



# INSTITUTIONAL BIOSAFETY COMMITTEE

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## UNIVERSITY of WASHINGTON

### Meeting Minutes

**Date:** Wednesday, April 15, 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 10:05 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:**
  - a. March 18, 2020
    - The IBC Chair sought a motion to approve the minutes from the March 18, 2020 meeting.
    - A member made a motion to approve the March 18, 2020 minutes. Another member seconded the motion.
    - The committee voted unanimously to approve the March 18, 2020 meeting minutes.
  - a. March 20, 2020
    - The IBC Chair sought a motion to approve the minutes from the March 20, 2020 meeting.
    - A member made a motion to approve the March 20, 2020 minutes. Another member seconded the motion.
    - The committee voted to approve the March 20, 2020 meeting minutes. There was one abstention.
4. **OLD BUSINESS:**
  - At the March 18, 2020 meeting, Dr. Clark's BUA was approved pending a successful lab inspection and completion of required training. This BUA has been sent out.
  - At the March 18, 2020 meeting, Dr. DePaolo's BUA was approved pending a successful lab inspection and completion of required training. This BUA has been sent out.
  - 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 March 18, 2020 meeting, Dr. Lingappa's BUA was approved pending a successful lab inspection. 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. Yager added a new room to the BUA *HIVAcute for Point-of-Care diagnosis of HIV*.
    - Dr. Wordeman renewed the BUA *Microtubule Dynamics and Chromosome Segregation* working with human cells and recombinant or synthetic DNA/RNA (non-viral) enhanced gene delivery methods.

- Dr. Silber renewed the BUA *Banking and characterization of human brain tumor tissue* working with human cells and recombinant or synthetic DNA/RNA (non-viral) enhanced gene delivery methods.
- Dr. Shendure added a room for running real-time PCR on extracted RNA from samples that may come from patients infected with SARS-CoV-2. No processing will take place in this space.
- Dr. Starita added a room for running real-time PCR on extracted RNA from samples that may come from patients infected with SARS-CoV-2. No processing will take place in this space.
- Dr. Rasmussen added two new rooms to the BUA *Interplay between skin and axons*.
- Dr. Gale 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 *The Host Response to Virus Infection*.
- Dr. Baneyx was approved to work with non-pathogenic strains of Escherichia coli and recombinant or synthetic DNA/RNA (non-viral) enhanced gene delivery methods.
- Dr. Allbritton was approved to work with human blood, tissue, body fluids, and cell lines and various agents at BSL-1.
- Dr. Marra renewed the BUA *Persistence of CNS T. pallidum in HIV Infection* working with Treponema pallidum and human blood, tissue, body fluids, and cells in vitro and in rabbits.
- 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. INDIVIDUAL PROJECT REVIEWS**

### **a. Catterall, William, renewal, *Catterall Biohazards***

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of this project is to understand the pathophysiological mechanisms that cause epilepsy, autism, cognitive impairment, and heart failure utilizing mouse models, cell biology, physiology, pharmacology, and crystallography. They will test novel drug combinations for efficacy in mouse models.
- Work includes use of adeno-associated viral vectors (adenovirus free) and baculoviral vectors in mice.
- 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. Catterall.
- The Committee voted unanimously to approve the draft BUA for Dr. Catterall.

### **b. Corey, Eva, renewal, *Pre-Clinical Models, Mechanisms, and Markers of Prostate Cancer and Prostate Cancer Metastasis***

- The assigned IBC Primary Reviewer presented the Primary Review.

