



# INSTITUTIONAL BIOSAFETY COMMITTEE

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## UNIVERSITY of WASHINGTON

### Meeting Minutes

**Date:** Wednesday, March 18, 2020

**Time:** 10:00 AM – 12:00 PM

**Location:** Foege N130A; 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 February 19, 2020 meeting.
  - A member made a motion to approve the February 19, 2020 minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the February 19, 2020 meeting minutes. There were three abstentions.
4. **OLD BUSINESS:**
  - At the February 2020 meeting, Dr. Mullins' BUA was approved pending changes to the BUA application. This BUA has been sent out.
  - At the February 2020 meeting, Dr. Sellers' BUA was approved pending an addition to the BUA letter. 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. Seshadri added lab spaces to the BUA *Human Immunity to Mycobacterial Diseases*.
    - Dr. Patton added use of non-recombinant *Neisseria macacae* to the BUA *Sexually Transmitted Disease Prevention – Primate Unit*.
    - Dr. Tian added use of the Immunology Cell Analysis Facility to the BUA *Energetics and Metabolism of the Heart*.
    - Dr. Mikacenic added a lab space to the BUA *Human Immune Response in the Lung*.
    - Dr. Hsu renewed the BUA *Murine norovirus infection in laboratory mice*. Work includes use of *Helicobacter bilis* and Murine norovirus in mice and in vitro.
    - Dr. Goverman renewed the BUA *Cell Analysis Core Facility*. Work involves in vitro use of cells pre-approved by the IBC for BSL-1 containment and practices.
    - Dr. Gelb renewed the BUA *Analysis of Inborn Errors of Metabolism in Human Blood Samples*, working with human blood, tissue, body fluids, and cell lines in vitro.
    - Dr. Greninger registered work with individual genes from SARS-CoV, SARS-CoV-2 and MERS-CoV to the BUA *Discovery and Characterization of Virus-Host Interactions*. These genes will be expressed in *E. coli* and human cells.
    - Dr. Fuller added a lab space to the BUA *Evaluation of SIV Co-Infection of ZIKV Pathogenesis in Pigtail Macaques*.
    - Dr. Meschke added a lab space to the BUA *Detection and Characterization of Pathogens in Environmental Media*.
    - Dr. Xu registered use of new stem cells to the BUA *Regulation of cardiac Na<sup>+</sup> channel*.

- Dr. Ligabue was approved for the new BUA *Development of new methods to purify/enrich sub population of human cells*. Work includes use of non-pathogenic Escherichia coli, enhanced gene delivery methods, and human blood, tissue, body fluids, and cell lines.
- Dr. Werth renewed the BUA *Pharmacokinetics and pharmacodynamics of antimicrobial agents on common bacterial pathogens*. Work includes use of various BSL-2 agents in vitro.
- Dr. Theriot added new lab space for Zebrafish to the BUA *Advances in cellular motility*.
- Dr. Murphy added new lab spaces to the BUAs *Immunity to malaria infection* and *NHP Study*.
- Dr. Liu renewed the BUA *Prostate and Bladder Cancer Differentiation* for work with human blood, tissue, body fluids, and cell lines.
- Dr. Weil was approved for the new BUA *Isolation of gut microbes from human stool/vomit, testing bacteria for pathogen interactions*. Work includes use of various BSL-2 and BSL-1 agents in vitro.
- Dr. Heath was approved for the new BUA *IR-PCCs vs. Resistant Bacteria*. Work includes use of Klebsiella pneumonia in mice.
- Dr. Wang was approved for the new BUA *Ultrasound treatment of Abscesses*. Work includes the use of various BSL-2 agents in vitro.
- Dr. Bertero was approved for the new BUA *Chromatin organization in cardiac development and disease*. Work includes use of human induced pluripotent stem cells and human blood, tissue, body fluids, and cell lines in vitro.
- 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. There was one abstention.

