INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, August 20, 2025
Time: 10:00 a.m. – 12:00 p.m.

Location: Zoom

Members Present:

1. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
2. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
3. Erin Heiniger, Department of Bioengineering *(Laboratory Specialist*)
4. Richard Grant, Washington National Primate Research Center
5. Kevin Hybiske, Allergy and Infectious Diseases *(IBC Vice Chair)*
6. Jennifer Iwamoto, Office of Animal Welfare *(Animal Containment Expert)*
7. David Koelle, Allergy and Infectious Diseases
8. Stephen Libby, Laboratory Medicine *(Animal Containment Expert)*
9. Scott Meschke, Environmental & Occupational Health Sciences
10. Susan Parazzoli *(Community Member)*
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
BBP: bloodborne pathogens
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) Vice Chair called the meeting to order at 10:03 a.m. A quorum was present.

2. **REMINDER:** The IBC Vice 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. The EH&S Biosafety Manager shared updates to the IBC no longer subject to the Open Public Meetings Act, though the IBC meeting will still be open to the public via Zoom.

3. **APPROVAL OF MINUTES:**
   - The IBC Vice Chair sought a motion to approve the minutes from the July 16, 2025, meeting.
   - A member made a motion to approve the July 16, 2025, meeting minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the July 16, 2025, meeting minutes, with one recusal and two abstentions.

4. **OLD BUSINESS:**
   - At the July 16, 2025 meeting, Dr. Chen's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
   - At the July 16, 2025 meeting, Dr. Heshmati's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
   - At the July 16, 2025 meeting, Dr. Hybiske's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the July 16, 2025 meeting, Dr. Mack's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the July 16, 2025 meeting, Dr. Ojo's BUA was approved pending clarification from PI regarding M. gentialium drug resistance. This BUA has been sent.
   - At the July 16, 2025 meeting, Dr. Raible's BUA was approved pending submission and review of IACUC. This BUA has been sent.
   - At the July 16, 2025 meeting, Dr. Riffell's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
   - At the July 16, 2025 meeting, Dr. Yang's BUA was approved pending successful completion of the required trainings. This BUA has been sent.

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. Fuller took over work previously overseen by Dr. Gale on the BUA *The Host Response to Virus Infection/NHP Host Immunity to Zika Virus infection.*
      - Dr. Lieber added work with non-human primate source material exposed to primate lentiviruses in vitro and a core facility on the BUA *Stem cell and gene therapy of cancer and hematological diseases.*
      - Dr. Roederer initiated work with Komagataella pastoris, E. coli and rDNA in vitro on the BUA *Pichia Produced Growth Factors by CET.* (Section III-E and III-F)
      - Dr. Wood added a new room for work with previously approved agents on the BUA *Multiple projects involving sexually transmitted bacterial pathogens.*

- Dr. Ferreira renewed work with human source material and rDNA in vitro on the BUA *Tissue Bank for the Investigation of the Genetics and Basic Biology of Human Vascular Malformations and Skull base tumors.* (Section III-E and III-F)
- Dr. Chu renewed work with human source material and rDNA in vitro on the BUA *SeaPrep.* (Section III-F)
- Dr. Fisher initiated work with human source material in vitro on the BUA *Fisher Clinical Research.*
- Dr. Kruse-Jarres added a new room for previously approved study product prep on the BUA *A Phase 1/2 Dose Escalation and Expansion Study of BE-101 for the Treatment of Adults with Moderately Severe or Severe Hemophilia B.*
- Dr. Montoya initiated work with human source material in vitro on the BUA *Human Corneal Endothelial Cell Culture and Cryopreservation - Puget Sound Therapeutics.*
- Dr. Kiem added use of a core facility for work with previously approved agents on the BUA *Cell and Gene Therapy for HIV Cure.*
- Dr. O'Connor added work with human cells and new spaces for work with previously approved agents on the BUA *Emerging infectious diseases and SIV co-infections.*
- Dr. Adams Waldorf renewed work with influenza viruses, RSV, human and NHP source material in non-human primates and in vitro, and rDNA in vitro on the BUA *Influenza and Coronavirus Model of Immunity in Pregnancy.* (Section III-F)
- Dr. Mondello took over work previously overseen by Dr. Moritz on the BUA *Combined Stem Cell Transplantation and Targeted Microstimulation to Direct the Formation of Functional Connections and Neural Repair in Rats.*
- Dr. Adams Waldorf added an additional room for work with previously approved agents in vitro on the BUA *Experimental Model for Chorioamnionitis and Preterm Labor.*
- Dr. Adams Waldorf added an additional room for work with previously approved agents in vitro on the BUA *Nonhuman primate model of congenital toxoplasmosis.*
- Dr. Adams Waldorf added an additional room for work with previously approved agents in vitro on the BUA *Influenza and Coronavirus Model of Immunity in Pregnancy.*
- Dr. Adams Waldorf added an additional room for work with previously approved agents in vitro on the BUA *Experimental Model of Viral-Induced Brain Injury.*
- Dr. Hyde lowered the containment of SARS-CoV-2 on the BUA *Pathogenesis studies of alphaviruses and +ssRNA viruses.*
- Dr. Kollman updated rooms for work with previously approved agents on the BUA *Allosteric Regulation of Metabolic Enzymes.*
- Dr. Paik took over work previously overseen by Dr. Mougous on the BUA *Mechanisms and consequences of interbacterial interactions.*
- The IBC Vice 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.
- <u>The Committee unanimously voted to approve this month's Biosafety Officer Report.</u>

