



# INSTITUTIONAL BIOSAFETY COMMITTEE

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## UNIVERSITY of WASHINGTON

### Meeting Minutes

**Date:** Wednesday, February 17, 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. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
  4. Richard Grant, Washington National Primate Research Center
  5. Garry Hamilton (*Community Member*)
  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. 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 10:01 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 January 20, 2021 meeting.
  - A member made a motion to approve the January 20, 2021 minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the January 20, 2021 meeting minutes.
4. **OLD BUSINESS:**
  - At the March 18, 2020 meeting, Dr. Lagunoff's BUA was approved pending training. This BUA is still pending.
  - At the June 17, 2020 meeting, Dr. Altemeier's BUA was approved pending review of the IACUC protocol and required training. This BUA has been sent out.
  - At the August 19, 2020 meeting, Dr. Voigt's BUA was approved pending a medical management plan, Occupational Health consultations, training, and edits to the BUA application. This BUA is still pending.
  - At the December 16, 2020 meeting, Dr. Ceze's BUA was approved pending a successful lab inspection. This BUA is still pending.
  - At the January 20, 2021 meeting, Dr. Bothwell's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. Geisse's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. Kawasumi BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. Kimelman's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. MacLellan's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. Mizumori's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. Moritz's BUA was approved pending an edit to the BUA letter. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. Tian's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. Wong's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the January 20, 2021 meeting, Dr. Yadav'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. Posner 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 *Point of Care HIV viral Load Test*. No viral isolation or culturing is permitted.
- Dr. Lingappa removed rooms from the BUA *International Clinical Research Center, Repository*.
- Dr. Hague renewed the BUA *GPCR Function*. Work includes use of *Escherichia coli*, exempt K-12 non-pathogenic strains, and recombinant or synthetic DNA/RNA (non-viral) in vitro.
- Dr. Pollack was approved for a new BUA for work with human blood, tissue, body fluids, and cell lines called *Morphochemical Characterisation of Diabetic Blood in the Presence of Insulin*.
- Dr. Shendure added use of a core facility to the BUA *Shendure: General Research*.
- Dr. Xia added vivarium spaces to the BUA *Neurogenesis*.
- Dr. Hull renewed the BUA *Islet Endothelial Dysfunction in Diabetes*. Work includes use of human cells in vitro.
- Dr. Thompson renewed the BUA *Impact of Aging on the Immune Response to Traumatic Brain Injury*. Work includes use of recombinant or synthetic DNA/RNA (non-viral).
- Dr. De Boer renewed the BUA *KRI Studies*. Work includes use of human blood, tissue, body fluids, and cell lines in vitro.
- Dr. Morishima renewed the BUA *Immunological Assay Development*. Work includes in vitro use of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), fixed or inactivated samples or tissue.
- Dr. Adams Waldorf added wild type human cytomegalovirus to the BUA *Experimental Model of Viral-Induced Brain Injury*.
- Dr. Thachuk was approved for a new BUA titled *Molecular computation via synthetic DNA oligos*. Work includes use of recombinant or synthetic DNA/RNA (non-viral).
- Dr. Arnold added an in vitro lab space to the BUA *iNPG-pDox efficacy*.
- 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**

- One project received renewal approval for use of *Francisella tularensis*. This work does not meet the DURC definition.
- The IBC Chair sought a motion to approve this month's DURC Report.
- A member made a motion to approve this month's DURC Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's DURC Report.

**7. BSL-3 INACTIVATION REPORT:**

- Two projects received approval for SARS-CoV-2 cell culture supernatant by formaldehyde and by heat treatment.
- 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 unanimously voted to approve this month's BSL-3 Inactivation Approvals Report.

## 8. INDIVIDUAL PROJECT REVIEWS

- a. Cookson, Brad, renewal, *Initiation and Regulation of Inflammation and Development of Protective Immunity*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The goals of this project are to identify the most effective and long-lasting way to generate reactive T cells that play key roles in the immunity generated by vaccination and to understand the cause and mechanism of inflammatory cell death to facilitate the design of effective therapies and better diagnostic tools.
  - Work includes use of various BSL-2 agents 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. Cookson.
  - The Committee voted unanimously to approve the draft BUA for Dr. Cookson.
  
- b. Dembrow, Nikolai, new, *Developing a primate culture platform for the treatment of degenerative*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this project is to develop a primate culture platform for use to investigate neurological disorders.
  - Work includes in vitro use of adeno-associated viral vectors (adenovirus free) and non-human primate blood, tissue, body fluids, cell lines.
  - 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. Dembrow.
  - The Committee voted unanimously to approve the draft BUA for Dr. Dembrow.
  
