# INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

**Meeting Minutes**

**Date:** Wednesday, December 14, 2022
**Time:** 10:00 AM – 12:00 PM

**Location:** Zoom

**Members Present:**

1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
2. Jason Cantera *(Community Member)*
3. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
4. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
5. Richard Grant, Washington National Primate Research Center
6. Erin Heiniger, Department of Bioengineering *(Laboratory Specialist*)
7. Kevin Hybiske, Allergy and Infectious Diseases *(IBC Vice Chair)*
8. Stephen Libby, Laboratory Medicine *(Animal Containment Expert)*
9. Scott Meschke, Environmental & Occupational Health Sciences
10. Susan Parazzoli *(Community Member)*
11. Jason Smith, Microbiology (*IBC 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
NHP: Non-Human Primate
NIH: National Institutes of Health
DURC: Dual Use Research of Concern

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.

3. **APPROVAL OF MINUTES:**
   - The IBC Chair sought a motion to approve the minutes from the November 16, 2022, meeting.
   - A member made a motion to approve the November 16, 2022, minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the November 16, 2022, meeting minutes.

4. **OLD BUSINESS:**
   - At the November 16, 2022, meeting, Dr. Fujise's BUA was approved pending edits to the BUA. This BUA is still pending.
   - At the November 16, 2022, meeting, Dr. Green's BUA was approved pending clarification of vector administration to NHPs. This BUA is still pending.
   - At the November 16, 2022, meeting, Dr. Schwartz's (001) BUA was approved pending edits to the BUA letter and clarification of vivarium locations used. This BUA is still pending.
   - At the November 16, 2022, meeting, Dr. Schwartz's (002) BUA was approved pending edits to the BUA addition of ABSL-2 vivarium locations on the letter. This BUA is still pending.
   - At the November 16, 2022, meeting Sniadecki's (002) BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
   - At the November 16, 2022, meeting Sniadecki's (002) 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 (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. Dodd renewed the BUA *Development and characterization of novel and existing advanced disinfection and oxidation processes for inactivation of chlorine-resistant pathogens, and elimination of antibiotic resistance genes and antibiotic resistant bacteria, in (waste)water and on surfaces* working with Risk Group 2 agents (bacterium and pathogenic strains of E. coli), and Risk Group 1 non-pathogenic E. coli strains in vitro (*NIH Guidelines* Section III-F and N/A).
      - Dr. Muller renewed the BUA *Andrology Research Lab / Male Fertility Lab* working with human and NHP blood, tissue, body fluids, and cell lines in vitro (*NIH Guidelines* Sections N/A).
      - Dr. Geisse added a new room for work with previously approved agents to the BUA *Development of cultureware and devices for human cells in vitro research* (*NIH Guidelines* Sections N/A).
      - Dr. Strand renewed the BUA *Phytoremediation: Transformation of Plants with Genes that are Capable to Degrade Pollutants* working with Risk Group 1 microorganisms and transgenic plants (*NIH Guidelines* Section III-E and N/A).

- Dr. Harwood added a new Risk Group 2 non-recombinant bacteria to previously approved rooms (*NIH Guidelines* Section N/A).
- Dr. Dhaka added a new room to the BUA *Dhaka Zebrafish* (*NIH Guidelines* Sections N/A).
- Dr. Dhaka added new rooms to the BUA *Transsynaptic Tracing of Somosensory Circuits* (*NIH Guidelines* Sections N/A).
- Dr. Rabinovitch renewed the BUA *Flow Cytometry Cost Center* working with pre-approved cells in vitro (*NIH Guidelines* Section N/A).
- Dr. Dembrow added new rooms to the BUA *Developing a primate culture platform for the treatment of degenerative disorders* (*NIH Guidelines* Section N/A).
- Dr. Ladiges removed previously approved agents and added new rooms. They also added the use of human blood, tissue, and body fluids to the BUA *Alzheimer's Disease Intervention* (*NIH Guidelines* Sections N/A).
- Dr. Koelle added work with non-lesion samples suspected to be infected with monkeypox virus and updated the agent names for their vaccinia virus strains to the BUA *Koelle Laboratory at UW* (*NIH Guidelines* Section N/A).
- Dr. Greninger added the use of inactivated Risk Group 2, 3, and 4 nucleic acids to the BUA *Discovery and Characterization of Virus-Host Interactions and Determination of Antiviral Drug Resistance* (*NIH Guidelines* Section III-F).
- Dr. Stekler registered work for clinical blood draws to the project *The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIVPoint-of-Care Nucleic Acid Tests (NATs)* (*NIH Guidelines* Section N/A). This work does not require a BUA.
- 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.
- <u>The Committee unanimously voted to approve this month's Biosafety Officer Report.</u>

## 6. INDIVIDUAL PROJECT REVIEWS

**a.** Ailion, Michael, renewal, *Dense-core vesicles*

- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Ailion lab aims to identify and characterize genes involved in release of peptide hormones.
- This lab works includes work with lentiviral vectors in vitro, transgenic C. elegans and Risk Group 1 microorganisms.
- 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. Ailion.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Ailion pending successful completion of the lab inspection.</u>

**b.** Bitto, Alessandro, change, *Pharmacological approaches to aging and mitochondrial disease*

- *NIH Guidelines* Sections III-D, III-E, and III-F apply.