6. BSL-3 INACTIVATION REPORT

- Dr. Skerrett requested approval for Qiagen Trizol (Qiazol) lysis reagent inactivation of Francisella tularensis.

- The subcommittee reviewed the procedures and inactivation data provided by the lab and approved their requests.
- The IBC Vice 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. IRE DURC-PEPP REPORT

- One project received renewal approval for use of Avian Influenza (Highly Pathogenic). The project does not meet the DURC definition.
- The IBC Vice Chair sought a motion to approve this month's IRE DURC-PEPP Report.
- A member made a motion to approve this month's IRE DURC-PEPP Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's IRE DURC-PEPP Report.

8. INDIVIDUAL PROJECT REVIEWS

a. Bothwell, Mark, change, *iPSC models of neuromuscular disease*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Bothwell lab is adding work with recombinant and wild-type Trypanosoma cruzi and NHP source material in vitro 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. Bothwell.
- The Committee voted unanimously to approve the draft BUA for Dr. Bothwell.

b. Chao, Jennifer, renewal, *In vitro models of retinal degenerative diseases*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Chao lab investigates in vitro mouse and human models of retinal degeneration to use for screening effective drugs.
- The lab works with AAV with oncogenic inserts, third generation lentiviral vectors with oncogenic inserts in vitro, Sendai viral vectors with oncogenic inserts, and human source material in vitro at BSL-2, and with AAV, third generation lentivirus, E. coli K-12 strains, and rDNA in vitro 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. Chao.
- The Committee voted unanimously to approve the draft BUA for Dr. Chao, pending successful completion of the lab inspection.

c. Fuller, Deborah Lynn (014), renewal, *Identification of T Cell Receptors, Epitopes, and Protective Responses that Occur During Coccidioidomycosis*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Fuller lab studies the natural disease progression and immune response of humans and NHPs against Coccidioides infection in an NHP model. As part of the

study, the lab will receive avirulent or vaccine strains of Coccidioides posadasii and clinical samples.

- The lab works with Coccidioides posadasii (avirulent or vaccine strains) and rDNA in vitro and in macaques at BSL-2. They also work with human and NHP source material in vitro at BSL-2 and with E. coli and rDNA at BSL-1.
- A discussion occurred about whether the lab was working with wildtype cultures of Coccidioides, and the biosafety officer confirmed that they are not and will only handle clinical samples in addition to the avirulent or vaccine strains.
- 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 Coccidioides posadasii (avirulent or vaccine strains).
- 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.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Fuller.</u>

d. Fuller, Deborah Lynn (020), new, *Vaccines against Hepatitis B Virus (HBV)*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Fuller lab develops therapeutic vaccines for Hepatitis B Virus in a mouse model. This project will involve an AAV expressing the full Hepatitis B viral genome.
- The IBC will require that administration of the AAV to mice take place at BSL-2w/3 practices. After administration, the animals can be housed at BSL-2. The lab will work with AAV in vitro at BSL-2 and with rDNA in vitro and in mice at BSL-1.
- A discussion occurred regarding the occupational health requirements for the AAV expressing the full Hepatitis B viral genome and if the Hepatitis B vaccine could be required for researchers, animal care, and veterinary staff. The occupational health nurse presented an option of requiring that the vaccine be offered as part of the bloodborne pathogens (BBP) program and training. If personnel involved with this project were to choose to decline the vaccine, they would be required to have medical counseling of the hazards and risks before documented declination.
- 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 Hepatitis B virus.
- 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.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Fuller, pending further occupational health review and implementation.</u>

e. Gillespie, Anna, new, *Manipulations of the hippocampal circuit to modulate memory*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Gillespie lab studies how neural mechanisms of long-term memory break down in advanced age and with neurodegenerative diseases such as Alzheimer's.
- The lab works with AAV in rats and 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. Gillespie.
- The Committee voted unanimously to approve the draft BUA for Dr. Gillespie.

