INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, May 21, 2025
Time: 10:00 a.m. – 12:00 p.m.

Location: Zoom

Members Present:

1. Jason Cantera *(Community Member)*
2. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
3. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
4. Erin Heiniger, Department of Bioengineering *(Laboratory Specialist*)
5. Richard Grant, Washington National Primate Research Center
6. Kevin Hybiske, Allergy and Infectious Diseases *(IBC Vice Chair)*
7. Jennifer Iwamoto, Office of Animal Welfare *(Animal Containment Expert)*
8. Stephen Libby, Laboratory Medicine *(Animal Containment Expert)*
9. Susan Parazzoli *(Community Member)*
10. Jason Smith, Microbiology (*IBC Chair*)
11. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)
12. Ana Weil, Allergy and Infectious Diseases

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
iPSCs: 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 April 16, 2025, meeting.
   - A member made a motion to approve the April 16, 2025, meeting minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the April 16, 2025, meeting minutes, with one abstention.

4. **OLD BUSINESS:**
   - At the April 16, 2025 meeting, Dr. Chavkin's BUA was approved pending successful completion of the lab inspection and submission and review of the IACUC protocol. This BUA is still pending.
   - At the April 16, 2025 meeting, Dr. Fuller's BUA was approved pending successful completion of the lab inspection and submission and review of the IACUC protocol. This BUA is still pending.
   - At the April 16, 2025 meeting, Dr. Giachelli's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the April 16, 2025 meeting, Dr. Jain's BUA was approved pending submission and review of the IACUC protocol. This BUA is still pending.
   - At the April 16, 2025 meeting, Dr. Kwon's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the April 16, 2025 meeting, Dr. Moreno's BUA was approved pending submission and review of the IACUC protocol. This BUA is still pending.
   - At the April 16, 2025 meeting, Dr. Odom's BUA was approved pending successful completion of the lab inspection and submission and review of the IACUC protocol. This BUA is still pending.
   - At the April 16, 2025 meeting, Dr. West's BUA was approved pending submission and review of the IACUC protocol. 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 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. Wei added a new room for work with previously approved agents on the BUA *Northwest Genomics Center*.
      - Dr. Posner renewed work with Chlamydia trachomatis, Hepatitis B virus, Hepatitis C virus, Human immunodeficiency virus 1, human source material, and rDNA on the BUA Point of Care Molecular Tests for Infectious Diseases. (III-F)
      - Dr. Kong added work with hiPSCs on the BUA *Signaling pathways in the context of development, disease, and regeneration*.

- Dr. Shi added work with human source materials in mice on the BUA *The Shi Laboratory Animal Use and Other Research.*
- Dr. Pirlamarla took over work previously overseen by Dr. Pamboukian on the BUA *A phase 2, adaptive, double-blinded, placebo controlled, randomized, multi-center trial to evaluate the efficacy, safety and tolerability of intracoronary infusion of AB-1002 in adult subjects with New York Heart Association (NYHA) Class III heart failure and non-ischemic cardiomyopathy.*
- Dr. Averkiou renewed work with human source material in vitro and in mice on the BUA *A novel paradigm of sensitization of the tumor microenvironment with image-guided ultrasound cavitation and mechanotherapeutics for targeted HCC treatment.*
- Dr. McClelland added a new clinical space for study product infusion on the BUA *A randomized, double-blind, placebo-controlled Phase 1 trial to evaluate the safety, tolerability, immunogenicity, and efficacy of Sanaria PfSPZ-LARC2 Vaccine, a late-arresting, replication-competent, genetically attenuated Plasmodium falciparum vaccine by controlled human malaria infection in malaria-naive healthy adults (DMID 23-0010).*
- Dr. McLean added a new room to work with previously approved agents on the BUA *Domestication and characterization of TM7.*
- Dr. O'Connor new rooms to work with previously approved agents on the BUA *Emerging infectious diseases and SIV co-infections.*
- Dr. Hamazaki new rooms to work with previously approved agents on the BUA *Hamazaki: General Research.*
- Dr. Eisenberg renewed work with NHP and human source material and rDNA in vitro on the BUA *Eisenberg's Anthropological Genetics Lab.* (Section III-F)
- Dr. Patton renewed work with Chlamydia trachomatis in macaques on the BUA *Sexually Transmitted Disease Prevention - Primate Unit.*
- Dr. Wang renewed work with E. coli, human source material, rDNA, and rDNA with enhanced gene delivery methods on the BUA *Transporters in Drug Disposition, Targeting and Drug-Drug Interactions.* (Section III-E and III-F)
- Dr. Freedman removed the use of BSL-3 containment for SARS-CoV-2 on the BUA *Differentiation of Human Pluripotent Stem Cells into Kidney Cells.*
- Dr. Fuller removed the use of BSL-3 containment for in vitro work with SARS-CoV-2 on the BUA *Mouse Models for Prophylaxis and Therapy.*
- Dr. Reed added a room for work with previously approved agents on the BUA *Extracellular Matrix in Aging.*
- Dr. Bermingham-McDonogh registered work with transgenic mice on the BUA *Sensory cell development and regeneration in the inner ear.*
- Dr. Bammler renewed work with human source material and rDNA on the BUA *Generating data for large-scale molecular epidemiology studies using genotyping capabilities, gene expression profiling, and immunoassays using magnetic beads.* (Section III-F)
- Dr. Havranek took over work previously overseen by Dr. Cammarata on the BUA *Arzeda strain and DNA design cell sorting.*
- Dr. Fu renewed work with E. coli, human source material, and rDNA on the BUA *Multimodal optical microscopy.* (Section III-F)
- Dr. Schweppe added work with new human cell lines and moved work with previously approved agents to a new room on the BUA *Chemical perturbation of bacterial and human cells.*

