



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Tuesday, June 18, 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. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 4. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 5. Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
 6. Richard Grant, Washington National Primate Research Center
 7. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 8. David Koelle, Allergy and Infectious Diseases
 9. Susan Parazzoli (*Community Member*)
 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 10:00 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. **IBC TRAINING PRESENTATION:** Dr. Zach Adelman from Texas A&M University gave a presentation about gene drive research including risk assessment and biocontainment for gene drive modified organisms. This topic was chosen based on the April 2024 revision to the NIH Guidelines to include IBC oversight for research involving gene drive modified organisms.
4. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the May 15, 2024 meeting.
 - A member made a motion to approve the May 15, 2024 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the May 15, 2024 meeting minutes.
5. **OLD BUSINESS:**
 - At the May 15, 2024 meeting, Dr. Baker's BUA was approved pending successful completion of the lab inspection response. This BUA has been sent.
 - At the May 15, 2024 meeting, Dr. Crudele's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
 - At the May 15, 2024 meeting, Dr. Lee's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the May 15, 2024 meeting, Dr. Singh's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
 - At the May 15, 2024 meeting, Dr. Woodward's BUA was approved pending a BUA application edit. This BUA has been sent.
6. **BIOSAFETY OFFICER (BSO) REPORT:** The Biosafety Officer Report includes projects involving: (1) recombinant or synthetic nucleic acids covered under Sections 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. Serio started new in vitro work with rDNA and exempt yeast and E. coli to the new BUA *Cellular Mechanisms and Consequences of Protein Misfolding and Resolution*. (Section III-F)
 - Dr. Eichler renewed in vitro work with human and NHP source material and rDNA on the BUA *Structural Variation, Disease, and Evolution*. (Section III-F)
 - Dr. Rieke renewed work with human and NHP source material on the BUA *Biophysical Mechanisms of Photo Detection*.
 - Dr. Robinson added new core facility locations for use with previously approved agents to the *Regeneration of the knee meniscus* BUA.
 - Dr. Valdmanis added a room for in vitro work with previously approved agents to the BUA *Mitigating host responses for effective gene therapy*.
 - Dr. Wang renewed work with wildtype Risk Group 2 bacteria both in vitro and in pigs to the *Ultrasound treatment of Abscesses* BUA.

- Dr. Morrissey added new lab strains of E. coli and new gene inserts for previously approved viral vectors on the *SLFN11 May be the Key to Identifying New Combination Treatments to Treat CRPC* BUA. (Section III-F)
- Dr. Sellers added new core facility locations for use with previously approved agents to the *Stem Cells and Regeneration of the Spinal Cord* BUA.
- Dr. Dale renewed work with rDNA and human source material on the *Severe Chronic neutropenia International Registry* BUA. (Section III-F)
- Dr. Liu removed in vivo work with human cells transfected with rDNA in mice from the *DNA and RNA aptamer development* BUA.
- Dr. Kim started new in vitro work with rDNA and non-pathogenic E. coli to the new BUA *Cytochromes of Nitrification for CryoEM*. (Sections III-E and III-F)
- Dr. Fuhrmeister added new wildtype Risk Group 2 bacteria and a new lab room to the *Environmental Reservoirs of Enteric Pathogens and Antimicrobial Resistance* BUA.
- Dr. Gao added rooms for in vitro work with previously approved agents to the BUA *Systemic Delivery of siRNA Drugs and Nanoparticle-based Tumor Detection*.
- Dr. Hawn removed two lab rooms from the *Innate Immunity and Susceptibility to Infectious Disease* 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.
- The Committee unanimously voted to approve this month's Biosafety Officer Report.

7. INDIVIDUAL PROJECT REVIEWS

- a. Alaei, Sarah, renewal, UWT Oral Microbiology Lab
 - Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Alaei lab aims to better understand how bacteria export proteins and other substances into the environment and how those shape the multicellular communities formed by oral bacteria responsible for periodontal disease.
 - This lab works recombinant Porphyromonas gingivalis, wildtype Fusobacterium nucleatum and Streptococcus gordonii, lab strains of E. coli, and rDNA.
 - 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. Alaei.
 - The Committee voted unanimously to approve the draft BUA for Dr. Alaei.

- b. Beliveau, Brian, change, *Probing the dynamics of chromosome organization in single cells*
 - Sections III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Beliveau lab is adding third generation lentiviral vectors for in vitro.
 - A lab inspection was not required as the lab was recently inspected.
 - 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. Beliveau.

- The Committee voted unanimously to approve the draft BUA for Dr. Beliveau.
- c. Crisa, Laura, renewal, *Immunobiology of bone marrow-derived endothelia and inflammatory cells in tissue repair*
- Section III-D, III-E, III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Crisa lab aims to investigate the cellular and molecular mechanisms by which vascular endothelial cells influence immune responses using in vivo and in vitro models of transplantation and angiogenesis as well as developmental models of stem cell-derived pancreatic progenitors.
 - The Crisa lab works with third generation lentiviral vectors with and without oncogenic inserts, AAV with oncogenic inserts, feline immunodeficiency virus (FIV) vectors, human cells, and rDNA. Murine cells transduced with lentiviral vectors are administered to mice.
 - A discussion took place discussing the appropriate biosafety level for the FIV vector.
 - 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. Crisa.
 - The Committee voted unanimously to approve the draft BUA for Dr. Crisa, pending changing the biosafety level of FIV to BSL-2 and successful completion of the inspection.
- d. Fuller, Deborah, renewal, *Emerging infectious diseases and SIV co-infections*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Fuller lab studies the immunological, virological, microbial, and pathological outcomes of infectious diseases to better understand the mechanisms of pathogenesis, which will improve their ability to develop vaccines and therapies.
 - This lab works with primate lentivirus at BSL-2 with BSL-3 practices and Zika virus, the TC-83 strain of Venezuelan equine encephalitis virus (exempt from select agent regulations), and NHP source material at BSL-2.
 - A lab inspection was not required as the lab was recently inspected.
 - 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. Fuller.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- e. Liu, Yusha, new, *Peripheral Nerve Injury*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Liu lab's research focuses on methods to improve peripheral nerve regeneration including whether it is possible to accelerate nerve regeneration. They will also explore how to prevent degeneration of motor endplates in the muscle which.
 - This lab works with AAV vectors (adenovirus free) in vitro and in mice at BSL-1 and with human cells transduced with Sendai viral vectors with oncogenic inserts and human cell lines at BSL-2.

