



# INSTITUTIONAL BIOSAFETY COMMITTEE

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UNIVERSITY *of* WASHINGTON

## Meeting Minutes

**Date:** Wednesday, June 15, 2022

**Time:** 10:00 AM – 12:00 PM

**Location:** Zoom

- Members Present:**
1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
  2. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
  3. Jason Cantera (*Community Member*)
  4. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
  5. Richard Grant, Washington National Primate Research Center
  6. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
  7. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
  8. Scott Meschke, Environmental & Occupational Health Sciences
  9. Jason Smith, Microbiology (*IBC 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

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. A physical location is now offered for attendance to IBC meetings. An update was given about changes related to the Washington State Open Public Meetings Act. Meetings that are open to the public are now required to have a physical meeting location for public attendees, but committee members can still attend virtually.
3. **APPROVAL OF MINUTES:**
  - The IBC Chair sought a motion to approve the minutes from the May 18, 2022 meeting.
  - A member made a motion to approve the May 18, 2022 minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the May 18, 2022 meeting minutes.
4. **OLD BUSINESS:**
  - At the May 18, 2022, meeting, Dr. Buckner's BUA was approved pending review of the IACUC protocol. The biosafety officer has sent out this BUA.
  - At the May 18, 2022, meeting, Dr. Buffalo's BUA was approved pending review of the IACUC protocol. The biosafety officer has sent out this BUA.
  - At the May 18, 2022, meeting, Dr. Cai's BUA was approved pending clarification on the nature of the recombinant bacteria use and a response to the lab inspection. The biosafety officer has sent out this BUA.
  - At the May 18, 2022, meeting, Dr. Chamberlain's BUA was approved pending review of the IACUC protocol. The biosafety officer has not sent out this BUA.
  - At the May 18, 2022, meeting, Dr. King's BUA was approved pending clarification on the use of an oncogenic insert in lentiviral vectors, completion of a successful lab inspection, and submission of the IACUC protocol. The biosafety officer has not sent out this BUA yet.
  - At the May 18, 2022, meeting, Dr. Moreno's BUA was approved pending a response to the lab inspection items and submission of the IACUC protocol. The biosafety officer has sent out this BUA.
  - At the May 18, 2022 meeting, Dr. Zweifel's BUA was approved pending completion of a successful lab inspection and completion of required trainings. The biosafety officer has sent out this BUA.
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. Marchand received approval for a new BUA *Development of synthetic biology tools for non-standard nucleic acids*.
    - Dr. Furlong renewed the BUA *Effects-Related Biomarkers of Environmental Neurotoxic Exposures*.

- Dr. Distilio added new transgenic plant species and a new room to the BUA *Functional Evolution of Floral Pathway Genes in the Angiosperm *Thalictrum* and the Fern *Ceratopteris richardii*.*
- Dr. Shendure added new room for use with existing agents to the BUA *Shendure: General Research.*
- Dr. Swisher added new rooms with previously approved agents to the BUA *Cancer Risks Associated with Inherited Mutations in Ovarian Cancer Susceptibility Genes Beyond BRACA1 and BRACA2.*
- Dr. Ratner renewed the BUA *Ratner Laboratory Antibiotic Delivery.*
- Dr. Fuller added fixed SARS-CoV-2 samples and recombinant RNA/DNA to new rooms to the BUA *DNA Vaccine Therapy.*
- Dr. Wang renewed their BUA *Transporters in Drug Disposition, Targeting and Drug-Drug interactions.*
- Dr. Stoll renewed their BUA *Proteins for EPR Spectroscopy.*
- Dr. Hyde added a modified strain of VEEV, designated as a select agent following a review by the CDC and USDA, to the BSL-3 facility on the BUA *Contribution of virus-host interactions to viral pathogenesis (BSL-3, non-select).*
- Dr. Olmos de Koo registered a change to their BUA *Gt005-03 (Horizon): A Phase II, Open-Label, Outcomes-Assessor Masked, Multicentre, Randomized, Controlled Study To Evaluate The Safety and Efficacy of Two Doses of Gt005 Administered As A Single Subretinal Injection In Subjects With Geographic Atrophy Secondary to Dry Age-Related Macular Degeneration.*
- Dr. Escobar added two non-recombinant lab adapted strains of lymphocytic choriomeningitis virus (LCMV) in mice: Armstrong 53b and Armstrong 53b clone 13 to the BUA *Chromatin dynamics in stem cells and immune cell function.*
- Dr. Ting added new gene inserts for AAV to the BUA *Gene Therapy in NHP.*
- Dr. Murphy registered recDNA in a lipid carrier in NHPs while already having enhanced gene insert on an existing BUA with the same gene inserts for the BUA *NHP Study.*
- Dr. Veessler added non-recombinant human coronavirus OC43 to the BUA *Expression of recombinant proteins using mammalian cell lines.*
- 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.