- The goal of this project is to explain the mechanisms of advanced prostate cancer and to evaluate new treatments for the disease.
  - Work includes use of human cells transfected with recombinant or synthetic DNA/RNA (non-viral) in mice.
  - 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. Corey.
  - The Committee voted unanimously to approve the draft BUA for Dr. Corey.
- c. Cui, Julia Yue, renewal, *Regulation of drug metabolism by developmental exposure to environmental chemicals and the gut microbiome*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the effects of environmental chemicals on human development, specifically the molecular mechanisms by which these chemicals remodel the chromatin epigenetic signatures and the subsequent alterations in the drug metabolism capacities during liver development using mice and human cell lines. They also study how alterations in intestinal bacteria effect the role of xenobiotic-sensing nuclear receptors and their effects on drug metabolism.
  - Work involves lactobacillus acidophilus, clostridium sporogenes, and human feces in mice.
  - 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. Cui.
  - The Committee voted to approve the draft BUA for Dr. Cui. There was one abstention.
- d. Folch, Albert, renewal, *Microfluidic analysis of neuronal development and function*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This research works with microfluidic devices in normal and cancerous tissue.
  - Work involves use of human cells transduced with gammaretroviral vectors, replication deficient, amphotropic and human cells transduced with lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient in mice.
  - 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. Folch.
  - The Committee voted unanimously to approve the draft BUA for Dr. Folch.
- e. Fujise, Kenichi, new, *Study of Fortilin*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this work is to determine the function of fortilin, a protein that inhibits cell death, in atherosclerosis, heart failure, liver damage and cancer using a mouse model.
  - Work involves use of adeno-associated viral vectors (adenovirus free), oncogenic inserts and lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient, oncogenic inserts.

- 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. Fujise.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fujise.
- f. Hoffman, Lucas, renewal, *Microbiology of people with cystic fibrosis and other chronic infections*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this project is to identify members of the microbial community that are present in clinical samples from children and adults with chronic infections, such as cystic fibrosis. They also examine the behavior of the microbial community and individual community members in relationship to causing chronic infections and the genetic mutations that emerge in bacteria during these infections.
  - Work includes in vitro use of pseudomonas aeruginosa and staphylococcus aureus.
  - 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. Hoffman.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hoffman.
- g. Sniadecki, Nathan, new, *Swine Model of Heart Disease and Novel Therapies*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This project seeks to develop new therapies for heart failure.
  - Work involves use of human cells, adeno-associated viral vectors (adenovirus free), and lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient in pigs.
  - 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. Sniadecki.
  - The Committee voted unanimously to approve the draft BUA for Dr. Sniadecki.
- h. Totah, Rheem, renewal, *Investigating pathophysiological reasons that influence cardiovascular disease*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This project investigates the role of CYP2J2 in cardiovascular diseases and kidney cancer.
  - Work involves in vitro use of human cells transduced with lentiviral vectors, non-HIV pseudotyped, replication deficient and non-pathogenic strains of Escherichia coli.
  - 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. Totah.
  - The Committee voted unanimously to approve the draft BUA for Dr. Totah.
- i. Yang, Xiaoming, renewal, *Interventional Oncology (Rats)*
- The assigned IBC Primary Reviewer presented the Primary Review.

- The goal of this project is to develop new technologies of radiofrequency heating, enhanced gene therapy, or chemotherapy for human pancreatobiliary, hepatic, and esophageal malignancies.
- Work involves use of human cells, lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient, and T-VEC (Talimogene laherparepvec), oncolytic herpesvirus 1 in rats.
- 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. Yang.
- The Committee voted unanimously to approve the draft BUA for Dr. Yang.

