



# INSTITUTIONAL BIOSAFETY COMMITTEE

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UNIVERSITY *of* WASHINGTON

## Meeting Minutes

**Date:** Wednesday, October 20, 2021

**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
  7. David Koelle, Allergy and Infectious Diseases
  8. Stephen Libby, Laboratory Medicine (*IBC Chair*)
  9. Scott Meschke, Environmental & Occupational Health Sciences
  10. Susan Parazzoli (*Community Member*)
  11. Jason Smith, Microbiology (*IBC Vice Chair*)
  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 10:00 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. **NATIONAL BIOSAFETY MONTH:** A presentation was given by EH&S regarding National Biosafety Month and how the University is participating.
4. **BIOSAFETY MANUAL UPDATES:** Minor updates were made to the Biosafety Manual. The updates were presented to the committee, which voted unanimously to approve.
5. **BSL-3 INACTIVATION POLICY UPDATES:** Updates were made to the Waiver of Verification Policy. Information was added regarding the minimum requirements before submitting a waiver request, annual validation, and information needed when transferring or shipping the inactivated samples. The updates were presented to the committee, which voted unanimously to approve.
6. **APPROVAL OF MINUTES:**
  - The IBC Chair sought a motion to approve the minutes from the September 15, 2021 meeting.
  - A member made a motion to approve the September 15, 2021 minutes. Another member seconded the motion.
  - The committee voted to approve the September 15, 2021 meeting minutes. There was one voting abstention.
7. **OLD BUSINESS:**
  - At the August 18, 2021 meeting, Dr. de la Igelisia's BUA was approved pending completion of training and a successful lab inspection. This BUA has been sent out.
  - At the September 15, 2021 meeting, Dr. Gale's BUA was approved pending completion of medical management review. This BUA has been sent out.
  - At the September 15, 2021 meeting, Dr. Greninger's BUA was approved pending clarification from the PI, BUA edits, and any necessary BUA letter edits. This BUA is still pending.
  - At the September 15, 2021 meeting, Dr. Hallstrand's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
  - At the September 15, 2021 meeting, Dr. Stuber's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
  - At the September 15, 2021 meeting, Dr. Tang's BUA was approved pending completion of a successful lab inspection. This BUA is still pending.
  - At the September 15, 2021 meeting, Dr. Polyak's BUA was approved pending BUA edits and completion of a successful lab inspection. This BUA has been sent out.
8. **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. Doty renewed the BUA *Transgenic plants for remediation* working with transgenic poplar plants.
- Dr. Brewer renewed the BUA *Genome Maintenance in Yeast* working with various BSL-1 agents in vitro.
- Dr. Hebert renewed the BUA *Obstetric-Fetal Pharmacology Research Unit Lab* working with non-viral recombinant or synthetic DNA/RNA.
- Dr. Trapnell was made the new PI of the BUA *Early Fish Development* working with transgenic zebrafish.
- Dr. Mustelin renewed the BUA *Molecular mechanism of Rheumatoid Arthritis and Lupus* working with enhanced gene delivery methods and non-pathogenic strains of Escherichia coli. An edit is needed on this BUA letter regarding the applicable NIH section.
- Dr. Zhang renewed the BUA *Exosomal protein study for breast cancer cell and Real time electrochemical sensing of spike protein* working with non-viral recombinant or synthetic DNA/RNA.
- Dr. Yeung renewed the BUA *Modulation of drug transport of the renal proximal tubule by uremic solutes -implications in chronic kidney disease* working with non-viral recombinant or synthetic DNA/RNA.
- Dr. Ingalls renewed the BUA *Analyzing metabolites from marine microorganisms* working with various BSL-1 agents in vitro.
- Dr. Sherman added work with previously approved agents to a new room on the BUA *MTB Disease and Drug Response*.
- Dr. De Boer was approved for work with human blood, tissue, body fluids, and cell lines on the BUA *The Kidney Research Institute Laboratory will measure and quantify proteins related to both acute and chronic kidney disease*.
- Dr. Hoffman added work with bacteriophages and non-viral recombinant or synthetic DNA/RNA, as well as a new room, to the BUA *Microbiology of people with cystic fibrosis and other chronic infections*.
- Dr. Colby renewed the BUA *Comparative Medicine Animal Biosafety Level 2 Biocontainment Facilities* for biological agents approved by the IBC using ABSL-2 containment and practices.
- Dr. Stella renewed the BUA *ST in PD-GBM* working with adeno-associated viral vectors in vitro.
- Dr. Hakimian added rooms to the BUA *CURE-PTE*.
- Dr. Koelle added use of human cells from HIV positive patients at BSL-2 w/3 practices to the BUA *Koelle Laboratory at UW*.
- Dr. Levitt added rooms to the BUA *Cerebrovascular pathobiology*.
- Dr. Brakenridge was approved for work with human blood, tissue, body fluids, and cell lines on the BUA *Sample Processing for Clinical Research Studies*.
- 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 pending two corrections identified. Another member seconded the motion.
- The Committee voted to approve this month's Biosafety Officer Report pending the corrections identified. There was one voting abstention.