- Dr. Seelig added a core facility for work with previously approved agents on the BUA *Seelig lab for synthetic biology.*
- 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.

6. BSL-3 INACTIVATION REPORT

- Dr. Sherman requested approval for inactivating *Mycobacterium tuberculosis* samples using 100% methanol with a contact time of 24 hours.
- Dr. West requested approval for inactivating *Burkholderia pseudomallei* infected plasma using filtration.
- The subcommittee reviewed the procedures and inactivation data provided by the lab and approved their requests.
- The IBC Chair made a motion to approve this month's BSL-3 Inactivation Report.
- The committee voted to approve this month's BSL-3 Inactivation Report.

7. BIOSAFETY MANUAL UPDATES

- A biosafety officer presented updates to the EH&S Biosafety Manual. The updated information covers hazards associated with the use of biohazardous agents and rDNA molecules, regulatory and permitting changes, inspections, shipping biohazards, and new safety guidance, among other changes.
- The IBC Chair made a motion to approve updates to the EH&S Biosafety Manual.
- The committee voted to approve updates to the EH&S Biosafety Manual.

8. ONCOGENE DATABASE UPDATES

- The Biosafety Manager presented updates to BUA applications regarding the oncogene database. The previously used database now requires accounts for access. The biosafety manager shared an introduction to alternative oncogene review websites. OncoKB will be used as the primary resource and Oncovar will be utilized as a secondary resource.

9. INDIVIDUAL PROJECT REVIEWS

a. Buckner, Frederick, renewal, *Buckner antiparasitic and antibacterial drug discovery*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Buckner lab researches drug discovery for diseases caused by pathogenic protozoan parasites and various RG2 bacteria.
- The lab works with recombinant Staphylococcus aureus, recombinant Trypanosoma cruzi, and wildtype Streptococcus pyogenes in mice at BSL-2, recombinant Entamoeba histolytica, Leishmania mexicana, Mycobacterium smegmatis, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes, Trypanosoma cruzi, various wildtype RG2 organisms, and human source material in vitro at BSL-2, and rDNA and non-pathogenic E. coli at BSL-1.
- A lab inspection was not required as the lab was recently inspected.
- All required trainings are complete.

