



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, April 17, 2024

Time: 10:00 AM – 12:00 PM

Location: Zoom

- Members Present:**
1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
 2. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 3. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 4. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 5. David Koelle, Allergy and Infectious Diseases
 6. Stephen Libby, Laboratory Medicine
 7. Scott Meschke, Environmental & Occupational Health Sciences
 8. Susan Parazzoli (*Community Member*)
 9. Jason Smith, Microbiology (*IBC Chair*)
 10. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)

Commonly Used Abbreviations

AAV: adeno-associated viral vector

BSL: Biosafety level

BSL-2w/3: BSL-2 with BSL-3 practices

BSO: Biosafety officer

BUA: Biological Use Authorization

DURC: Dual Use Research of Concern

IACUC: Institutional Animal Care and Use Committee

IBC: Institutional Biosafety Committee

iPS: induced pluripotent stem cells

NHP: non-human primate

NIH: National Institutes of Health

PI: Principal Investigator

rDNA: Recombinant or synthetic DNA/RNA

RG: Risk Group

SOP: standard operating procedure

Source material: blood, tissue, body fluids, and cell lines

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.
 - The June 18, 2024 IBC meeting is on Tuesday due to the Juneteenth holiday on Wednesday.
3. **2024 BUA APPLICATION UPDATES:** Revisions were made to the Biological Use Authorization application (BUA), the BUA Change (BUAC) application, and supplemental forms associated with the applications.
 - The IBC Chair made a motion to approve changes to the BUA, BUAC, and supplemental applications forms.
 - A member made a motion to approve changes to the BUA and BUAC, and supplemental applications forms. Another member seconded the motion.
 - The Committee unanimously voted to approve the changes to the BUA, BUAC, and the supplemental application forms.
4. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the March 20, 2024 meeting.
 - A member made a motion to approve the March 20, 2024 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the March 20, 2024 meeting minutes, with one abstention.
5. **OLD BUSINESS:**
 - At the March 20, 2024, meeting, Dr. Disis' BUA was approved pending successful resolution of the lab inspection findings. This BUA has been sent.
 - At the March 20, 2024, meeting, Dr. Gu's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the March 20, 2024, meeting, Dr. Shendure's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the March 20, 2024, meeting, Dr. Stuber's BUA was approved pending a written procedure and determination of the animal procedure room location. This BUA is still pending.
 - At the March 20, 2024, meeting, Dr. Xin's BUA was approved pending clarification of the use of ecotropic gammaretroviral vectors in human cells and successful resolution of inspection findings. This BUA has been sent.
 - At the March 20, 2024, meeting, Dr. Gore's BUA was approved pending completion of the required training and creation of a medical management plan. This BUA is still pending.
6. **BIOSAFETY OFFICER (BSO) REPORT:** The Biosafety Officer Report includes projects involving: (1) recombinant or synthetic nucleic acids covered under section III-E and III-F of the *NIH Guidelines*, (2) non-recombinant biological agents requiring BSL-2 with BSL-3 practices containment or lower, and (3) administrative updates, such as room additions.
 - a. Biosafety Officer Report

- Dr. Morishima renewed in vitro work with fixed or inactivated SARS-CoV-2 and clinical samples from patients suspected to be infected with SARS-CoV-2 at BSL-2 to the BUA *Immunological Assay Development*.
- Dr. Bhardwaj was approved for in vitro work with non-pathogenic strains of E. coli, rDNA, and Saccharomyces cerevisiae on the BUA *Yeast display screening and bacterial protein expression of designed peptides and miniproteins* (Section III-E).
- Dr Wang added a cell sorting facility for use with previously approved agents to the BUA *Role of mitochondria in cardiac physiology and disease*.
- Dr. Kong registered non-biohazardous work to the BUA *Signaling pathways in the context of development, disease, and regeneration*.
- Dr. York registered in vitro work with mouse cells and recombinant or synthetic DNA/RNA to the BUA *Immune Cell Metabolism* (Section III-F).
- Dr. Frey was approved for in vitro work with human source material on the BUA *Freeze dry human blood*.
- Dr. Adams Waldorf added the use of Respiratory syncytial virus (RSV) in vitro and in NHPs at A/BSL-2 to the BUA *Influenza and Coronavirus Model of Immunity in Pregnancy*.
- Dr. Mu was approved for in vitro work with non-viral rDNA with enhanced gene delivery methods and human source material on the BUA *Combination therapeutic nanoparticles for enhanced cancer treatment* (Sections III-E and III-F).
- Dr. Totah added rooms for in vitro work with previously approved agents to the BUA *Investigating pathophysiological reasons that influence cardiovascular disease*.
- Dr. West added the use of wildtype Francisella tularensis subsp. Holarctica live vaccine strain (LVS) for in vitro and in vivo work in previously approved A/BSL-2 spaces to the BUA *Host genetics and response to infection*.
- Dr. Veesler added a new room for in vitro work with previously approved agents to the BUA *Expression of recombinant proteins using mammalian cell lines*.
- The IBC Chair made 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.

