



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, September 20, 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. Susan Parazzoli (*Community Member*)
 11. Jason Smith, Microbiology (*IBC Chair*)
 12. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
 13. 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 10:01 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 August 16, 2023, meeting.
 - A member made a motion to approve the August 16, 2023, minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the August 16, 2023, meeting minutes, with two members not voting.
4. **OLD BUSINESS:**
 - At the August 16, 2023, meeting, Dr. Fuller's BUA was approved pending clarification of adjuvant containment and updated language on the BUA letter. This BUA is still pending.
 - At the August 16, 2023, meeting, Dr. Keel's BUA was approved pending successful completion of the lab inspection. This BUA has been sent out.
 - At the August 16, 2023, meeting, Dr. Kennedy's BUA was approved pending successful completion of the lab inspection response. This BUA has been sent out.
 - At the August 16, 2023, meeting, Dr. Servetnick'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. Fu renewed in vitro work with non-viral rDNA, and non-pathogenic strains of *E. coli* to the BUA *Mechanoregulatory mechanisms of von Willebrand disease and thrombosis* (Sections III-E and III-F).
 - Dr. Perkel was approved to take over Dr. Brenowitz's BUA *Comparative Studies of Vocal Control*. This work was previously approved for use of AAV, foamy viral vectors and lentiviral vectors in white-crowned sparrows (Section III-D).
 - Dr. Scott added core facilities for use with previously approved agents to the BUA *AKAP structure and Function*.
 - Dr. Erasmus added the use of a Japanese encephalitis virus vaccine strain (SA14-14-2) in mice to the BUA *RNA vaccines*.
 - Dr. Lockwood renewed in vitro work with rDNA and human source material to the BUA *Northwest Clinical Genomics Laboratory* (Section III-F).
 - Dr. Cirrincione was approved for in vitro work with human source material on the BUA *Effect of gender-affirming estrogen therapy on drug metabolism, transport, and gut microbiota*.
 - Dr. McLean added new rooms to work with previously approved agents and human cells to the BUA *Domestication and characterization of TM7*.
 - Dr. Papayannopoulou added new rooms to work with previously approved agents to the BUA *Gene therapy for hemoglobinopathies: bone marrow conditioning*.

- Dr. Robinson was approved for in vitro work with rDNA and human source material on the BUA *Regeneration of the knee meniscus* (Section III-F).
- Dr. Vaughan renewed in vitro work with rDNA, non-pathogenic E. coli, and human and NHP source material on the BUA *Development and Application of Imaging Tools for Super-resolution Fluorescence Microscopy* (Section III-F).
- Dr. Hotchkiss renewed the primate center core facility BUA for work with NHPs and NHP source material on the BUA *Operation of WaNPRC Animal Housing and Support Facilities* (Section III-D).
- Dr. Hamazaki was approved for in vitro work rDNA, human and NHP source material, and non-pathogenic strains of E. coli on the BUA *Hamazaki: General Research* (Sections III-E and III-F).
- Dr. Yang was approved for in vitro work rDNA, human and NHP source material, and non-pathogenic strains of E. coli on the BUA *Yang Lab General Research* (Sections III-E and III-F).
- Dr. Woodward added in vitro with wildtype *Klebsiella pneumoniae* to the BUA *Targeted bacterial eradication using designed chimeric molecules*.
- Dr. Sakiyama-Elbert registered work adding additional transgenic mouse lines to the BUA *Developing New Tools to Understand the Role of Interneurons in Rewiring After SCI*.
- Dr. Fuller was approved for work with influenza A and B and non-viral rDNA in mice. on the BUA *Design and Optimization of a Clinical Gene Gun* (Section III-D). This work was previously approved at the February 2023 IBC meeting on the BUA *Mouse Models for Prophylaxis and Therapy*.
- Dr. DeForest added previously approved agents in the Foege Flow Facility and Pathology Flow Cytometry Core Facility to the BUA *Protein Engineering in E. coli*.
- Dr. Yazdan-Shahmorad registered work adding new gene inserts for AAV to the BUA *Understanding the underlying mechanisms of neural stimulation*.
- 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. DURC REPORT

- One project received approval for continued use of Avian influenza virus. The work does not meet the DURC definition.
- The IBC Chair sought a motion to approve this month's DURC Report.
- A member made a motion to approve this month's DURC Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's DURC Report, with one member not voting.