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. SECTION III-D AMENDMENTS

- a. Kim, Jeansok, change, *Using molecular biological approaches to understand fear related behavior in predatory prey interactions*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab is requesting to add the use of commercially available mice to a previously approved project involving the use of adeno-associated, adenovirus free viral vectors and canine adenoviral vector 2 in rats.
  - 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. Kim.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kim.
- b. Regnier, Michael, change, *Rodent Striated Muscle*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This change adds human induced pluripotent stem cells for in vivo use. The lab was already approved for in vitro use of these cells.
- 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. Regnier.
- The Committee voted unanimously to approve the draft BUA for Dr. Regnier.

## 8. INDIVIDUAL PROJECT REVIEWS

- c. Clark, John I., renewal, *Development and Maintenance of Lens Transparency*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This project creates and uses transgenic zebrafish to study lens transparency in living cells during normal development and aging.
  - A committee member had a question about how the zebrafish are disposed of, which will be clarified by the biosafety officer.
  - A successful lab inspection is still required.
  - Required training has not yet been completed.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Clark pending a successful lab inspection and completion of required training.
  - The Committee voted unanimously to approve the draft BUA for Dr. Clark pending a successful lab inspection and completion of required training.
- d. DePaolo, William, renewal, *Determine the role of TLR1 signaling in chronic inflammation and colorectal cancer*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this research is to examine how mucosal pathogens, colonic injury, and colon cancer impact gut homeostasis in mice with genetic defects in molecules that recognize bacteria. The lab uses multiple model systems to study the microbiome interaction with the host gut.
  - Work involves use of risk group 2 pathogens in vitro and in transgenic mice.
  - A successful lab inspection is still required.
  - Required training has not yet been completed.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. DePaolo pending a successful lab inspection and completion of required training.
  - The Committee voted unanimously to approve the draft BUA for Dr. DePaolo pending a successful lab inspection and completion of required training.
- e. Horwitz, Greg, change, *Neurophysiology of Vision*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This change requests the use of glycoprotein deficient avian pseudotyped rabies vector for use in vitro and in macaques.
  - 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. Horwitz.
  - The Committee voted unanimously to approve the draft BUA for Dr. Horwitz.
- f. Jerome, Keith, renewal, *Targeted nanocarriers to accelerate depletion of the HIV reservoir*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This renewal is for handling human blood, tissue, and fluids with HIV, as well as non-human primate blood, tissue, and fluids with SHIV. The only work is DNA extraction, PCR, and sequencing.
  - 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. Jerome pending completion of the BUA application.
  - The Committee voted unanimously to approve the draft BUA for Dr. Jerome pending completion of the BUA application.
- g. Ladiges, Warren, new, *Alzheimer's Disease Intervention*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this research is to develop and test drugs with anti-aging effects that slow or halt the progression of Alzheimer's disease pathology.
  - Work involves use of adeno-associated viral vectors in mice.
  - A lab inspection wasn't required, as the rooms were recently inspected.
  - 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. Ladiges.
  - The Committee voted unanimously to approve the draft BUA for Dr. Ladiges.
- h. Lagunoff, Michael, renewal, *Molecular Virology of Human Herpes Virus 8*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this project is to determine how viruses cause disease and to examine how viruses alter host cell gene expression, signal transduction, and metabolism to ensure maintenance of the virus and replication.
  - Work includes use of viral vectors and wild type human viruses in human cells.
  - A successful lab inspection is still required.
  - Required training has not yet been completed.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Lagunoff pending a successful lab inspection and training completion.
  - The Committee voted to approve the draft BUA for Dr. Lagunoff pending a successful lab inspection and training completion. There was one abstention.
- i. Lingappa, Jaisri, renewal, *Capsid Assembly Studies*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the assembly of retroviruses using mouse, human, and non-human primate cells and cell lines.
  - Work includes in vitro use of recombinant retroviruses and liposome transfection.