- There are occupational health requirements for work with Streptococcus pneumoniae and a medical management plan in place for work with Plasmodium falciparum.
- 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. Buckner.
- The Committee voted unanimously to approve the draft BUA for Dr. Buckner.

b. Buffalo, Elizabeth, renewal, *Neurobiology of Memory*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Buffalo lab researches neural mechanisms that support learning and memory
- The lab works with AAV and lentiviral vectors in NHPs at BSL-2.
- 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. Buffalo.
- The Committee voted unanimously to approve the draft BUA for Dr. Buffalo.

c. Chamberlain, Jeff, renewal, *Gene Therapy for Neuromuscular Disorders*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Chamberlain lab develops treatments for muscular dystrophies, involving delivery of therapeutic genes to the muscles.
- The lab works with human source material in vitro at BSL-2, AAV, lentiviral vectors, and rDNA in vitro and in mice and E. coli at BSL-1.
- 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. Chamberlain.
- The Committee voted unanimously to approve the draft BUA for Dr. Chamberlain.

d. Daggett, Valerie, renewal, *Peptide-Based Diagnostics and Inhibitors for Amyloid Diseases*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Daggett lab develops novel peptide-based amyloid inhibitors that bind toxic oligomers during amyloidogenesis to neutralize toxicity in human and mammalian cell lines.
- The lab works with recombinant strains of pathogenic E. coli, Pseudomonas aeruginosa, Staphylococcus aureus (non-MRSA), and human source material in vitro at BSL-2 and with non-pathogenic E. coli and rDNA at BSL-1.
- 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. Daggett.

- The Committee voted unanimously to approve the draft BUA for Dr. Daggett, pending successful completion of lab inspection.

e. Fuller, Deborah, renewal, *Umoja NHP Study*
- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Fuller lab tests CAR platform technology designed to engineer T cells within the body of a patient in a macaque model.
- The lab works with lentiviral vectors with oncogenic inserts in NHPs at BSL-2.
- A lab inspection was not required as all work takes place inside a vivarium.
- 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 pending IACUC.

f. Golden, Sam, renewal, *Functional connectomics of maladaptive social motivation and neuropsychiatric disease*
- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Golden lab studies cell-type and circuit-specific mechanisms that underlie maladaptive social motivations and their interaction with neuropsychiatric disorders such as addiction and depression.
- The lab works with AAV in vitro and in mice at BSL-1.
- 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. Golden.
- The Committee voted unanimously to approve the draft BUA for Dr. Golden, pending successful completion of the lab inspection.

g. Gu, Liangcai, new, *Analgesic Spatial Transcriptomics*
- NIH Guidelines Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Gu lab researches space and time dynamics of tissue changes in response to aging, disease, and other physiological conditions.
- The laboratory conducts in vitro work with human-derived materials at BSL-2, utilizes AAV in mice and in vitro, and handles rDNA exclusively 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. Gu.
- The Committee voted unanimously to approve the draft BUA for Dr. Gu.

h. Guo, Monica, change, *Chromosome organization in microbes*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Guo lab is adding work with laboratory strains of Listeria monocytogenes, Salmonella Typhimurium, and Shigella flexneri, and clinical E. coli strains in vitro at BSL-2. Knockouts and protein structure plasmids to be introduced to the organisms.
- A discussion occurred regarding the antibiotic resistance markers used with the Risk Group 2 bacteria. The Campus Health Physician and MD IBC member will review the markers to confirm that no frontline treatment resistance is being conferred.
- 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. Guo.
- The Committee voted unanimously to approve the draft BUA for Dr. Guo, pending review of antibiotic resistance markers.

i. Heath, James, renewal, *Identifying effective combination therapy for metastatic cancers*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Heath lab researches effective combination therapies for metastatic cancers through tumor transplantation of human and murine cell lines into mice.
- The lab works with human source material in mice at BSL-2 and mouse cells transfected with DNA in mice at BSL-1.
- 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. Heath.
- The Committee voted unanimously to approve the draft BUA for Dr. Heath.

j. Ho, Rodney, new, *Targeting Drug to HIV Sanctuary in Lymphatics*

- NIH Guidelines Sections III-D and III-E
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Ho lab aims to develop a drug delivery platform that can target drugs to potential latent lentivirus reservoirs in the lymphatic system and peripheral blood mononuclear cells.
- The lab works with Simian-Human Immunodeficiency Virus in NHPs and in vitro and with HIV-1 in vitro at BSL-2w/3 practices. They also work with NHP and human source material in vitro at BSL-2, and rDNA with enhanced gene delivery methods in vitro at BSL-1.
- 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. Ho.
- The Committee voted unanimously to approve the draft BUA for Dr. Ho, pending successful completion of the lab inspection.