7. INDIVIDUAL PROJECT REVIEWS

- a. Abuzeid, Al Waleed, renewal, *Disruption of Pseudomonas aeruginosa biofilms in a rabbit sinusitis model using a nitric-oxide releasing nanoparticle*
 - Section III-D

- The assigned IBC Primary Reviewer presented the Primary Review.
 - The Abuzeid lab aims to study bacterial evolution and functional characteristics critical to growth in the sinus environment, the effects of infection on inflammation in the sinus, and to determine the effectiveness of a nanoparticle-based treatment on the treatment of sinusitis.
 - This lab works with *Pseudomonas aeruginosa* in vitro and in rabbits.
 - 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. Abuzeid.
 - The Committee voted unanimously to approve the draft BUA for Dr. Abuzeid, with one member not voting.
- b. Buckner, Fred, change, *Buckner antiparasitic and antibacterial drug discovery***
- Sections III-D, III-E and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Buckner lab is adding the use of recombinant and wildtype *Mycobacterium smegmatis* and *Entamoeba histolytica*.
 - 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. Buckner.
 - The Committee voted unanimously to approve the draft BUA for Dr. Buckner, with one member not voting.
- c. Chamberlain, Jeffrey, renewal, *Gene therapy for muscular dystrophy***
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Chamberlain lab aims to develop a treatment for muscular dystrophy.
 - This lab works with non-viral rDNA and human source material in vitro. They also work with AAV in vivo and in vitro.
 - 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. Chamberlain.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chamberlain, pending successful completion of the lab inspection, with one member not voting.
- d. Fuller, Deborah, renewal, *Prophylactic SHIV Vaccines in NHP***
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Fuller lab aims to investigate the effects of a vaccine in a SHIV NHP challenge model to understand the mechanisms influencing its ability to succeed or fail in protection.
 - This lab works with primate lentivirus in NHPs and in vitro.

- A lab inspection was not required as the lab was recently inspected.
 - All required trainings are complete.
 - The IACUC protocol is 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 two members not voting.
- e. Fuller, Deborah, renewal, *Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP (IACUC 4266-09)*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Fuller lab aims to optimize a novel adjuvant for a HIV DNA vaccine.
 - This lab works with primate lentivirus in NHPs and in vitro. Additionally, they work with non-viral rDNA and NHP source material in vitro.
 - A lab inspection was not required as the lab was recently inspected.
 - 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. Fuller.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller, with two members not voting.
- f. Fuller, Deborah, change, *Nucleic Acid Mediated Protein Expression*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Fuller lab is adding recombinant Plasmodium berghei and wildtype Plasmodium knowles in NHPs.
 - 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 two members not voting.
- g. Mack, David, renewal, *GeneTherapy in Canine Myotubular Myopathy phase 2 Canine XLMTM and CXMD Colony*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Mack lab aims to develop and test viral vector mediated gene therapy approaches to treat neuromuscular diseases in canine models.
 - This lab works with AAV in vivo and in dogs.
 - 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. Mack.

- The Committee voted unanimously to approve the draft BUA for Dr. Mack, with two members not voting.
- h. Pepper, Marion, renewal, *The Differentiation and Function of Memory T and B cells*
- Sections III-D, III-E, and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Pepper lab aims to understand how cells of the adaptive immune system develop to either prevent disease or cause allergic responses.
 - This lab works with *Listeria monocytogenes*, influenza virus, and several *Plasmodium* species both in vitro and in mice. They also use lentiviral vectors, non-viral rDNA, and non-pathogenic strains of *E. coli* in vitro.
 - A lab inspection has been performed and is still pending a response.
 - All required trainings are complete.
 - There are occupational health requirements for work with influenza virus, diphtheria toxin, and fixed/inactivated SARS-CoV-2 samples.
 - 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. Pepper.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pepper, with two members not voting.
- i. Pillarisetty, Venu, renewal, *Testing immunotherapy for solid tumors in slice cultures*
- Sections III-D and III-F
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Pillarisetty lab aims to study human pancreatic tumors, liver tumors, and other solid tumors to identify new targeted immunotherapy therapies and to test and predict patient response to therapy.
 - This lab works with lentiviral vectors, non-viral rDNA, and human source material in vitro.
 - 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. Pillarisetty.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pillarisetty, pending successful completion of the lab inspection, with two members not voting.
- j. Skerrett, Shawn, renewal, *Host Defense Against Bacterial Pneumonia*
- Section III-D
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Skerrett lab aims to understand essential mechanisms of resistance against bacterial infections of the lungs and to identify new ways to treat respiratory tract infections.
 - This lab works with several RG2 respiratory pathogens in vitro and in mice, including *Legionella pneumophila*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*.
 - The lab was inspected, and all deficiencies have been corrected.
 - The required trainings are still pending.

- There are occupational health requirements for work with *Streptococcus pneumoniae*.
 - 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. Skerrett.
 - The Committee voted unanimously to approve the draft BUA for Dr. Skerrett, pending completion of the required trainings, with two members not voting.
- k. 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 proposing genetic modifications to antibiotic resistant clinical strains of *Klebsiella pneumoniae* to be used both in vitro and in mice.
 - A discussion took place regarding antibiotic resistant *Klebsiella pneumoniae* strains and the need for occupational health review. The Campus Health Physician and Employee Health Center will review the strains and their specific antibiotic susceptibilities and resistances to ensure treatments are available.
 - 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 committee deferred the vote for occupational health review of the antibiotic resistant *Klebsiella pneumoniae* strains.