## 6. **BSL-3 INACTIVATION REPORT**

- Dr. Sims requested DDM (n-dodecyl-beta-maltoside detergent extraction) treatment of SARS-CoV-2 samples.
- The subcommittee reviewed procedure and inactivation data provided by the lab and approved the request.
- The IBC Chair a motion to approve this month's BSL-3 Inactivation Report.
- A member made a motion to approve this month's BSL-3 Inactivation Report. Another member seconded the motion.
- The committee voted to approve this month's BSL-3 Inactivation Report with one member not submitting a vote.

## 7. INDIVIDUAL PROJECT REVIEWS

- a. Darvas, Martin, renewal, *Genetic analysis of mouse behavior*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the influence of genes and neuropathologic proteins on neural activity and connectivity.
  - This lab works with human cell lines, foamy viral vectors, canine viral vectors, and adeno-associated viral vectors for use in vitro and mouse models, recombinant E. coli, and diphtheria toxin.
  - The lab was inspected, and all deficiencies have been corrected.
  - All required trainings are complete.
  - The IACUC protocol is still pending.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Darvis.
  - The Committee voted unanimously to approve the draft BUA for Dr. Darvis.
- b. Gale, Michael, change, *The Host Response to Virus Infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the innate immune response to viral infection and virus-host interactions.
  - This lab is adding inactivated samples of Chikungunya virus, Yellow Fever virus, and Japanese Encephalitis virus. The lab is also adding Spondweni virus and new influenza A virus strains for use in vitro.
  - A discussion occurred about the appropriate biosafety level for Spondweni virus. As it is a Risk Group 2 agent, BSL-2 was determined to be appropriate.
  - A lab inspection was not required as the lab was recently inspected.
  - All required trainings are complete.
  - An occupational health review is still pending for Spondweni virus.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gale.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gale pending the occupational health review.
- c. Geisse, Nicholas, renewal, *Development of cultureware and devices for human cells in vitro research*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab manufactures devices that characterize cells from culture.
  - This lab works with human and mouse cell lines, lentiviral and adeno-associated viral vectors, and recombinant DNA and RNA.
  - The lab inspection is scheduled for after the IBC meeting.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Geisse.
  - The Committee voted unanimously to approve the draft BUA for Dr. Geisse pending successful completion of inspection.
- d. Heath, James, renewal, *Identifying effective combination therapy for metastatic cancers*
- The assigned IBC Primary Reviewer presented the Primary Review.

