



# INSTITUTIONAL BIOSAFETY COMMITTEE

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## UNIVERSITY of WASHINGTON

### Meeting Minutes

**Date:** Wednesday, March 20, 2024

**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 Colby, Comparative Medicine (*Animal Containment Expert*)
  5. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
  6. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
  7. David Koelle, Allergy and Infectious Diseases
  8. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
  9. Scott Meschke, Environmental & Occupational Health Sciences
  10. Jason Smith, Microbiology (*IBC Chair*)
  11. 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.
3. **APPROVAL OF MINUTES:**
  - The IBC Chair sought a motion to approve the minutes from the February 21, 2024 meeting.
  - A member made a motion to approve the February 21, 2024 minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the February 21, 2024 meeting minutes, with one abstention.
4. **OLD BUSINESS:**
  - At the February 21, 2024 meeting, Dr. Fuller's BUA was approved pending completion of the required trainings. This BUA is still pending.
  - At the February 21, 2024 meeting, Dr. Hofstetter's BUA was approved pending completion of the required trainings. This BUA is still pending.
  - At the February 21, 2024 meeting, Dr. Kerr's BUA was approved pending successful completion of the lab inspection. This BUA has been sent out.
  - At the February 21, 2024 meeting, Dr. Shechner's BUA was approved pending successful completion of the lab inspection. This BUA has been sent out.
  - At the February 21, 2024 meeting, Dr. Xu's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
  - At the February 21, 2024 meeting, Altemeier's BUA was approved pending successful completion of the lab inspection and an edit to the application. This BUA was sent out.
  - At the February 21, 2024 meeting, Hyde's BUA was approved pending IACUC protocol edits. This BUA was sent out.
  - At the February 21, 2024 meeting, Mitchell's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
5. **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. Guttman renewed in vitro work with non-pathogenic strains of *E. coli*, non-viral rDNA, and *Lysobacter* enzymogenes to the BUA *Epitope mapping of neutralizing antibodies on staphylococcal enterotoxins* (Sections III-E and III-F).
    - Dr. Rieke added a room for previously approved in vitro work to the BUA *Biophysical Mechanisms of Photo Detection*.
    - Dr. Varani renewed in vitro work with non-pathogenic strains of *E. coli* and non-viral rDNA to the BUA *RNA Structure/Function* (Sections III-E and III-F).
    - Dr. Thachuk renewed in vitro work with non-viral rDNA to the BUA *RNA Molecular computation via synthetic DNA oligos* (Section III-F).

- Dr. Escobar added in vitro work with mouse cells exposed to lab adapted Lymphocytic choriomeningitis (LCMV) strains to the BUA *Chromatin dynamics in stem cells and immune cell function*.
- Dr. Di Stilio registered work sorting transgenic plant cells to the BUA *Functional Evolution of Floral Pathway Genes*.
- Dr. Panyam was approved for in vitro work with non-pathogenic strains of E. coli and non-viral rDNA on the BUA *Anticancer studies in mice models* (Section III-F).
- Dr. Gao renewed in vitro work with human source materials to the BUA *RNA Cryopreservation of Cells and Tissues*.
- Dr. Swisher renewed in vitro work human source materials and non-viral rDNA to the BUA *Cancer Risks Associated with Inherited Mutations in Ovarian Cancer Susceptibility Genes Beyond BRCA1 and BRCA2* (Section III-F).
- Dr. Giacani was approved for in vitro and in vivo work in mice with Treponema pallidum on the BUA *Mouse model for syphilis*.
- Dr. Paik added in vitro work with Fusobacterium nucleatum in mice at ABSL-2 to the BUA *GNAC facility*.
- Dr. Capozzi registered work with additional AAV inserts with no change in biosafety level to the BUA *Glucagon-insulin Hepatic Glycogen*.
- Dr. Chen added a room for in vitro work with previously approved agents to the BUA *Druggable pathways in rhabdomyosarcoma*.
- Dr. Derdeyn added new rooms for in vitro work with previously approved agents to the BUA *Virus neutralization, diversity, and B cell immunology*.
- Dr. Winkler renewed in vitro work with multiple RG 1 bacteria and protozoa, wastewater samples, human source materials, non-pathogenic strains of E. coli, and non-viral rDNA to the BUA *Winkler Lab* (Section III-F).
- Dr. Theberge added in vitro with Streptococcus pneumoniae, Streptococcus mitis, and Candida albicans to the BUA *Studying cell signaling and cell-microenvironment interactions with new analytical tools*.
- 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. INDIVIDUAL PROJECT REVIEWS