## 9. BSL-3 INACTIVATION REPORT

- Dr. Kreuzer requested validation of SARS-CoV-2 inactivation: Qiagen Viral RNA Extraction Kit.
- Dr. Gale requested a waiver for verification of SARS-CoV-2 inactivation using Trizol.

- The subcommittee reviewed procedure and inactivation data provided by the labs and approved all requests.
- 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 unanimously voted to approve this month's BSL-3 Inactivation Report.

## 10. 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.

## 11. INDIVIDUAL PROJECT REVIEWS

- a. Bornfeldt, Karin, renewal, *Vector and Transgenic Mouse Core (VTMC)*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This core lab produces plasmids and viral vectors for requesting investigators who want to overexpress, knockdown, knockout, or alter expression of RNAs and proteins of interest in cultured cells, isolated tissues, and rodents. All PIs requesting services from VTMC will have their own active BUAs that include the biomaterials made in the VTMC.
  - A lab inspection has been successfully 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. Bornfeldt.
  - The Committee voted unanimously to approve the draft BUA for Dr. Bornfeldt.
  
- b. Bruchas, Michael, renewal, *Neuromodulation in Affective Behavior*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the role of G-protein coupled receptors in the contexts of stress, depression, addiction, and pain.
  - A lab inspection has been successfully 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. Bruchas.
  - The Committee voted unanimously to approve the draft BUA for Dr. Bruchas.
  
- c. Darnell, Max, new, *Comotion Labs -Modulus Therapeutics*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab works to engineer immune cell therapies, and wants to engineer immune cells with enhanced anti-tumor powers.
  - There was discussion about what if a PI targets an oncogene or tumor suppressor when screening to create lentiviral libraries. The BUA letter needs to include a footnote to state action if an oncogene is discovered, including information on screening gene libraries. This will also be included in an email to the PI to accompany the BUA letter.
  - A lab inspection has been successfully completed.
  - All of the required trainings have been completed.

- The draft BUA letter was shown. A necessary footnote on oncogenes was found to be missing and needs to be added.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Darnell pending the additional footnote.
  - The Committee voted unanimously to approve the draft BUA for Dr. Darnell pending the additional footnote.
- d. Deng, Xinxian, renewal, *Studies of dosage regulation of X-linked genes and their roles in health and disease*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This project aims to study dosage regulation pathways of X-linked genes to better understand the molecular mechanisms involved in this dosage regulation (up-regulation or inactivation of dosage-sensitive genes) and the effects of abnormal copy numbers of dosage-sensitive X-linked genes to phenotypes.
  - A lab inspection has been successfully completed.
  - Required trainings have yet to be completed.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Deng pending completion of required trainings.
  - The Committee voted unanimously to approve the draft BUA for Dr. Deng pending completion of required trainings.
- e. Dichek, David, renewal, *Gene Transfer in Cardiovascular Disease (Mice)*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall goals of this research are to understand the mechanisms through which blood vessels become diseased and to develop genetic or other molecular therapies to prevent or reverse blood vessel disease utilizing the following procedures.
  - A lab inspection has been successfully completed with all findings resolved.
  - 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. Dichek.
  - The Committee voted unanimously to approve the draft BUA for Dr. Dichek.
- f. Dichek, David, renewal, *Gene Transfer in Cardiovascular Disease (Rabbits)*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall goals of this research are to understand the mechanisms through which blood vessels become diseased and to develop genetic or other molecular therapies to prevent or reverse blood vessel disease utilizing the following procedures.
  - A lab inspection has been successfully completed with all findings resolved.
  - 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. Dichek.
  - The Committee voted unanimously to approve the draft BUA for Dr. Dichek.
- g. Gerner, Michael, renewal, *Organization of Immunity*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The main research aim is to test the functional ability of T cells to mount a response to immune challenge.