- The assigned IBC Primary Reviewer presented the Primary Review.
- The Bitto lab is taking over this BUA from a retiring PI and adding the use of adeno-associated viral vectors and lentiviral vectors for in vitro work.
- 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. Bitto.
- The Committee voted unanimously to approve the draft BUA for Dr. Bitto.

**c.** Bothwell, Mark, change, *iPSC models for neuromuscular diseases*

- *NIH Guidelines* Sections III-D applies.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Bothwell lab is adding the use of West Nile Virus for in vitro work at BSL-2.
- A discussion occurred regarding the biosafety officer advising the lab on substituting and eliminating sharps usage with West Nile Virus.
- The lab was inspected, and no deficiencies were noted.
- 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. Bothwell.
- The Committee voted unanimously to approve the draft BUA for Dr. Bothwell.

**d.** Geng, Yijie, new, *The Molecular Basis of Social Behavior*

- *NIH Guidelines* Sections III-D, III-E, and III-F apply.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Geng lab aims to use zebrafish and mouse models to study the molecular mechanisms that regulate social behavior; specifically, how environment and genetics determine social behavior.
- This lab works with transgenic zebrafish and lentiviral vectors in vitro and in vivo and non-pathogenic strains of E. coli in vitro.
- 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. Geng.
- The Committee voted unanimously to approve the draft BUA for Dr. Geng.

**e.** Giacani, Lorenzo, change, *Studies on the pathogenesis of syphilis and human treponematoses*

- *NIH Guideline* Sections N/A (no recombinant or synthetic nucleic acid work).
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Giacani lab is adding an antibiotic resistance experiment with Treponema pallidum and doxycycline for in vitro work at BSL-2. No genetic manipulations are involved.
- A lab inspection was not required as the lab was recently inspected.
- All required trainings are complete.
- Medical counseling is required prior to starting this specific experiment with Treponema pallidum.

- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Giacani.
- The Committee voted unanimously to approve the draft BUA for Dr. Giacani

**f.** Grant, Richard, renewal, *Primate Diagnostic Services Laboratory*

- *NIH Guidelines* Sections III-D and III-F apply.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Grant lab provides diagnostic services and reagents for specialized assays to allow detection and characterization of infectious agents in nonhuman primates to help maintain animal health.
- This work includes handling non-human primate (NHP) blood, fluids, and cells that may contain herpes B virus, samples exposed to primate lentiviruses, and Simian Immunodeficiency Virus.
- A lab inspection has been performed 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. Grant.
- The Committee voted unanimously to approve the draft BUA for Dr. Grant with one member recusing themself pending addition of wildtype agent to the BUA letter.

**g.** Johnsen, Jill, new, *Studies of variation impacting traits and disease in classical hematology*

- *NIH Guidelines* Sections III-D and III-F apply.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Johnsen lab aims to study variation in blood-associated traits and disorders.
- This lab works with replication deficient lentiviral vectors, non-pathogenic strains of E. coli and Epstein Barr virus 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. Johnsen.
- The Committee voted unanimously to approve the draft BUA for Dr. Johnsen pending one correction to the BUA letter.

**h.** Paik, Jisun, change, *Microbiome and Immunity*

- *NIH Guidelines* Section III-D applies.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Paik lab is adding 10 recombinant bacteria strains that were isolated from the mouse gastrointestinal tract. The strains are engineered for deficient expression of interbacterial antagonists.
- This change includes administering Risk Group 1 and 2 bacteria in vivo to 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. Paik.
- The Committee voted unanimously to approve the draft BUA for Dr. Paik pending one update to the BUA letter.