k. Kiem, Hans-Peter, renewal, *Cell and Gene Therapy for HIV Cure*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Kiem lab researches gene therapies as a potential treatment modality for HIV/AIDS in an NHP model.
- All work on this BUA is in vivo in NHPs. The lab works with primate lentivirus in BSL-2w/3 practices, and with AAV, adenoviral vectors, human and NHP cells transduced with lentiviral vectors, NHP cells transfected with rDNA, and rDNA at BSL-2.
- 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. Kiem.
- The Committee voted unanimously to approve the draft BUA for Dr. Kiem.

l. King, Neil, renewal, *Institute for Protein Design: King Lab*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The King lab studies the computational design of self-assembling protein nanomaterials for medical applications.
- The lab works with human cell lines in vitro and lentiviral vectors at BSL-2, mRNA in mice at BSL-1, and with Saccharomyces cerevisiae, Saccharomyces uvarum, various E. coli cloning strains, and rDNA in vitro at BSL-1.
- 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. King.
- The Committee voted unanimously to approve the draft BUA for Dr. King.

m. Marchiano, Silvia, new, *Conduction regeneration using hPSC-CMs*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Marchiano lab researches the efficacy and safety of cell-based therapies using human stem cell-derived cardiomyocytes for treatment of heart diseases arising after a heart attack.
- The lab works with human cells transduced with third generation lentiviral vectors and human cells transfected with rDNA in guinea pigs at BSL-2, human source material in vitro at BSL-2, and third generation lentiviral vectors, rDNA with enhanced gene delivery methods, and E. coli at BSL-1.
- 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. Marchiano.
- The Committee voted unanimously to approve the draft BUA for Dr. Marchiano.

n. Som, Avik, new, *Som Startup Lab*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Som lab utilizes enhanced gene delivery to liver and prostrate cells in vitro and in vivo to induce cancer competition and suppression.
- The lab works with human source material in vitro and in mice at BSL-2 and rDNA i in vitro and in mice at BSL-1.
- 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. Som.
- The Committee voted unanimously to approve the draft BUA for Dr. Som, pending successful completion of the lab inspection and review of the IACUC protocol.

o. Stevens, Kelly, renewal, *Heart Regenerative Technologies*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Stevens lab develops cell-based treatments for patients with organ failure due to heart and liver disease.
- The lab works at BSL-2 with various primary human cell lines, hiPSCs, and murine cell lines implanted into mice and rats. The implanted cells may be transduced with AAV and rDNA for expression of fluorescence reporters and DREDDs. Oncogenes used are related only to the creation of iPSCs. In vitro the lab works with human cell lines at BSL-2 and with third generation lentiviral vectors and rDNA at BSL-1.
- 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. Stevens.
- The Committee voted unanimously to approve the draft BUA for Dr. Stevens.

p. Subramanian, Naeha, renewal, *A systems approach to understanding NLR function*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Subramanian lab studies how intracellular innate immune receptors (NLRs) carry out their functions against infectious insult or sterile inflammation to design new therapies.
- The lab works with human source material, Salmonella Typhimurium, and Sendai virus in mice at BSL-2 and rDNA in mice at BSL-1.
- 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. Subramanian.
- The Committee voted unanimously to approve the draft BUA for Dr. Subramanian.

q. Tait Wojno, Elia, renewal, *Regulation of immunity and inflammation at mucosal surfaces.*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Tait Wojno lab studies intestinal helminth bacterial and protozoal infection and allergic diseases in a mouse model to characterize immune responses and understand their regulation during disease states.
- The lab works with Salmonella Typhimurium in mice and in vitro at BSL-2 and with rodent nematodes at BSL-1.
- The committee discussed that the attenuated strain of Salmonella Typhimurium still requires BSL-2.
- The lab was inspected, and no deficiencies were noted.
- All required trainings are complete.
- There are occupational health requirements for work with diphtheria and pertussis toxins.
- 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. Tait Wojno.
- The Committee voted unanimously to approve the draft BUA for Dr. Tait Wojno, with one recusal.

r. Villen, Judit, renewal, *Cell signaling and proteomics*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Villen lab studies proteins to understand cellular biology and diseases.
- The lab works with human source material at BSL-2 and with third generation lentiviral vectors, E. coli, and various yeast strains at BSL-1.
- 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. Villen.
- The Committee voted unanimously to approve the draft BUA for Dr. Villen.