- A lab inspection has been successfully completed.
  - All of the required trainings have been completed.
  - The PI needs to list the exact Listeria strain used and confirm that P. aeruginosa is not multi-drug resistant. Neither item would change containment.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gerner pending the additional Listeria and P. aeruginosa information requested of the PI above.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gerner pending the item stated above.
- h.** Keene, C. Dirk, renewal, *Neurogenerative Disease & Disorder*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This project includes human, non-human primate, and other animal brain tissue banking, dissection, and processing for various studies.
  - A lab inspection has been successfully 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. Keene.
  - The Committee voted unanimously to approve the draft BUA for Dr. Keene.
- i.** Ligabue, Alessio, change, *Develop of new method to purify/enrich sub population of human cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The PI has requested to add use of AAV and lentiviral vectors in vitro.
  - A lab inspection was recently completed and is 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. Ligabue.
  - The Committee voted unanimously to approve the draft BUA for Dr. Ligabue.
- j.** Mack, David, renewal, *Stem cell-derived Disease-in-a-Dish Models to Study Neuromuscular Conditions*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This research is intended to study Duchenne Muscular Dystrophy (DMD) patient heart cells generated from stem cells and compare them with heart cells derived from healthy individuals and to identify potential effective drugs that are beneficial for DMD patients with heart problems.
  - A lab inspection has been successfully completed.
  - All of the required trainings have been completed.
  - The draft BUA letter was shown. One necessary correction was identified.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Mack pending a correction to the BUA letter.
  - The Committee voted unanimously to approve the draft BUA for Dr. Mack pending a correction to the BUA letter.
- k.** Murry, Charles, renewal, *Myocardial Infarction Repair in Mice*
- The assigned IBC Secondary Reviewer presented the Primary Review.

- This lab studies cell development in cardiovascular lineages and strategies to repair myocardial injury.
  - A lab inspection has been successfully completed.
  - 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. Murry.
  - The Committee voted unanimously to approve the draft BUA for Dr. Murry.
- I. Reh, Thomas, renewal, *Retinal Ganglion Cell Replacement in Optic Neuropathies*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the development and regeneration of the neural retina in mice and humans.
  - A lab inspection has been successfully 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. Reh.
  - The Committee voted unanimously to approve the draft BUA for Dr. Reh.

## 12. SUBCOMMITTEE REPORTS:

- m. Gauthier, Jordan, new, *A two-stage Phase 1 open-label study of huJCAR014, CD19-targeted chimeric antigenreceptor (CAR)-modified T cells bearing a human binding domain, in adult patients with relapsed or refractory B-cell non-Hodgkin lymphoma and acute lymphocytic leukemia*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is a renewal of a protocol previously headed by Dr. Turtle. CAR-T cells are genetically modified autologous cells that target specific cells for destruction by expressing a specificity conferring protein on their surface to bring about physical binding to the target cells, and also possess executioner function(s). In this clinical trial, CAR-T cells created at a company will be infused intravenously in a UW facility.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Gauthier. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gauthier.
- n. Murry, Charles, renewal, *Myocardial Infarction Repair in Rats*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The overall research goals are to examine differentiation of stem cells (embryonic stem cells and induced pluripotent stem cells) into cardiovascular lineage cells as well as their ability to repair myocardial injury following implantation in mice. They also study the ability of various genes to improve graft survival.
  - A lab inspection has been successfully completed.
  - All of the required trainings have been completed.
  - Review of the IACUC protocol is required once it has been submitted by the lab.
  - The draft BUA letter was shown.

- A member made a motion to approve the draft BUA letter for Dr. Murry pending review of the IACUC protocol. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Murry pending review of the IACUC protocol.
- o. *Walter, Roland, new, A First-In-Human, Open-Label, Multicenter Study of VOR33 in Patients with Acute Myeloid Leukemia who are at High-Risk for Leukemia Relapse following Hematopoietic Cell Transplantation*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is an industry-sponsored, multi-center, first-in-human, phase I study of VOR33 (a new class of genome edited allogeneic hematopoietic stem cells targeting CD33) for treatment of acute myeloid leukemia. VOR33 will be administered as a single intravenous infusion to a patient with AML.
  - A committee member asked why the agent was just plain human cells into humans. No recombinant DNA is involved, so the agent name will be updated on the BUA letter to reflect that.
  - The draft BUA letter was shown. The agent name will be changed to human cells transfected with rec/synthetic DNA/RNA.
  - A member made a motion to approve the draft BUA letter for Dr. Walter pending the change stated above. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Walter pending the change stated above.

## **10. FOR YOUR INFORMATION**

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:54 A.M.**