The injury occurred after the coverslip was transferred, as the research assistant prepared to disinfect the forceps. There was a small wound. The employee received medical care after the incident and is being monitored by the University Employee Health Clinic. This incident has been reported and is awaiting response from NIH.
- **11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:** There were no issues from the floor, and no public comments.
- 12. MEETING ADJOURNED AT APPROXIMATELY 11:37 A.M.