- 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. Liu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Liu, pending successful completion of the lab inspection and review of the IACUC protocol.
- f. Lood, Christian, change, *Neutrophil contribution to inflammation and autoimmunity in rheumatic diseases*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Lood lab is adding third generation lentiviral vectors and lab strains of E.coli for in vitro work.
 - A lab inspection was not required as the lab was recently inspected.
 - 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. Lood.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lood.
- g. Marchiano, Silvia, new, *Pharmacology of cell-based therapy*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Marchiano lab will investigate the efficacy and safety of using human stem cell-derived cardiomyocytes (hPSC-CMs) to treat heart disease including heart rhythm disturbances arising after heart attacks.
 - The lab will transfect human cells with rDNA and administer to rabbits at ABSL-2
 - 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. Marchiano.
 - The Committee voted unanimously to approve the draft BUA for Dr. Marchiano, pending successful completion of the lab inspection.
- h. Murphy, Sean, renewal, *NHP Study*
- Sections III-D and III-E
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Murphy lab aims to develop NHP models for evaluating malaria infections and testing promising vaccination strategies in NHPs.
 - This lab works with several Risk Group 2 species of Plasmodium in vitro at BSL-2, in NHPs at ABSL-2, and in Anopheles mosquitoes at ACL-2. They also administer adenoviral vectors and rDNA to NHPs at ABSL-2 and use human and NHP source material at BSL-2.
 - 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. Murphy.
 - The Committee voted unanimously to approve the draft BUA for Dr. Murphy.
- i. Raskind, Wendy, renewal, *Genetic Contributions to Dyslexia Animal Models of Human Disease Genetics of Human Diseases*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Raskind lab studies inherited human diseases to identify genes that cause or contribute to them and the effects of mutations on the function of the genes using in vitro and in vivo studies.
 - The lab works with third generation lentiviral vectors and Sendai viral vectors with oncogenic inserts, human cells, and wildtype Epstein-Barr virus at BSL-2. They also use rDNA, lab strains of E. coli, and third generation lentiviral vectors without oncogenic inserts.
 - The lab inspection is scheduled for after the IBC meeting.
 - 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. Raskind.
 - The Committee voted unanimously to approve the draft BUA for Dr. Raskind, pending successful completion of the lab inspection.
- j. Scott, John, change, *AKAP structure and Function*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Scott lab is adding human cells transduced with third generation lentiviral vectors 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. Scott.
 - The Committee voted unanimously to approve the draft BUA for Dr. Scott.
- k. Swalla, Billie, change, *Activation of Developmental Gene Networks in Invertebrate Embryos*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Swalla lab is adding the creation and use of 14 transgenic marine invertebrate species at BSL-1, including sea squirts, anemones, urchins, and stars and jellyfish.
 - The lab has applied for permits from Washington Department of Fish and Game that are required for importation and maintenance of certain non-native species.
 - 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. Swalla.
 - The Committee voted unanimously to approve the draft BUA for Dr. Swalla.

8. SUBCOMMITTEE REPORTS:

- I. Greninger, Alex, change, *Isolation, propagation, and characterization of clinically relevant human viral pathogens*
- NIH Guidelines not applicable
 - Information about the current H5 avian influenza exemption from CDC and USDA select agent regulations was presented. H5 strains of avian influenza have been exempted from select agent regulations for the next three years.
 - Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The Greninger lab is adding cell culture and sequencing work with highly pathogenic avian influenza virus (HPAI) and low pathogenic avian influenza virus (LPAI). Human and/or animal clinical specimens may be received, and virus stocks will be obtained from collaborators and other sources.
 - The medical management plan for HPAI is in review.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Greninger. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Greninger, pending updates to the medical management plan.
- m. Zhen, David, new, *EVEREST-2: A Seamless Phase 1/2 Study to Evaluate the Safety and Efficacy of A2B694, an Autologous Logic-gated Tmod™ CAR T, in Heterozygous HLA-A*02 Adults with Recurrent Unresectable, Locally Advanced, or Metastatic Solid Tumors That Express MSLN and Have Lost HLA-A*02 Expression*
- 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 phase 1/2, industry-sponsored, multi-site trial to evaluate the safety and tolerability of an autologous CAR-T cell product for solid tumors expressing mesothelin but have lost HLA-A*02 expression.
 - Human cells transduced with third generation lentiviral vectors are administered to human subjects.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Zhen. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Zhen.

10. FOR YOUR INFORMATION:

- **NIH Incident Response:**
 - The NIH has responded that no further information or action was required for a recent reportable rDNA incident involving a scratch from an NHP that had previously been exposed to recombinant simian-human immunodeficiency virus (SHIV).

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:45 a.m.