**7. SUBCOMMITTEE REPORTS:**

**i.** Disis, Mary (Nora), renewal, *Phase 1/2 expansion cohorts trial of intravenous administration of TAEK-VAC-HerBy vaccine alone and in combination with HER2- and PD-1/PD-L1 antibodies in patients with advanced HER2-expressing cancer*

- *NIH Guidelines* Section III-C applies.
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is an industry-sponsored (Bavarian Nordic), multi-center, open-label, phase 1/2 trial of the safety and tolerability of IV administered TAEK-VAC-HerBy (TVH) vaccine in patients with HER2-expressing tumors.
- The biggest risk involved is the risk of percutaneous sharp inoculation during preparation or administration of drug.
- All required trainings are complete.
- The Employee Health Center reviewed the study. No medical management plan or specific occupational health requirements are required for this project.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Disis. Another member seconded the motion.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Disis.</u>

**j.** Gwin, William, renewal, *A Phase II Study of Concurrent WOKVAC Vaccination with Neoadjuvant Chemotherapy and HER2-Targeted Monoclonal Antibody Therapy*

- *NIH Guidelines* Section III-C applies.
- 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 non-industry-sponsored, single center, open-label, single-arm phase II clinical trial to evaluate the safety and immunogenicity of neoadjuvant WOCVAC plasmid DNA multi-antigen (HER2, IGFBP-2, and IGF-1R) vaccination, given with neoadjuvant chemotherapy and anti-HER2 antibodies) for stages I-III breast cancer.
- The biggest risk involved is the risk of percutaneous sharp inoculation during preparation or administration of drug.
- 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. Gwin. Another member seconded the motion.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Gwin.</u>

**k.** Hall, Evan, new, *An Open-Label, Multicenter, Phase 1 Study of RP3 as a Single Agent and in Combination with PD1 Blockade in Patients with Solid Tumors*

- *NIH Guidelines* Section III-C applies.
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a new industry-sponsored, multi-center, phase I clinical trial of recombinant replication-competent herpes simplex virus 1 (HSV-1) to treat solid tumors.
- Risk of percutaneous sharp inoculation during preparation or administration of drug.

- A discussion occurred with the following questions: Is infection control notified when a medical management plan is required? Will the product also kill healthy cells? Data provided by sponsor only refers to action of product on cancer cells.
- All required trainings are complete.
- A medical management plan (MMP) for work with oncolytic HSV-1 is required before work can proceed.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Hall. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Hall pending update of the medical management plan.

**l.** Krakow, Elizabeth, renewal, *Phase I study of adoptive immunotherapy with CD8* and CD4* memory T cells transduced to express an HA-1- specific T cell receptor (TCR) for children and adults with recurrent acute leukemia after allogeneic hematopoietic stem cell transplantation (HCT).*
- *NIH Guidelines* Section III-C applies.
- 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 single-center, non-industry-sponsored, investigator-initiated (Marie Bleakley), open-label phase I clinical trial to evaluate the feasibility and safety of HA-1 TCR T cells.
- Risk of percutaneous exposure of staff handling, preparing, and administering drug.
- All required trainings are complete.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Krakow. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Krakow.

**m.** Polyak, Steve, change, *Virus-Host Interactions in Cell Culture*
- *NIH Guidelines* Section III-D applies.
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The Polyak lab is adding recombinant SARS-CoV-2 and new non-recombinant SARS-CoV-2 variants for in vitro work at BSL-3.
- A lab inspection was not required.
- All required trainings are complete.
- Medical management plan is in place for SARS-CoV-2.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Polyak. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Polyak.

**n.** Shadman, Mazyar, renewal, *A Phase I/II Study to Evaluate the Safety of Cellular Immunotherapy Using Autologous T Cells Engineered to Express a CD 20-Specific Chimeric Antigen Receptor for Patients with Relapsed or Refractory B Cell Non-Hodgkin's Lymphomas.*
- *NIH Guidelines* Section III-C applies.

- 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 single-center, non-industry-sponsored (but supported by Mustang Bio) phase I/II clinical trial to determine the maximum tolerated dose of an ex-vivo lentivirus transduced and expanded autologous T cell product expressing fully human CD20-specific CAR for patients with relapsed/refractory B-cell NHL.
- Risk of percutaneous exposure of staff handling, preparing, and administering drug.
- All required trainings are complete.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Shadman. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Shadman.

**10. FOR YOUR INFORMATION:**

- **NIH Incident Reports**:
    - The NIH responded that no further information or action was required for a recent NIH reportable incident involving a mouse that escaped from a biosafety cabinet in an ABSL-3 lab. The mouse did not escape containment and there was no personnel exposure.
    - A recent incident is being investigated involving a splash to the eye of mouse blood from a mouse that had previously been exposed to recombinant Risk Group 1 mouse plasmodium that is non-infectious to humans.
    - A second incident is being investigated involving a needlestick that had been used with a non-human primate that had previously been exposed to SHIV.
    - A third incident is being investigated involving a needlestick from a needle that may have been used with recombinant Listeria monocytogenes.

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:46 A.M.**