7. INDIVIDUAL PROJECT REVIEWS

- a. Bengtsson, Niclas, renewal, *Muscle gene therapy*
 - Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Bengtsson lab aims to develop novel ways to correct genetic mutations causing muscular dystrophies.
 - This lab works with AAV and murine cells transduced with AAV in mice. They also work with AAV, non-pathogenic E. coli, and non-viral rDNA in vitro.
 - 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. Bengtsson.

- The Committee voted unanimously to approve the draft BUA for Dr. Bengtsson.
- b. Cabernard, Clemens, renewal, *Snail Asymmetry***
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Cabernard lab aims to investigate asymmetric cell division in marine mollusk embryos.
 - This lab works with non-viral rDNA in snails. They also work with non-viral rDNA and non-pathogenic strains of *E. coli* in vitro.
 - 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. Cabernard.
 - The Committee voted unanimously to approve the draft BUA for Dr. Cabernard.
- c. Disis, Mary, new, *Vaccine to Prevent Colorectal Cancer***
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Disis lab aims to develop diagnostic, preventative, and treatment strategies to combat cancer and modulate the immune system as it relates to cancers or inflammatory diseases.
 - This lab works with rDNA with and without enhanced gene delivery methods in mice and in vitro.
 - 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. Disis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis.
- d. Froehner, Stanley, renewal, *Froehner Muscular Dystrophy Projects***
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Froehner lab aims to understand the causes of muscle disease and to develop rational therapies for these diseases.
 - This lab works with AAV and non-viral rDNA in mice and in vitro.
 - 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. Froehner.
 - The Committee voted unanimously to approve the draft BUA for Dr. Froehner.
- e. Guo, Monica, renewal, *Chromosome organization in microbes***
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.

- The Guo lab aims to understand the chromosome organization of microbes and how chromosome structure affects DNA replication.
 - This lab does in vitro work with several bacteria species at BSL-1 and with *Pseudomonas aeruginosa* and *Enterococcus faecalis* at BSL-2.
 - 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. Guo.
 - The Committee voted unanimously to approve the draft BUA for Dr. Guo, pending successful completion of the lab inspection response.
- f. Kim, Jeansok, renewal, *Using molecular biological approaches to understand fear related behavior in predatory prey interactions*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Kim lab aims to investigate fear-related behaviors in ecological settings using molecular biological techniques to inhibit and stimulate neurons in specific brain fear circuits.
 - This lab works with AAV and canine adenoviral vectors (E1a deleted) in murine species at ABSL-1.
 - 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. Kim.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kim.
- g. Klevit, Rachel, renewal, *Structural Biology of Proteins*
- Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Klevit lab aims to gain an understanding of how the three-dimensional structures of proteins give rise to their biological function.
 - This lab works with non-pathogenic strains of *E. coli*, baculoviral vectors, human source material, and non-viral rDNA in vitro.
 - 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. Klevit.
 - The Committee voted unanimously to approve the draft BUA for Dr. Klevit.
- h. Parrish, Jay, renewal, *Structural and functional coupling of epidermis to somatosensory neurons in *Drosophila**
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Parrish lab aims to understand nervous system organization and function in invertebrates.