- This lab studies effective combination therapies for metastatic cancers
  - This lab works with human cells and recDNA in mouse models.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Heath.
  - The Committee voted unanimously to approve the draft BUA for Dr. Heath.
- e. Kiem, Hans-Peter, change, *Strategies to Improve Hematopoietic Stem Cell Transduction*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies gene therapy as a treatment for genetic disorders and acquired diseases
  - This lab is adding adenoviral vectors and third generation lentiviral vectors administered to NHPs.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kiem.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kiem.
- f. Kiem, Hans-Peter, renewal, *Cell and Gene Therapy for HIV Cure*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies gene therapy as a treatment for HIV/AIDS
  - This lab works with lentiviral vectors, adenovirus, adeno-associated viral vectors, and engineered nucleases in macaques infected with simian immunodeficiency virus (SIV) or a chimeric SIV-HIV (SHIV) using lipid nanocarriers.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kiem.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kiem.
- g. Manoil, Colin, renewal, *Genetic analysis of Gram-negative bacterial pathogens (BSL-2 experiments)*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies genetic and genomic approaches to identify targets for new antibiotics and antibiotic adjuvants and characterization of novel antibiotic resistance genes.
  - This lab works with plasmids and transposon mutants in recombinant Risk Group 1 and 2 bacteria.
  - The lab was inspected, and all deficiencies have been corrected.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Manoil.
  - The Committee voted unanimously to approve the draft BUA for Dr. Manoil.

- h.** Miller, Dana, new, *Stress homeostasis*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies how cells and organisms sense and respond to environmental conditions.
  - This lab works with recombinant Risk Group 1 E. coli, recombinant DNA, and transgenic C. elegans.
  - A lab inspection has been performed and is still pending a response.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Miller.
  - The Committee voted unanimously to approve the draft BUA for Dr. Miller pending successful completion of the lab inspection.
- i.** Oshima, Junko, renewal, *International Registry of Werner*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the genetic mechanisms and causes of accelerated aging syndromes.
  - This lab works with E. coli for cloning, human cells, Epstein-Barr virus and lentiviral, foamy virus, and gammaretroviral vectors.
  - A discussion occurred regarding the gene insert TERT as an oncogene, but the committee determined TERT is not a true oncogene because it is not transforming. A discussion also occurred about whether or not the lab uses any oncogenes on their viral vectors.
  - A lab inspection has been performed and is still pending a response.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Oshima.
  - The Committee voted unanimously to approve the draft BUA for Dr. Oshima pending clarification of use of oncogenes with viral vectors and successful completion of the lab inspection.
- j.** Park, Jim, renewal, *Liver cancer theranostics (4/26/22)*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the therapeutic efficacy and potential toxicity of a targeted antibody treatment for liver cancer.
  - This lab works with human liver cancer cells transfected with lentiviral vectors in vivo in mouse models.
  - The lab was inspected, and no deficiencies were noted.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Park.
  - The Committee voted unanimously to approve the draft BUA for Dr. Park.
- k.** Perlmutter, Steve, renewal, *Cellular Properties of NHP Cortical Neurons*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies subpopulations of cortical neurons and their cellular properties to understand their role in the pathophysiology of neurological disorders.

- This lab works with non-human primate tissues, and adeno-associated viral vectors administered into non-human primates.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - All required trainings are complete.
  - The IACUC protocol is still pending.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Perlmutter.
  - The Committee voted unanimously to approve the draft BUA for Dr. Perlmutter.
- I. Plymate, Stephen R., renewal, *Mechanisms of transition to castrate resistant prostate cancer*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the development of inhibitors to the mechanisms that cause treatment-resistant prostate cancer.
  - This lab works with human cancer cells transduced with lentiviral vectors.
  - The lab was inspected, and all deficiencies have been corrected.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Plymate.
  - The Committee voted unanimously to approve the draft BUA for Dr. Plymate.
- m. Stevens, Kelly, renewal, *Heart Regenerative Technologies*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the development of cell-based treatment for organ failure due to heart disease.
  - This lab works viral vectors transduction in vitro in mice and rats.
  - A lab inspection was not required as the lab was recently inspected.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Stevens.
  - The Committee voted unanimously to approve the draft BUA for Dr. Stevens.
- n. Villen, Judit, renewal, *Cell signaling and proteomics*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the development and application of novel computational technologies to characterize global proteome.
  - This lab works with human cells, yeast, and E. coli, recDNA, and lentiviral vectors.
  - The lab inspection is scheduled for after the IBC meeting.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Villen.
  - The Committee voted unanimously to approve the draft BUA for Dr. Villen pending successful completion of the lab inspection.
- o. von Moltke, Jakob, renewal, *Initiation of Type 2 Immune Responses*
- The assigned IBC Primary Reviewer presented the Primary Review.