- a. Cookson, Brad, change, *Initiation and Regulation of Inflammation and Development of Protective Immunity*
  - Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Cookson lab added recombinant RG 2 Yersinia pseudotuberculosis in mice at ABSL-2.
  - A lab inspection was not required as the lab was recently inspected.
  - All required trainings are complete.
  - This project has an IACUC protocol in post review.
  - 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. Disis, Mary, renewal, *Evaluation of Multi-Antigen, Multi-Epitope Th1 Selective Vaccine Against Ovarian Cancer*
- Sections III-D, III-E, and III-F.
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Disis lab aims to understand Th1 selective vaccine against ovarian cancer, study its safety and efficacy, and determine if efficacy is improved with combination therapy.
  - This lab works with non-viral rDNA with enhanced gene delivery methods and lentiviral vectors in vitro and 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. Disis.
  - The Committee voted unanimously to approve the draft BUA for Dr. Disis, pending successful resolution of the lab inspection findings.
- c. Duthie, Malcolm, renewal, *Evaluation of treatments to interrupt tumor development*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Duthie lab aims to develop immune intervention strategies to disrupt tumor formation or progression.
  - This lab works with human source material, murine cells transduced with gammaretroviral vectors, and non-viral rDNA with enhanced gene delivery methods in mice.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - The required trainings are still pending.
  - 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. Duthie.
  - The Committee voted unanimously to approve the draft BUA for Dr. Duthie.
- d. Gu, Liangcai, renewal, *Study of small molecule-controlled CAR-T cell activation in mice*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Gu lab aims to engineer small-molecule drug-controlled protein biosensors to improve efficacy and safety of chimeric antigen receptor (CAR) T-cell-based cancer immunotherapy.
  - This lab works with human source material and human cells transduced with lentiviral vectors in mice. They also work with non-pathogenic strains of E. coli and non-viral rDNA with enhanced gene delivery methods 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. Gu.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gu, pending successful completion of the lab inspection.

- e. **Kawasumi, Masaoki, renewal, *Skin Cancer Research***
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Kawasumi lab aims to better understand the mechanisms of skin carcinogenesis and develop methods of prevention and/or treatment.
  - This lab works with human source material, human and murine cells transduced with lentiviral vectors in mice. They also work with AAV and gammaretroviral vectors 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. Kawasumi.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kawasumi.
- f. **Ladiges, Warren, renewal, *Xenograft Program***
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Ladiges lab aims to provide a model for investigation of human xenografts in mice representing a variety of tissues.
  - This lab works with human source material in mice and lentiviral vectors in vitro.
  - The lab was inspected, and no deficiencies were notes.
  - 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. Ladiges.
  - The Committee voted unanimously to approve the draft BUA for Dr. Ladiges.
- g. **Ojo, Kayode, change, *Development of target-based inhibitors of Giardia intestinalis/Giardia lamblia, Trichomonas vaginalis as new treatment options***
- Sections III-D and III-E
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Ojo lab added work with wildtype and recombinant Giardia and Plasmodium species in vitro and in mice.
  - 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. Ojo.
  - The Committee voted unanimously to approve the draft BUA for Dr. Ojo.
- h. **Shendure, Jay, renewal, *Shendure: General Research***
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.