- c. Dhaka, Ajay, renewal, *Transsynaptic Tracing of Somosensory Circuits*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab uses mice to work on pain and temperature sensing.
  - Work includes use of adeno-associated viral vectors (adenovirus free), Herpes simplex viral vector, HSV 129-TK-TT, and Rabies virus vector, avian pseudotyped (RVdeltaG-EnvA) in mice.
  - Completion of 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. Dhaka pending completion of a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Dhaka pending completion of a successful lab inspection.

- d. Hofstetter, Christoph, renewal, *Viral Neuronal Tracing in Rodents with Spinal Cord Injury*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab focuses on the spinal cord, targeting systems of the spinal cord that may have a direct impact on patient care, including various experimental treatment strategies to enhance nerve fiber plasticity and regeneration following spinal cord injury.
  - Work includes use of adeno-associated viral vectors (adenovirus free) in rats.
  - A successful lab inspection has been completed.
  - All of the required trainings have been completed.
  - Review of the IACUC protocol is required once submitted by the PI.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hofstetter pending submission and review of the IACUC protocol.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hofstetter pending submission and review of the IACUC protocol.
- e. Ladiges, Warren, renewal, *Aging Intervention*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall goals of the research are to investigate the mechanisms of aging and age-related diseases and determine how intervention and treatment strategies can be developed and applied.
  - Work includes use of adeno-associated viral vectors (adenovirus free), recombinant or synthetic DNA/RNA (non-viral), and Foamy viral vectors, replication competent in mice.
  - Completion of 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. Ladiges pending completion of a successful lab inspection and clarification of replication competence.
  - The Committee voted unanimously to approve the draft BUA for Dr. Ladiges pending the items above.
- f. Lutz, Barry, change, *Covid-19 test development*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab wants to develop new diagnostic tests for COVID-19. They plan to use: clinical samples known to be positive and negative for SARS-CoV-2, nucleic acids extracted from clinical samples known to be positive and negative for SARS-CoV-2, and alphavirus-based vectors or VLPs that encode fragments of the SARS-CoV-2 genome. No viral or cell culture will take place.
  - 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. Lutz.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lutz.
- g. Meeske, Alexander, new, *CRISPR-Cas Immunity in Prokaryotes*

- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab is focused on how diverse bacterial CRISPR-Cas systems naturally function in anti-bacteriophage immunity (CRISPR systems) and how they can be harnessed for nucleic acid manipulation and other biotechnologies.
  - Work includes various BSL-2 agents in vitro.
  - Completion of 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. Meeske pending completion of a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Meeske pending completion of a successful lab inspection.
- h. Paik, Jisun, renewal, *Vitamin A , gut and reproductive health***
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This research focuses on the role of nutrition in various inflammatory diseases such as obesity and inflammatory bowel disease (IBD). Two main areas of this current research are targeted inhibition of retinoic acid synthesis to develop non-hormonal male contraceptives and to treat obesity and the role of the microbiome in the development of IBD and colon cancer.
  - Work includes in vitro use of lentiviral vectors, non-HIV pseudotyped, replication deficient.
  - 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. Paik pending an edit to the BUA application.
  - The Committee voted unanimously to approve the draft BUA for Dr. Paik pending an edit to the BUA application.
- i. Pasupathy, Anitha, renewal, *2-photon imaging in awake monkey visual cortex***
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this research project is to understand the relationship between brain activity and higher level cognitive functions such as visual perception, recognition, memory, and decision making.
  - Work includes use of adeno-associated viral vectors (adenovirus free) in macaques.
  - This lab is covered under a core BUA and does not require an additional inspection for this renewal.
  - 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.
- j. Reh, Thomas, change, *Retinal Ganglion Cell Replacement in Optic Neuropathies***
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab is working to create methods of regenerating or reconstructing damaged retinas using stem cells and reprogramming.

- This change adds the use of adeno-associated viral vectors (adenovirus free) in macaques.
  - The lab was recently inspected and does not require an additional inspection for this change 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. Reh.
  - The Committee voted unanimously to approve the draft BUA for Dr. Reh.
- k. Thomas, Wendy, renewal, *Biological Adhesion in Flow and under Force*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab in bioengineering studies adhesion.
  - Work includes in vitro use of Lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient and various agents at BSL-2.
  - Completion of 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. Thomas pending completion of a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Thomas pending completion of a successful lab inspection.

## 9. SUBCOMMITTEE REPORTS:

- l. Altemeier, William, renewal, *Inflammatory response modification by mechanical ventilation*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This lab works to determine mechanisms by which lung injury and extra-pulmonary organ injury develop in a variety of different models, including high oxygen exposure, mechanical ventilation, and exposure to infectious agents and byproducts.
  - Work includes use of *Lactobacillus lactis* and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in mice. Various viral vectors are also used in vitro at BSL-2.
  - The reviewers cited the greatest biohazard risk likely to be the use of SARS-CoV-2 in mice.
  - Completion of a successful lab inspection is still required.
  - All of the required trainings have been completed.
  - A medical management plan is in place for work with SARS-CoV-2.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Altemeier pending completion of a successful lab inspection. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Altemeier pending completion of a successful lab inspection.
- m. Fink, Susan, change, *Host-Pathogen Interactions During Viral Infection*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.

