



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, June 17, 2020

Time: 10:00 AM – 12:00 PM

Location: Remote via 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:**
 - The IBC Chair sought a motion to approve the minutes from the May 20, 2020 meeting.
 - A member made a motion to approve the May 20, 2020 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the May 20, 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 May 20, 2020 meeting, Dr. Duthie's BUA was approved pending additions to the BUA application. This BUA has been sent out.
 - 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 is still pending.
 - At the May 20, 2020 meeting, Dr. Rathod's BUA was approved pending occupational health concerns and training completion. This BUA has been sent out.
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. Hallstrand added research involving clinical samples from patients known or suspected to be infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to the BUA *Asthma and Translational Research Core*. No viral isolation or culturing is permitted.
 - Dr. Kennedy added use of a core facility to the BUA *Somatic mutagenesis in aging and neurodegenerative diseases*.
 - Dr. Schwartz added the use of human blood, tissue, body fluids, and cells lines for in vitro work to the BUAs *Neuro-Endocrine Control of Energy Balance (Rat)* and *(Mice)*.
 - Dr. Gao renewed the BUA *Systemic Delivery of siRNA Drugs and Nanoparticle-based Tumor Detection*. Work includes in vitro use of recombinant or synthetic DNA/RNA (non-viral) – enhanced gene delivery methods and human blood, tissue, body fluids, and cell lines.
 - Dr. An was approved for a new BUA, *Gingival-Periodontal Interface System*. Work includes in vitro use of *Lactobacillus reuteri* and human and non-human primate blood, tissue, body fluids, and cell lines.
 - Dr. Landis renewed the BUA *HCV*. Work includes in vitro use of human blood, tissue, body fluids, and cell lines.
 - 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.
 - The Committee unanimously voted to approve this month's Biosafety Officer Report.
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. **CURRENT BIOSAFETY LAB INSPECTIONS:** EH&S presented on current biosafety lab inspection processes due to COVID-19.

8. **INDIVIDUAL PROJECT REVIEWS**

- a. Brockerhoff, Susan, new, *Determinants of Rod and Cone Response Characteristics*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project aims at demonstrating how the metabolic state of the retina changes in response to shifts between light and dark conditions. The lab is breeding lines of transgenic zebrafish, some with GFP-fusion proteins, in order to study their retinas.
 - 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. Brockerhoff.
 - The Committee voted unanimously to approve the draft BUA for Dr. Brockerhoff.
- b. Fowler, Douglas, renewal, *Large-Scale Phenotyping of Tumor Suppressor Variants in Human Cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the consequences of mutations in proteins important for cancer, Alzheimer's, Parkinson's disease, and developmental problems.
 - Work includes in vitro use of lentiviral vectors and recombinant or synthetic DNA/RNA (non-viral) enhanced gene delivery methods.
 - The lab inspection checklist was completed by the PI and no deficiencies were identified. An in-person lab inspection is postponed due to COVID-19.
 - 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. Fowler.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fowler.
- c. Gallagher, Evan, renewal, *Molecular and Biochemical Effects of Pollutants on Fish*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab works on aquatic toxicology, specifically looking at how pollutants such as heavy metals effect the sense of smell in fish.
 - Work includes 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. Gallagher.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gallagher.
- d. Greninger, Alex, change, *Discovery and Characterization of Virus-Host Interaction*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds in vitro use of G protein deficient Vesicular stomatitis virus (VSV), Indiana Strain.
 - The lab aims to understand the interaction of SARS-CoV-2 with host cells. They want to produce G protein deficient vesicular stomatitis virus pseudovirus containing the spike protein of SARS-CoV-2 for use in neutralization assays.
 - A successful lab inspection was recently conducted, so one is not needed 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. Greninger.
 - The Committee voted unanimously to approve the draft BUA for Dr. Greninger.
- e. Hoppins, Suzanne, renewal, *Mitochondrial Behavior*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to study the behavior of mitochondria including the mechanism of mitochondrial movement on microtubules and the mechanism of mitochondrial fusion using biochemical and cell biology techniques.
 - Work includes use of transgenic *Caenorhabditis elegans*, replication deficient ecotropic gammaretroviral vectors, and recombinant or synthetic DNA/RNA (non-viral) enhanced gene delivery methods.
 - 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. Hoppins pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hoppins pending a successful lab inspection.
- f. Hu, Shiu-lok, renewal, *Virus-like particles (VLP) with stabilized trimeric envelope (ENV) for prime-boost immunization*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research goal is to explore novel immunogens and immunization approaches to improve the protective efficacy of prime-boost immunization against HIV/AIDS.
 - Work includes in vitro use of primate lentivirus. It also includes work with vaccinia virus in vitro and 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. Hu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hu.