- This lab works with transgenic *Aedes aegypti* (larvae only) and *Drosophila* at all life stages; they also work with non-pathogenic strains of *E. coli* and non-viral rDNA in vitro.
 - 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. Parrish.
 - The Committee voted unanimously to approve the draft BUA for Dr. Parrish.
- i. Pasupathy, Anitha, renewal, *Neural basis of visual shape representation and recognition*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Pasupathy lab aims to understand the relationship between brain activity and higher-level cognitive functions such as visual perception, recognition, memory, and decision making.
 - This lab works with AAV in 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. Pasupathy.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pasupathy.
- j. Scatena, Marta, renewal, *Endothelial cells for tissue engineering and osteoprotegerin in atherosclerosis*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Scatena lab aims to create a cell therapeutic aimed at improving the aberrant inflammatory in response to biomaterials.
 - This lab works with murine cells transduced with lentiviral vectors in mice. They also work with gammaretroviral vectors, lentiviral vectors, non-viral rDNA with enhanced gene delivery systems, and human and NHP source material in vitro.
 - The lab inspection is scheduled for after the IBC meeting.
 - 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. Scatena.
 - The Committee voted unanimously to approve the draft BUA for Dr. Scatena pending successful completion of the lab inspection.
- k. Theriot, Julie, renewal, *Advances in cellular motility*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Theriot lab aims to understand the biophysics of how cells move and change shape.
 - This lab works with transgenic zebrafish. They also work with *Staphylococcus aureus*, *Candida albicans*, and *Listeria monocytogenes* at BSL-2, and with lentiviral

vectors, non-pathogenic strains of E. coli, and rDNA with enhanced gene delivery methods at BSL-1.

- The lab was inspected, and all deficiencies have been corrected.
- The Biological Reproductive Hazards focus sheet with information about Listeria monocytogenes is linked to on the BUA letter.
- 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. Theriot.
- The Committee voted unanimously to approve the draft BUA for Dr. Theriot.

I. Wayne, Elizabeth, new, *Design of Immune Cell as biosensors and therapeutic tools*

- Sections III-D, III-E, and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Wayne lab aims to understand how monocyte polarization impacts drug delivery and disease progression.
- This lab works with non-pathogenic strains of E. coli, lentiviral vectors rDNA with enhanced gene delivery methods, and human source material in vitro.
- The lab inspection is scheduled for after the IBC meeting.
- The required trainings are still pending.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Wayne
- The Committee voted unanimously to approve the draft BUA for Dr. Wayne, pending successful completion of the lab inspection.

8. SUBCOMMITTEE REPORTS:

m. Loggers, Elizabeth, new, *A First-in-Human, Phase 1/2, Dose Escalation Study of BOXR1030 T cells in Subjects With Advanced GPC3-Positive Solid Tumors*

- Section III-C
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a first in humans, dose-escalation, multi-center, open-label, industry-sponsored trial to evaluate the safety of transduced CAR-T cells in subjects with advanced solid tumors that express the GPC3 protein.
- Human cells transduced with gammaretroviral vectors are administered to 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. Loggers. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Loggers.

n. Milano, Filippo, new, *A Phase I, First in Human Open Label Study to Evaluate the Safety and Tolerability of TRX103 cell infusion in subjects with hematological malignancies undergoing HLA-mismatched related or unrelated hematopoietic stem cell transplantation (HSCT).*

- Section III-C
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.

- This is an industry-sponsored, phase 1, first-in-human, multi-center, open label, single-arm study to evaluate safety of a cell infusion in patients undergoing haploidentical or unrelated allogeneic hematopoietic stem cell transplant for hematologic malignancies.
- Human cells transduced with lentiviral vectors are administered to 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. Milano. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Milano.

10. FOR YOUR INFORMATION:

- **EH&S is investigating the following incident:**
 - A research technician experienced a needlestick from a needle that had gone through a glove that had been in contact with an NHP previously inoculated with cells modified with rDNA. The employee washed the injury for 15 minutes with a herpes B scrub kit containing a chlorhexidine solution and then reported to the emergency department for treatment. They have consulted with the UW Employee Health Center (EHC) for follow up care and monitoring.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:28 A.M.