8. SUBCOMMITTEE REPORTS:

- I. Babu, Tara, new, *A randomized, partially observer-blind, dose-escalation, Phase I/II trial evaluating the safety and immunogenicity of investigational RNA-based mpox vaccine candidates*
- 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, industry-sponsored clinical trial, phase 1/2 to evaluate BNT166a and BNT166c mRNA multivalent vaccines for safety and immunogenicity against monkeypox virus.
 - Recombinant nucleic acid vaccines will be 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. Babu. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Babu, with two members not voting.
- m. Chiorean, Gabriela, new, *Phase I study of autologous CD8+ and CD4+ Transgenic T cells expressing high affinity KRASG12V mutation-specific T cell receptors in participants with metastatic pancreatic, colorectal and non-small cell lung cancers with KRAS G12V mutations*
- 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 company sponsored, phase 1, clinical trial to evaluate the safety of FH-A11KRASG12V-TCR for HLA-A11+ patients with metastatic pancreatic, colorectal, and non-small cell lung cancers carrying a KRAS G12V mutation.
 - Human cells transduced with third generation lentiviral vectors will be administered to human subjects.
 - 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. Chiorean. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chiorean, with one member not voting.
- n. *Disis, Mary, renewal, A Multicenter Phase II Study of Vaccines to Prevent Recurrence in Patients with HER-2 Positive Breast Cancer*
- 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, multicenter, phase 2 clinical trial for HER2+ breast cancer patients with residual disease after neoadjuvant chemotherapy.
 - rDNA vaccines will be 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. Disis. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis, with one member not voting.
- o. *Gale, Michael, renewal, Host Response to BSL3 Pathogens*
- Sections III-D, III-E, and III-F
 - The Gale lab aims to understand how viral and host factors impact innate immune defenses, to develop antiviral therapeutics and vaccines, and to provide quality control virus stocks to support objectives.
 - This lab works with several RG3 pathogens both in vitro and in mice, including highly pathogenic avian influenza virus, Hantavirus, monkeypox virus, Powassan virus, SARS-CoV, SARS-CoV-2, and yellow fever virus.
 - The BSL-3 facility is inspected quarterly and not in association with BUAs.
 - All required trainings are complete.
 - Federal select agent approval is in place for work with select agents.
 - A medical management plan is in place for Yellow Fever virus, Chikungunya virus, Powassan virus, Venezuelan Equine Encephalitis virus, Japanese Encephalitis virus, SARS-CoV, SARS-CoV-2, and monkeypox. An enhanced medical management plan is in place for highly pathogenic avian influenza virus.
 - This project has an IACUC protocol in review.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Gale. Another member seconded the motion.

- The Committee voted unanimously to approve the draft BUA for Dr. Gale, with one recusal and one member not voting.
- p. Johnston, Christine, new, *A Phase 1/2, Randomized, Observer-Blind, Controlled, Dose-Ranging Study of mRNA-1608, an HSV-2 Therapeutic Candidate Vaccine, in Healthy Adults 18 to 55 Years of Age with Recurrent HSV-2 Genital Herpes*
- 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, industry-sponsored phase 1/2, randomized, dose ranging trial of an mRNA-based therapeutic vaccine for the treatment of HSV-2 genital ulcers.
 - Recombinant nucleic acid vaccines will be 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. Johnston. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Johnston, with one member not voting.
- q. Stacey, Andrew, new, *A Phase 3 Randomized, Masked, Controlled Trial to Evaluate Efficacy and Safety of Belzupacap Sarotalocan (AU-011) Treatment Compared to Sham Control in Subjects with Primary Indeterminate Lesions or Small Choroidal Melanoma*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a new, industry-sponsored, Phase 3, multi-site, randomized trial of a human papillomavirus (HPV)-based virus-like particle (VLP) conjugated to a drug called sarotalocan for the treatment of choroidal melanoma, a vision- and life-threatening form of eye cancer.
 - Although this project does not involve administration of rDNA to human subjects, the use of virus like particles in humans warranted IBC review.
 - 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. Stacey. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stacey, with one member not voting.

10. FOR YOUR INFORMATION:

- **NIH Incident Report:**
 - An animal technician experienced a splash to the eye when removing goggles that were worn while cleaning a room housing NHPs. There were NHPs present in the rooms that had previously been exposed to either recombinant simian-human immunodeficiency virus (SHIV) or recombinant vaccinia virus. The animal technician washed their eyes at an emergency eyewash for 15 minutes and then reported to the emergency department for treatment. They have consulted with the UW Employee Health Center (EHC) for follow-up care.
 - A veterinary technician experienced a scratch to the hand while distributing medication from a NHP that had been previously exposed to recombinant

simian-human immunodeficiency virus (SHIV). The veterinary technician washed with a herpes B scrub kit and then reported to the emergency department for treatment. They have consulted with the UW EHC for follow-up care.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:55 A.M.