- g. Hyde, Jennifer, change, *Contribution of virus-host interactions to viral pathogenesis*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds use of recombinant SARS-CoV-2 and new human cell lines.
 - A successful lab inspection was recently conducted, so one is not needed 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. Hyde.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hyde.
- h. Koelle, David, renewal, *Immune response and pathogenesis of viral infections*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies T cell responses to human pathogens and develops vaccines. They perform immunologic and virologic assays on a broad range of viral pathogens. Some of their work includes other types of microbes. They also analyze primary human cells.
 - Work includes in vitro use of various agents at BSL-2, such as Herpes simplex virus 1 and 2, Talimogene laherparepvec (T-VEC), vaccinia virus, varicella zoster virus, lentiviral vectors, and gammaretroviral 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. Koelle.
 - The Committee voted unanimously to approve the draft BUA for Dr. Koelle.
- i. Lieber, Andre, change, *Stem cell gene therapy of cancer and hematological diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds in vitro work with primate lentiviruses and heat killed SARS-CoV-2 obtained from ATCC.
 - A successful lab inspection is 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. Lieber pending review of SOPs, a change to BUAL, and a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lieber pending the items above.
- j. Monnat, Raymond, renewal, *Small Molecule Protection of Bone Marrow Hematopoietic Stem Cells*
- The assigned IBC Secondary Reviewer presented the Primary Review.
 - The goal of this project is to use genomic data on head-neck squamous cell carcinoma (HNSCC) arising in Fanconi Anemia (FA) patients to identify better ways to treat these aggressive cancers.
 - Work includes in vitro use of 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 Secondary Reviewer made a motion to approve the draft BUA for Dr. Monnat.
 - The Committee voted unanimously to approve the draft BUA for Dr. Monnat.
- k.** Moritz, Chet, renewal, *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.
 - The overall research goal is to develop treatments for traumatic brain injury, stroke, or spinal cord injury through administration of human induced pluripotent stem cells that are then activated with electrical microstimulation.
 - Work includes use of Pseudorabies virus (PRV), Bartha strain, Adeno-associated viral vectors (adenovirus free), and human induced pluripotent stem (iPS) cells in rats.
 - The lab inspection checklist was completed by the PI and no deficiencies were identified. An in-person lab inspection is postponed due to COVID-19.
 - 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.
- l.** Moussavi-Harami, Farid, new, *Cardiomyopathy Mechanisms and Therapies*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab is interested in genetic determinants of cardiac cardiomyopathies, and in testing novel therapies to treat these diseases.
 - Work includes in vitro use of Adeno-associated viral vectors (adenovirus free), Adenoviral vector (E1a deleted), >2/3 adenovirus genome, and Lentiviral vectors, 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. Moussavi-Harami.
 - The Committee voted unanimously to approve the draft BUA for Dr. Moussavi-Harami.
- m.** Parsek, Matthew, renewal, *Responses of Pseudomonas aeruginosa to other bacteria in the CF Lung*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The focus of this project is to examine the molecular biology of Pseudomonas aeruginosa biofilms and the matrix components that hold these communities together.
 - Work includes in vitro use of Pseudomonas aeruginosa, Pseudomonas fluorescens, Staphylococcus aureus, Sulfitebacter SA11, and Burkholderia thailandensis.
 - 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. Parsek pending changes to the BUAA.
 - The Committee voted unanimously to approve the draft BUA for Dr. Parsek.