- This BUA change adds in vitro use new recombinant strains of SARS-CoV-2 and coronavirus replicons, replication deficient.
  - 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.
- n. Gale, Michael, change, *The Host Response to BSL-3 Pathogens*
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This change expands current BSL-3 program activities to include studies involving aerosolized SARS-CoV-2 that would mimic real life virus exposure. The lab plans to produce SARS-CoV-2 aerosols in a chamber containing various PPE surfaces that have been treated with antiviral chemicals. The lab will then assess the viability of the virus that is engaged on the PPE surface. This work is to be supported by a partnering company who has seen in preliminary studies that these chemicals produce local oxygen radicals following light exposure that can damage and inactivate the virus.
  - This change also includes studies involving a “Light Rig: which is designed to support specialized light bulbs for use in the biosafety cabinet. This work is to be supported by a partnering company who has seen in preliminary studies that certain antiviral chemicals produce local oxygen radicals that damage and inactivate virus following light exposure.
  - A biosafety officer will perform an airflow test when the light rig system is set up in the biosafety cabinet, a leak test on the chamber by running hydrogen peroxide through the system and checking for leaks with hydrogen peroxide monitor, and a test of the biosafety cabinet containment by opening the chamber door during operation to simulate a major leak and check for hydrogen peroxide levels outside the biosafety cabinet.
  - 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.
- o. Gale, Michael, change, *The Host Response to BSL-3 Pathogens*
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This change adds work with new strains of SARS-CoV-2. None of these new strains are recombinant, and there are no plans to genetically modify these strains.
  - No updates to the medical management plan are required.
  - 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.
- p. Lieber, Andre, change, *Cell and Gene therapy in mice*



- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This change adds use of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in vitro and in mice.
  - 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. Lieber. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lieber.
- q. Maloney, David, renewal, *A Multicenter, Open-Label, Expanded Access Study of Axicabtagene Ciloleucel for the Treatment of Subjects with Relapsed/Refractory Large B-Cell Lymphoma*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - Axicabtagene ciloleucel is an autologous cell therapy for certain B cell malignancies that targets CD19 on malignant cells. The cell product has to meet certain release criteria to be included in the FDA approval. The investigators and manufacturers believe that patients may still benefit from receiving the cells. The main release criteria that is not met is the percent of patient cells that express the CD19 CAR molecule of interest. All safety and sterility related manufacturer's release criteria are still met.
  - Percutaneous exposure to pharmacy or medical staff of the infusion product containing retrovirally transduced live cells 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.
- r. Skerrett, Shawn, renewal, *A Multicenter, Human Alveolar Macrophage Interactions with Francisella tularensis*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The overall goal is to explore the interactions of Francisella tularensis, the bacterial cause of tularemia, with human alveolar macrophages in comparison with mouse alveolar and bone marrow derived macrophages.
  - This project involves work with a select agent (Francisella tularensis). Select agent protocols are in place.
  - DURC approval for use of Francisella tularensis was approved by the DURC IRE.
  - All of the required trainings have been completed.
  - A medical management plan is in place for work with Francisella tularensis.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Skerrett. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Skerrett.

- s. Wald, Anna, new, *A Phase 1 Trial to Evaluate the Safety, Immunogenicity, and Reactogenicity of Heterologous and Homologous Chimpanzee Adenovirus and Self-Amplifying mRNA Prime-Boost Prophylactic Vaccines Against SARS-CoV-2 in Healthy Adults*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - Development of an effective and safe COVID-19 vaccine is underway to limit the occurrence of debilitating or lethal COVID-19 and to control the spread in the general population.
  - This is an NIH-sponsored, multicenter, first in human Phase 1 study that will explore the ability of two vaccine formats (self- amplifying mRNA, also known as samRNA, and a replication-incompetent chimp adenovirus vector, also known as ChAd), administered as either two doses of the same format or one format followed by the other (termed heterologous prime-boost).
  - Vaccines will be administered to male and non-pregnant female participants  $\geq 18$  years of age who are in good health, do not have high risks for SARS-CoV-2 infection or for severe COVID-19 disease progression, and meet all eligibility criteria.
  - There is potential percutaneous exposure to staff preparing or administering the vaccine. There is theoretical risk for shedding of the adenoviral vector, but this is low risk based on other studies using this methodology.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Wald. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Wald.

**10. FOR YOUR INFORMATION:**

- The NIH has stated that Emergency Use Authorized (EUA) COVID-19 vaccines are not subject to the *NIH Guidelines* as long as they are being used as approved by the FDA. If the vaccine is used in a way that is not a part of the EUA approved criteria then this work is subject to Section III-C of the *NIH Guidelines*.

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:53 A.M.**