



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, October 18, 2023

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. Richard Grant, Washington National Primate Research Center
 7. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 8. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 9. Stephen Libby, Laboratory Medicine (*Animal Containment Expert*)
 10. Scott Meschke, Environmental & Occupational Health Sciences
 11. Jennifer Nemhauser, Department of Biology (*Plant Expert*)
 12. Jason Smith, Microbiology (*IBC Chair*)
 13. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
 14. Elyse Verstelle, Department of Immunology (*Laboratory Specialist*)

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 10:02 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 September 20, 2023, meeting.
 - A member made a motion to approve the September 20, 2023, minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the September 20, 2023, meeting minutes, with one abstention and one member not voting.
4. **OLD BUSINESS:**
 - At the September 20, 2023, meeting, Dr. Chamberlain's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the September 20, 2023, meeting, Dr. Pillarisetty's BUA was approved pending successful completion of the lab inspection. This BUA has been sent out.
 - At the September 20, 2023, meeting, Dr. Skerrett's BUA was approved pending completion of the required trainings. This BUA is still pending.
 - At the September 20, 2023, meeting, Dr. Woodward's BUA was deferred for voting on pending further occupational health review of the antibiotic resistant *Klebsiella pneumoniae* strains. 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. Arnold added a new lab location to the BUA *iNPG-pDox efficacy*.
 - Dr. Zhang was approved for in vitro work human source material on the BUA *Transjugular intrahepatic portosystemic shunt (TIPS)*.
 - Dr. Turner was approved for in vitro work with non-pathogenic strains of *E. coli* and rDNA on the BUA *Source tracking of E. coli and other microbes from streams within King and Snohomish counties* (Sections III-E and III-F).
 - Dr. Simpson renewed in vitro work with human source material to the BUA *Biomarkers of exposure to chemicals in the workplace and the environment*.
 - Dr. Sweetwyne was approved for in vitro work with rDNA and human source material on the BUA *Renal progenitor cells from human urine*.
 - Dr. Vinayak was approved as the new PI on the clinical trial BUA *A Phase II Randomized Study of Safety and Efficacy of a Multiple Antigen Vaccine (STEMVAC) in Non-Squamous Non-Small-Cell Lung Cancer Patients*, originally approved at the January 19, 2022, meeting (Section III-C).
 - Dr. Lieberman added wild-type strains of bacteria and fungal agents for in vitro work to the BUA *Development of rapid POC assays for infections and whole genome sequencing of leishmania*

- Dr. Fuller added wild-type *Staphylococcus aureus* for in-vitro use to the BUA *Mouse Models for Prophylaxis and Therapy*.
- Dr. McCabe registered teaching work with cadavers to the BUA *Center for Cardiovascular Innovation*.
- Dr. Imaizumi renewed the BUA *Molecular Mechanisms in Seasonal Time Management* to continue work in transgenic plants (Section III-E).
- Dr. Ting registered additional AAV capsids for in vivo work to the BUA *Gene Therapy Vectors in NHP*.
- Dr. Chiu renewed in vitro work with human source material and rDNA to the BUA *Development of technologies for early detection and stratification of breast cancer* (Section III-F).
- Dr. Paredez added rooms to work with previously approved agents to the BUA *Study of the Cytoskeleton and Development in Giardia lamblia*.
- Dr. Wener was approved for in vitro work with rDNA and human source material on the BUA *Biomarker Resource Laboratory*.
- Dr. Levy added previously approved agents to a new lab space on the BUA *Levy Research Group: ChEEP ChEEP, EcoMiD, EcoZUR, PAASIM*.
- Dr. Neitz registered work with exempt transgenic hamsters (rodents) to the BUA *Hamsters with S cones*.
- Dr. Simpson registered field work that does not require a BUA, lab processing was previously approved on the BUA *Biomarkers of exposure to chemicals in the workplace and the environment*.
- 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 with one member not voting.

6. **BSL-3 INACTIVATION REPORT**

- Dr. Sherman requested review of 3 inactivation methods for their work with *Mycobacterium tuberculosis*. The methods are Boilate Heat Sterilization, Lysozyme and Chloroform Isoamyl Alcohol, and a modification to their Trizol™ reagent inactivation protocol.
- The subcommittee reviewed procedures and inactivation data provided by the lab and approved the request.
- 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 voted to approve this month's BSL-3 Inactivation Report.

7. **INDIVIDUAL PROJECT REVIEWS**

- a. Arnold, Samuel, renewal, *Antibacterial and cancer therapeutic studies*
 - Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Arnold lab aims to understand the preclinical activities of a novel nanodrug and the pathogenesis of *Klebsiella* and *Shigella*.