9. SUBCOMMITTEE REPORTS:

- n. Altemeier, William, change, *Inflammatory Response Modulation by Mechanical Ventilation*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This change adds SARS-CoV-S in vitro and in transgenic mice at BSL-3.
 - BSL-3/ABSL-3 trainings require completion.
 - The PI must submit all SOPs and inactivation-validation protocols prior to beginning any work.
 - The IACUC Protocol has not been submitted yet, and will require review.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Altemeier pending review of the IACUC protocol and required training. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Altemeier pending review of the IACUC protocol and required training.
- o. Hyde, Jennifer, change, *Contribution of virus-host interactions to viral pathogenesis (BSL3, non-select)*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This change adds recombinant SARS-CoV-2 and new human cell lines for in vitro use.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The subcommittee had questions regarding the proposed genetic modifications to SARS-CoV-2. The IBC was concerned the proposed mutations may cause unintended consequences such as an increase in tropism, enhanced replication, and overall increased in potential virulence. The IBC recognizes that the only way to determine this is through experimentation by making the mutations and determine experimentally their effects. The committee also had concerns that if these mutations where to increase replication and/or increase tropism, the work may fall under Dual Use Research of Concern (DURC) regulations.
 - The Subcommittee recommends to have this application reviewed by ad hoc reviewers with more expertise than we currently have on the IBC.
 - The Subcommittee recommends that all work to generate wild type and NeoGreen-tagged virus can proceed.
 - A member made a motion to approve the draft BUA letter for Dr. Hyde pending the recommendations stated above.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hyde pending the recommendations stated above.
- p. Kreuzer, Helen, new, *Evaluation of CoV lipidomics data and How MERS-CoV regulates the innate immune response in primary human lung cells*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The overall goals of the project are to understand the host response to highly pathogenic human coronaviruses including severe acute respiratory syndrome

coronavirus (SARS-CoV 2002 strain) and Middle east respiratory syndrome coronavirus (MERS-CoV).

- All of the required trainings have been completed.
- Currently, there is not a medical management plan in place yet to work with these viruses. This will be a preliminary review contingent on completion of medical management.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Kreuzer pending the medical management plan. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Kreuzer pending the medical management plan.

q. Murry, Charles, change, *Myocardial Infarct Repair*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This change is to add wild type and recombinant SARS-CoV-2 for in vitro work.
- SARS-CoV-2 wild type and mNeogreen-tagged virus will be used to infect human pluripotent stem cell derived cardiomyocytes and engineered heart tissues. Infected tissues and cells will be processed for removal from the BSL-3. Inactivation protocols will follow for IBC review before being removed from the BSL-3.
- All of the required trainings have been completed.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Murry. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Murry.

r. Konkle, Barbara, new, *Open-label, dose escalation, safety, tolerability, and efficacy study of SIG-001 in Adult patients with severe or moderately-severe Hemophilia without inhibitors*

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This first in humans study focuses on male patients with factor VIII gene mutations with hemophilia. Improved therapies requiring less frequent dosing are being sought.
- Genetically modified human cells designed to express a form of factor VIII will be encapsulated in alginate and administered intraperitoneally to patients with hemophilia.
- Percutaneous exposure to hospital personnel is the greatest biosafety issue.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Konkle. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Konkle.

s. Maloney, David, renewal, *A Phase 2 Multicenter Study of Axicabtagene Ciloleucel in Subjects with Relapse/Refractory Indolent Non-Hodgkin Lymphoma (INHL)*

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This study is designed to estimate the efficacy of KTE-C19 in patients with follicular lymphoma and patients with indolent NHL who have experienced disease progression or are refractory to standard therapies. This is an autologous T cell product engineered to target CD19

- Percutaneous exposure to hospital personnel is the greatest biosafety issue.
 - 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.
- t. Turtle, Cameron, new, *A PHASE 1/2 OPEN-LABEL CLINICAL TRIAL OF TC-110 T CELLS IN ADULTS WITH RELAPSED OR REFRACTORY NON-HODGKIN LYMPHOMA (NHL) OR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a first in humans phase 1/2 open-label study to evaluate the safety and efficacy of autologous genetically engineered TC-110 T cells in adults with relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL) or acute lymphoblastic leukemia (ALL).
 - Percutaneous exposure to hospital personnel is the greatest biosafety issue.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Turtle. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Turtle.
- u. BSL-3 SOP Review Process
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Subcommittee reviewed an SOP for inactivating risk group 3 agents so that they may be brought out of the BSL-3 facility and manipulated at lower containment or shipped. Overall, the subcommittee felt that the methods are robust and conform to current guidelines. The subcommittee had suggestions and minor comments on the clarification of the SOP.
 - A member made a motion to approve the draft SOP with edits. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft SOP.

10. FOR YOUR INFORMATION:

- **EH&S COVID-19 Webpage:** A new web page regarding COVID_19 research biosafety guidance has been developed and can be accessed here: <https://www.ehs.washington.edu/biological/covid-19-research-biosafety-guidance>. This guidance is intended to assist investigators planning research involving SARS-CoV-2 to understand the health and safety considerations and compliance expectations necessary to safely facilitate the research.

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

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