## 8. SUBCOMMITTEE REPORTS:

- j. Gale, David, policy, Inactivation
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - A request has been made for approval of methods for the inactivation of SARS-CoV-2 containing samples in order to facilitate reduction in containment level. The investigator has provided two documents to support 1) chemical methods for inactivation of SARS-CoV-2 and 2) UV inactivation methods.
  - A member made a motion to approve the subcommittee's recommendation to authorize reduced containment pending satisfactory addressing of issues stated by the subcommittee. Another member seconded the motion.
  - The Committee voted unanimously to approve the subcommittee's recommendation for Dr. Gale.
- k. Gale, Michael, change, *The Host Response to BSL-3 Pathogens*
- Five members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This change is to add infection of mice with SARS-CoV-2.
  - All work involving viral replication in culture is required at BSL3 containment.
  - The lab was inspected and no deficiencies were identified.
  - 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. Gale. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gale.
- l. Hyde, Jennifer, change, *Contribution of virus-host interactions to viral pathogenesis (BSL3, non-select)*
- Five members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This change is to add in vitro work with SARS-CoV-2.
  - All work involving viral replication in culture is required at BSL3 containment.
  - The lab was inspected and no deficiencies were identified.
  - 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. Hyde. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hyde.
- m. Polyak, Stephen, change, *Virus-host interactions in cell culture*
- Five members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This change is to add in vitro work with SARS-CoV-2 and register new work with Murine Leukemia Virus pseudovirus.
  - All work involving viral replication in culture is required at BSL3 containment.
  - The lab was inspected and no deficiencies were identified.
  - 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. Polyak. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Polyak.
- n. Fink, Susan, change, *Host-Pathogen Interactions During Viral Infection*
- Five members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This change is to add culture of SARS-CoV-2 and pseudotyped lentiviral vectors.
  - All work involving viral replication in culture is required at BSL3 containment.
  - The lab was inspected and no deficiencies were identified.
  - 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. Fink. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fink.
- o. Oberst, Andrew, change, *Programmed cell death and immunity*
- Five members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This change is to add in vitro work with SARS-CoV-2.
  - All work involving viral replication in culture is required at BSL3 containment.
  - The lab was inspected and no deficiencies were identified.
  - All of the required trainings have been completed.
  - The draft BUA letter was shown.
  - 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.
- p. Koelle, David, change, *Koelle Laboratory at UW*
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.

- This change adds research involving clinical samples from patients known or suspected to be infected with SARS-CoV-2. No viral isolation or culturing is permitted.
  - The lab was inspected and no deficiencies were identified.
  - 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. Koelle. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Koelle. There was one abstention.
- q. Cowan, Andrew, new, *A PHASE 1, OPEN-LABEL, MULTICENTER STUDY TO EVALUATE THE SAFETY OF BB2121 IN SUBJECTS WITH HIGH RISK, NEWLY DIAGNOSED MULTIPLE MYELOMA (NDMM)*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - Previously, patients with later stage or previously treated Multiple Myeloma have been treated with BCMA-targeting CAR-T. This trial extends use to newly diagnosed patients.
  - Intravenous infusion will take place at UW Medical Center.
  - The greatest risk to medical staff is percutaneous contact with the CAR-T product during preparation or infusion.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Cowan. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Cowan.
- r. Konkle, Barbara, new, *Phase 3, Open-label, Single-Arm Study to Evaluate the Efficacy and Safety of PF 07055480 (Recombinant AAV2/6 Human Factor VIII Gene Therapy) in Adult Male Participants with Moderately Severe to Severe Hemophilia A (FVIII:C<1%)*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - Hemophilia A is due to mutations in the factor VIII gene. The therapy aims to use recombinant AAV encoding a version of human factor VIII to transduce liver cells to produce enough factor VIII to limit bleeding complications and use of factor VIII products.
  - The product will be prepared and infused into patients at UW Medical Center.
  - The greatest risk to medical staff is percutaneous contact with the adeno-associated viral vector product during preparation or infusion.
  - 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.

## 10. FOR YOUR INFORMATION:

- **NIH Incident Report:** A veterinary specialist was working with a sedated macaque to weigh the animal and obtain an accurate blood pressure. An accurate blood pressure was needed in case additional sedation was required which would affect the blood pressure. The individual was assisted by another veterinary specialist. During the transfer the animal turned his head and bit the affected individual on the right forearm



resulting in an open puncture wound. The animal appeared sedated enough for the transfer according to the individuals performing the transfer. The animal was experimentally infected with SHIV. The SHIV plasma viral load on the day of exposure was undetectable. The employee went to the Emergency Room for medical attention and was also seen the next day by the University Employee Health Clinic. This incident has been reported and is awaiting response from NIH.

- **EHSA Inspection Update:** This item is tabled until the next IBC meeting due to time constraints.

**11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:**

There were no issues from the floor, and no public comments.

**12. MEETING ADJOURNED AT APPROXIMATELY 12:10 P.M.**