s. Walker, Matthew, renewal, *Dissecting the mitochondrial RNase P complex in heart failure*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Walker lab researches genes related to heart failure and if restoring its expression can improve symptoms.
- The lab works with human cell lines at BSL-2 and with AAV in vitro and in mice BSL-1.
- 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. Walker.
- The Committee voted unanimously to approve the draft BUA for Dr. Walker.

t. Wang, Pei, new, *Epicardial Adipose Tissue in Myocardial infarction*

- NIH Guidelines Sections III-D

- The assigned IBC Primary Reviewer presented the Primary Review.
- The Wang lab researches the role of adipose tissue in myocardial infarction.
- The lab works with AAV in rats 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. Wang.
- The Committee voted unanimously to approve the draft BUA for Dr. Wang.

u. Yang, Mia, change, *Yang Lab General Research*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Yang lab is adding AAV, third generation lentiviral vectors, and Sendai viral vectors to generate iPSCs.
- 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. Yang.
- The Committee voted unanimously to approve the draft BUA for Dr. Yang.

v. Zweifel, Larry, renewal, *Genetic Dissection of the Emotional Basis of Learning*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Zweifel lab researches how genes affect brain function and behavior and how alterations to gene function can result in neurological and psychiatric disorders.
- The lab works with human source material at BSL-2, AAV and canine adenoviral vectors in mice and in vitro at BSL-1, rDNA including enhanced gene delivery methods, E. coli, and mouse and dog cells at BSL-1.
- 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. Zweifel.
- The Committee voted unanimously to approve the draft BUA for Dr. Zweifel, pending submission and review of the IACUC protocol.

10. SUBCOMMITTEE REPORTS:

w. Appelbaum, Jacob, new, *Phase 1/1 b First-in-human Study of Autologous Chimeric Engulfment Receptor T-Cell CER-1236 in Patients with Acute Myeloid Leukemia (CertainT-1)*

- NIH Guidelines Sections III-C
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is an industry-sponsored, multi-site, first-in-humans, multi-site clinical trial of human CAR T-cells in patients with acute myeloid leukemia.

- Human cells transduced with third generation lentiviral vectors are administered to human study participants.
- All required trainings are complete.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Applebaum. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Applebaum.

x. Disis, Mary (021), new, *A phase II study of STEMVAC vaccine therapy for patients with hormone receptor positive metastatic breast cancer*

- NIH Guidelines Sections III-C
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a foundation-sponsored, single-site, non-first in humans vaccine for patients with hormone receptor positive metastatic breast cancer.
- An rDNA vaccine study product will be administered to human study participants.
- 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.

y. Disis, Mary (022), new, *A Phase II Trial of the Immunogenicity of a DNA Plasmid-Based Vaccine (STEMVAC) Encoding Th1 Selective Epitopes from Five Antigens Associated with Breast Cancer Stem Cells (MDM2, YB1, SOX2, CDH3, CD105) in Patients with Metastatic Triple-Negative Breast Cancer*

- NIH Guidelines Sections III-C
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a foundation-sponsored, single-site, non-first in humans vaccine for patients with metastatic triple-negative breast cancer.
- A rDNA vaccine study product will be administered to human study participants.
- 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.

z. Loggers, Elizabeth T. , new, *A Phase 2 Single Arm Open-Label Clinical Trial of ADP-A2M4 SPEARTM T cells in subjects with Advanced Synovial Sarcoma or Myxoid/Round Cell Liposarcoma (SPEARHEAD 1 Study)*

- NIH Guidelines Sections III-C
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is an industry-sponsored, multicenter, non-first in-humans, multicenter international study with an aim to treat patients with advanced synovial sarcoma or myxoid/round cell liposarcoma.

- Human cells transduced with third generation lentiviral vectors are administered to human study participants.
- All required trainings are complete.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Loggers. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Loggers.

aa. Prion-like proteins (PLPs)/Proteopathic Seeds Subcommittee

- A BSO shared the Proteopathic Seeds Safety Policy, including high and low risk activities, vocabulary, hazard assessment, containment guidelines, safe handling practices, and decontamination and disposal.
- A member made a motion to approve the Proteopathic Seeds Safety Policy. Another member seconded the motion.
- The Committee voted unanimously to approve the policy.

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

11. MEETING ADJOURNED AT APPROXIMATELY 12:08p.m.