December 14, 2022, IBC Meeting Minutes
Prepared by JC

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. **REMININDER:** 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 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.

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.
      • The Committee voted unanimously to approve the draft BUA for Dr. Ailion pending successful completion of the lab inspection.

   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.
   - The Committee voted unanimously to approve the draft BUA for Dr. Disis.

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.
   - The Committee voted unanimously to approve the draft BUA for Dr. Gwin.

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.

I. 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:
  o 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.
  o 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.
  o 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.
  o 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.