- This lab studies mammalian type 2 immune response to helminths and allergens.
  - This lab works with Risk Group 1 helminths, human cells, recDNA, gammaretroviral vectors and lentiviral vectors as well as Risk Group 1 and 2 viruses and bacteria.
  - A discussion occurred regarding the appropriate biosafety level for *Trichuris muris* when used in mice.
  - A lab inspection has been performed and is still pending a response.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. von Moltke.
  - The Committee voted to approve the draft BUA for Dr. von Moltke with one abstention pending successful completion of the lab inspection, IACUC protocol revisions, and confirmation of the biosafety level for *Trichuris muris* in mice.
- p. Walker, Matthew, new, *Dissecting the mitochondrial RNase P complex in heart failure*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies gene down regulation in heart failure and the use of therapy as a treatment.
  - This lab works with human, mouse, and rat cells transduced with adeno-associated viral vectors.
  - The lab inspection is scheduled for after the IBC meeting.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Walker.
  - The Committee voted unanimously to approve the draft BUA for Dr. Walker pending successful completion of the lab inspection.
- q. Young, Jessica, renewal, *Modeling late-onset sporadic Alzheimer's disease using human stem cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies genes that increase the risk for late-onset sporadic Alzheimer's disease.
  - This lab works with *E. coli*, human cells, gene delivery using plasmids and lentiviral vectors, and gene knock-in and knock-out using CRISPR/Cas9.
  - A lab inspection has been performed and is still pending a response.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Young.
  - The Committee voted unanimously to approve the draft BUA for Dr. Young pending successful completion of the lab inspection.

## 8. SUBCOMMITTEE REPORTS:

- r. Gale, Michael, change, *The Host Response to BSL3 Pathogens*



- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This lab studies immune response during viral infections and works to develop antiviral therapeutics or vaccines to treat and prevent virus infection.
  - This lab works with BSL-3 viral pathogens in vitro and in vivo in mice.
  - This lab is adding a wild-type strain of Japanese Encephalitis virus for use in vitro.
  - A lab inspection was not required as the BSL-3 facility is inspected on a routine schedule.
  - All required trainings are complete.
  - A medical management plan for Japanese encephalitis virus is still pending.
  - 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 pending the medical management plan for Japanese encephalitis virus.
- s. Nakamura, Kenta, new, *A Phase 1/2 Trial of the Safety and Efficacy of SRD-001 (AAV1/SERCA2a) in Subjects with Heart Failure with Reduced Ejection Fraction*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This lab studies the treatment of heart failure in subjects with reduced ejection fraction.
  - This lab works with recombinant adeno-associated viral vectors in humans.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Nakamura. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Nakamura.
- t. Specht, Jennifer, new, *A Phase 1, First in Human Study of Adenovirally Transduced Autologous Macrophages Engineered to Contain an Anti-HER2 Chimeric Antigen Receptor in Subjects with HER2 Overexpressing Solid Tumors*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This lab studies engineered macrophages as a treatment for solid tumors.
  - This lab works with adenovirus vectors in humans.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Specht. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Specht.

#### 10. FOR YOUR INFORMATION:

- The biosafety group has shared that the Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) is seeking public feedback on its revised draft of the *Screening Framework Guidance for Providers and Users of Synthetic Oligonucleotides*.

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

- J. Scott Meschke brought to the floor an issue of Canadian Border Patrol policies regarding transit of biohazard.

**12. MEETING ADJOURNED AT APPROXIMATELY 12:02 P.M.**