- 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. Lingappa pending a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lingappa pending a successful lab inspection. There was one abstention.
- j. Paik, Jisun, change, *Nutrition, Inflammation and Obesity*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This is a change to an existing project that involves the colonization of different mouse strains with *Fusobacterium nucleatum* and *Bacteroides fragilis* to determine whether these bacteria cause gut inflammation and colon cancer.
  - 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. Paik.
  - The Committee voted unanimously to approve the draft BUA for Dr. Paik. There were two abstentions.
- k. Stetson, Daniel, renewal, *Mechanisms and Consequences of Innate Immune Detection of Nucleic Acids*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the mechanisms of innate immune detection of viruses.
  - Work includes use of viral vectors, cell culture models, and transgenic mice.
  - The greatest risk to lab staff are the transduction of cell lines with oncogene-expressing retroviruses.
  - 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. Stetson.
  - The Committee voted unanimously to approve the draft BUA for Dr. Stetson. There was one abstention
- l. Woodward, Joshua, change, *Pathogenesis of Listeria monocytogenes and Staphylococcus aureus*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This project change is to add *Francisella novicida* and *Bacillus cereus* to characterize their sensitivity to various aldehyde stresses in vitro, as well as to add *Enterococcus faecalis*, both wild type and recombinant strains carrying mutations hypothesized to impact colonization of the murine gastrointestinal tract.
  - 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. Woodward.

- The Committee voted unanimously to approve the draft BUA for Dr. Woodward. There was one abstention.

## 9. SUBCOMMITTEE REPORTS:

- m. Fuller, Deborah, change, *DNA Vaccine Therapy*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is a change application to study SARS-CoV-2 (COVID19) in the SLU 3.1 BSL3 suite. Experiments will include amplification of the virus, virus neutralization assays, and plaque assays in human and non-human primate cells. The lab will be working with sera and cells from convalescent SARS-CoV-2 patients to examine virus specific antibodies and T-cells.
  - No recombinant work is proposed, nor is any work with cell lines with oncogene manipulation.
  - Questions regarding procedures related to disinfection of the facility, agents moving in and out of facility, etc. were addressed.
  - 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.
  - A member made a motion to approve the draft BUA letter for Dr. Fuller. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- n. Lynch, Ryan, new, *A Phase 2 Open-Label, Multicenter Study Evaluating the Safety and Efficacy of Axicabtagene Ciloleucef in Combination with Either Rituximab or Lenalidomide in Subjects with Refractory Large B-Cell Lymphoma (ZUMA-14)*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This clinical trial proposes use of FDA-approved CAR-T product “Yescarta” for B cell lymphoma. The cell therapy will be combined with either Rituximab or lenalidomide. The CAR-T cells will be administered with other FDA approved cytotoxic chemotherapy pre-treatments to enhance expansion and persistence of the CAR-T cells. This is not a first in humans.
  - The greatest risk to clinical personnel is accidental parenteral exposure while preparing or administering.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Lynch. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lynch.
- o. Sherman, David, change, *MTB Disease and Drug Response*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This research aims to identify MTB regulators that affect disease progression and treatment response in vitro and in lungs. Mice will be infected to identify individual MTB mutants with in vivo growth defects.

- This is a preliminary approval to allow the PI to begin work at UW. A lab inspection and trainings are still required. Additional biohazardous work will be reviewed by the IBC prior to use. Animal work will not take place at UW. EH&S will review SOPs as they are developed by the lab.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Sherman. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Sherman. There was one abstention.

**10. FOR YOUR INFORMATION:**

- **NIH Incident Report:** The incident report of the research scientist bitten by a mouse infected with a gutless human adenovirus (reported out at the February 19 IBC meeting) was reviewed by the NIH. The NIH OSP stated that the University's response was appropriate, and that no further action was required.
- **Clinical Trials on Hold:** Dose finding or Phase I clinical trial projects are currently on hold (with certain exceptions) due to the influx of COVID-19.

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:40 A.M.**