- The Shendure lab aims to advance the capabilities of next generation sequencing, both physically and computationally, and to use next generation sequencing to advance understanding of genetics on a single cell level.
  - This lab works with lentiviral vectors, non-pathogenic strains of E. coli, and non-viral rDNA with enhanced gene delivery methods 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. Shendure.
  - The Committee voted unanimously to approve the draft BUA for Dr. Shendure, pending successful completion of the lab inspection..
- i. Stuber, Garrett, change, *Neural Circuits for Motivation and Reward*
- Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Stuber lab is adding a RG 2 G-deleted rabies viral vector for in vitro work and for use in mice at ABSL-2.
  - 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. Stuber.
  - The Committee voted unanimously to approve the draft BUA for Dr. Stuber, pending a written procedure and determination of the animal procedure room location.
- j. Tang, Gale, renewal, *Mechanisms of Arteriogenesis in Mice and Rats*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Tang lab aims to build and verify a new ex vivo model for intimal hyperplasia.
  - This lab works with non-viral rDNA and human cells transduced with AAV in murine species and in vitro. They also work with rDNA with enhanced gene delivery methods in vitro.
  - The lab was inspected, and no deficiencies were noted.
  - 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. Tang.
  - The Committee voted unanimously to approve the draft BUA for Dr. Tang.
- k. Xin, Li, renewal, *Studies on prostate homeostasis and prostate-related diseases*
- Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Xin lab aims to understand the molecular mechanisms that regulate prostate development and homeostasis, as well as those that regulate initiation and progression of prostate related diseases.

- This lab works with lentiviral vectors, AAV, non-pathogenic strains of E. coli, gammaretroviral vectors, and non-viral rDNA with enhanced gene delivery methods in vitro. They also work with murine cells transduced with lentiviral vectors, AAV or gammaretroviral vectors and human cells transduced with AAV 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. Xin.
- The Committee voted unanimously to approve the draft BUA for Dr. Xin, pending clarification of the use of ecotropic gammaretroviral vectors in human cells and successful resolution of inspection findings.

**I. Yadav, Smita, change, *Signaling in neuronal development and disease***

- Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Yadav lab is adding the use of Sendai virus and human cells for iPS cell creation in vitro at BSL-2 in the stem cell core facility.
- A lab inspection was not required as all work takes place inside a core facility.
- 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. Yadav.
- The Committee voted unanimously to approve the draft BUA for Dr. Yadav.

**m. Yazdan-Shahmorad, Azadeh, renewal, *Novel neural technologies for neurorehabilitation***

- Section III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Yazdan-Shahmorad lab aims to develop novel neural interfaces and determine underlying mechanisms that lead to functional recovery from stroke.
- This lab uses AAV and lentiviral vectors in NHPs and in vitro.
- A lab inspection has been performed 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. Yazdan-Shahmorad.
- The Committee voted unanimously to approve the draft BUA for Dr. Yazdan-Shahmorad.

**7. SUBCOMMITTEE REPORTS:**

**n. Chiorean, Gabriela, new, *Phase I Study Of Autologous Cd8+ And Cd4+ Engineered T Cell Receptor T Cells In Subjects With Advanced Or Metastatic 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 multi-center, industry sponsored, first in human dose-escalation trial, restricted to persons with one HLA allele.

- Human cells transduced with lentiviral vectors will be 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. Chiorean. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Chiorean.
- o. Gore, John, new, A Phase 3, Randomized Study of Adjuvant Cretostimogene Grenadenorepvec versus Observation for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR-NMIBC) Following Transurethral Resection of Bladder Tumor (TURBT)
- Sections III-C and III-D
  - Two 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, open-label, randomized, new phase III study for adults with intermediate-risk non-muscle invasive bladder cancer (IR-NNIBC)
  - A conditionally replication competent adenoviral vector (Ad5) will be administered to humans.
  - A discussion took place regarding processes to mitigate risk of exposure to the study product to healthcare employees and study staff. The Employee Health Center will develop a medical management plan to provide information to personnel working with the adenoviral agent or patients exposed to the study agent to include personal protective equipment (PPE), pre-work counseling, and coordination with hospital infection control if a study subject requires hospitalization after infusion.
  - The lab inspection is scheduled for after the IBC meeting.
  - The required trainings are still pending.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Gore. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gore, pending completion of the required trainings and creation of a medical management plan.

#### 10. FOR YOUR INFORMATION:

- **NIH Incident Response:**
  - The NIH has responded that no further information or action was required for a recent incident involving a biosafety cabinet failure during work with recombinant Mycobacterium tuberculosis in a BSL-3 lab.
  - The NIH has responded that no further information or action was required for a recent incident involving a scratch from a non-human primate that had previously been exposed to recombinant biological agents.

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:48 AM.**