- This lab works with human cells transduced with lentiviral vectors and Shigella species in mice and in vitro. Additionally, they work with rDNA and Klebsiella pneumoniae in vitro.
 - 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. Arnold.
 - The Committee voted unanimously to approve the draft BUA for Dr. Arnold, with one member not voting.
- b. Capozzi, Megan, new, *Glucagon-insulin Hepatic Glycogen***
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Capozzi lab aims to understand how insulin and glucagon work together in the liver to regulate glycogen and how that may break down during metabolic disease.
 - This lab works with AAV in vitro and in mice.
 - The lab inspection is scheduled for after the IBC meeting.
 - 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. Capozzi.
 - The Committee voted unanimously to approve the draft BUA for Dr. Capozzi, pending successful completion of the lab inspection, with one member not voting.
- c. Fuller, Deborah, change, *Identification of T Cell Receptors, Epitopes, and Protective Responses that Occur During Coccidioidomycosis***
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Fuller lab is adding the use of avirulent or vaccine strains of Coccidioides posadasii in NHPs and work with NHP tissue experimentally infected with recombinant and wildtype Coccidioides posadasii.
 - 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. Fuller.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller with one member not voting.
- d. Iritani, Brian, renewal, *Gene Function in Lymphopoiesis and Cancer***
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Iritani lab aims to understand the roles and mechanisms of action of specific genes in the development, function, and transformation of immune cells to provide information towards better development of therapies.

- This lab works with gammaretroviral vectors, rDNA, mouse adapted strains of influenza virus, *Streptococcus pneumoniae*, and non-pathogenic strains of *E. coli* in vitro and in mice.
 - A discussion took place regarding if occupational health requirements for *Streptococcus pneumoniae* apply to animal husbandry staff.
 - The lab was inspected, and all deficiencies have been corrected.
 - 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. Iritani.
 - The Committee voted unanimously to approve the draft BUA for Dr. Iritani pending additional occupational health review.
- e. Lee, Donghoon, renewal, *MR Methods for Small Animal Imaging*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Lee lab aims to develop MRI methods to noninvasively monitor disease progression and therapy responses against AAV vector-mediated gene therapy for the mdx mouse model of Duchenne muscular dystrophy.
 - This lab works with AAV in mice.
 - A lab inspection has been performed and is still pending a response.
 - 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. Lee.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lee, pending successful completion of the lab inspection response, with one member not voting.
- f. Nemhauser, Jennifer, new, *A synthetic genetic platform to deliver higher precision care for recurrent or refractory cancers with Wnt pathway activation*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Nemhauser lab aims to engineer an improved programmable dCas9-based synthetic transcriptional repressor in human cells using naturally occurring repression domains isolated from proteins found in plants and animals.
 - This lab works with lentiviral vectors, rDNA, non-pathogenic strains of *E. coli*, and uses enhanced gene delivery methods in vitro.
 - 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. Nemhauser.
 - The Committee voted unanimously to approve the draft BUA for Dr. Nemhauser, pending successful completion of the lab inspection response with one abstention and one recusal.
- g. Woodward, Joshua, change, *Targeted bacterial eradication using designed chimeric molecules*

- Section III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Woodward lab is adding antibiotic resistant strains of *Klebsiella pneumoniae* strains and proposes genetic modifications to express fluorescent proteins and knock out genes of interest.
- A discussion took place regarding recommended practices for working safely with antibiotic resistant strains.
- 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. Woodward.
- The Committee voted unanimously to approve the draft BUA for Dr. Woodward.

8. SUBCOMMITTEE REPORTS:

- h. Chiorean, Elena, renewal, *Phase I Study of Autologous Transgenic T-Cells Expressing High Affinity Mesothelin-Specific T-Cell Receptor (TCR) (FH-TCR TMSLN) in Patients with Metastatic Pancreatic Ductal Adenocarcinoma*
- 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 renewal application for a phase I single center study of the safety and anti-tumor efficacy of autologous transgenic CD8 T cells expressing a T cell receptor targeting mesothelin for patients with metastatic pancreatic ductal adenocarcinoma that has progressed despite prior chemotherapy.
 - 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.
- i. Gauthier, Jordan, new, *An Open-label, Multicenter Phase 2 Study Evaluating the Efficacy and Safety of CRG-022, a CD22-Directed Autologous Chimeric Antigen Receptor (CAR) T-cell Therapy in Participants With Relapsed/Refractory Large B-Cell Lymphoma after CD19-Directed CAR T-cell Therapy*
- 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 new application for an industry-sponsored, multi-center, phase 2 study of an autologous CAR T cell therapy targeting CD22 for patients with relapsed/refractory B cell lymphoma who have failed prior CD19-directed CAR T cell therapy.
 - Human cells transduced with third generation 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. Gauthier. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gauthier.
- j. Kruse-Jarres, Rebecca, new, *A Phase 3, single -arm, open -label, multicenter study of the safety and efficacy of dirloctocogene samoparvovec {SPK- 8011, adeno- associated viral vector with B- dom ain deleted human factor VIII gene} in adults with severe or moderately severe hemophilia A (KEYSTONE 1)*
- 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 a gene therapy trial using IV injection of a recombinant AAV encoding a modified form of the blood clotting protein, factor VIII, for patients with hemophilia A.
 - An AAV study vector 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. Kruse-Jarres. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kruse-Jarres.
- k. Sherman, David, new, *Orientia tsutsugamushi*
- Section III-F
 - Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Sherman lab aims to characterize and study the growth requirements of *O. tsutsugamushi* and the response of *O. tsutsugamushi* exposure to antibiotics.
 - This lab works with rDNA and scrub typhus in vitro.
 - The BSL-3 facility is inspected on a routine basis and not in association with BUAs/projects.
 - All required trainings are complete.
 - A medical management plan is in review for *Orientia tsutsugamushi*.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Sherman. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sherman, pending completion of the medical management plan.

10. FOR YOUR INFORMATION: Biosafety Month presentation was shown.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11.29 A.M.