f. Jain, Sumita, renewal, *P. gingivalis lipid A/ OMVs/Stannous fluoride*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Jain lab studies the bacterial mechanisms in promoting periodontal disease using bacterial cultures and human cell-line based model systems in vitro.
- The lab works with B. thetaiotaomicron, P. gingivalis, and human source material in vitro at BSL-2 and with rDNA and E. coli 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. Jain.
- The Committee voted unanimously to approve the draft BUA for Dr. Jain.

g. Kiem, Hans-Peter, renewal, *Strategies to Improve Hematopoietic Stem Cell Transduction*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Kiem lab studies gene therapy as a treatment modality for genetic disorders and acquired diseases such as AIDS and cancer in an NHP model.
- The lab primate lentivirus in NHPs at BSL-2w/3 practices, and with lentiviral vectors, rDNA, and transduced human and NHP cells 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. Kiem.
- The Committee voted unanimously to approve the draft BUA for Dr. Kiem.

h. King, Mary-Claire, renewal, *King Lab Research*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The King lab researches genes responsible for complex traits in humans and cultures and transforms human lymphoblasts with Epstein-Barr Virus.
- The lab works with human iPSCs made with Sendai viral vectors with oncogenes, human source material, and Epstein-Barr Virus at BSL-2, and with third generation lentiviral vectors, rDNA, and E. coli at BSL-1.
- 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. King.
- The Committee voted unanimously to approve the draft BUA for Dr. King, pending successful completion of the lab inspection.

i. Koelle, David, change, *Koelle Laboratory at UW*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Koelle lab is adding work with AAV and rDNA in vitro and in mice at BSL-1.
- 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. Koelle.
- The Committee voted unanimously to approve the draft BUA for Dr. Koelle, with one recusal, pending submission and review of the IACUC protocol.

j. Kong, Jennifer, renewal, *Signaling pathways in the context of development, disease, and regeneration*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Kong lab studies highly conserved signaling pathways that regulate functions such as embryonic development, tissue patterning, and organ regeneration.
- The lab works with human source material in vitro at BSL-2, and with third generation lentiviral vectors, E. coli, and rDNA in vitro 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. Kong.
- The Committee voted unanimously to approve the draft BUA for Dr. Kong, pending submission and review of the IACUC protocol.

k. Ong, Shao-En, renewal, *Defining Pathway-Specific Kinase Signaling Modules with Proteomics*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Ong lab studies effects of cell signaling pathways to cellular phenotypes.
- The lab works with third generation lentiviral vectors with oncogenic inserts and human source material in vitro at BSL-2, and with third generation lentiviral vectors, rDNA, and E. coli in vitro 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. Ong.
- The Committee voted unanimously to approve the draft BUA for Dr. Ong.

l. Park, Jim, renewal, *Immunotheranostics for cancer*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Park lab researches the therapeutic efficacy and potential toxicity of beta- and alpha-particle emitting radioisotope-labeled targeted antibody treatment in a mouse model for liver and pancreatic cancer.

- The lab works with human cells transduced with first/second/unknown generation lentiviral vectors and human source material in vitro and in mice 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. Park.
- The Committee voted unanimously to approve the draft BUA for Dr. Park, pending successful completion of the lab inspection and submission and review of the IACUC protocol.

m. Perlmutter, Steve, renewal, *Cellular Properties of NHP Cortical Neurons*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Perlmutter lab researches cell type specific properties in the cerebral cortex of nonhuman primates.
- The lab works with AAV in NHPs and with NHP source material at BSL-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. Perlmutter.
- The Committee voted unanimously to approve the draft BUA for Dr. Perlmutter.

n. Poolos, Nicholas P, renewal, *Epilepsy and Dendritic Excitability*

- NIH Guidelines Sections III-D and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Poolos lab studies epilepsy, both inherited and acquired forms to investigate links between the tau protein and dysfunctions within ion channels after insults to the brain.
- The lab works with human source material in vitro at BSL-2, and with AAV in vitro and in rats and E. coli in vitro at BSL-1.
- The lab inspection is scheduled for after the IBC meeting.
- The required trainings are still pending.
- 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. Poolos.
- The Committee voted unanimously to approve the draft BUA for Dr. Poolos, pending successful completion of the lab inspection, completion of required trainings, and submission and review of the IACUC protocol.

o. Shears, Melanie J, renewal, *Shears NHP studies*

- NIH Guidelines Sections III-D, III-E and III-F
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Shears lab studies malaria in NHPs to evaluate infections and test vaccination strategies.

- The lab works with rDNA and wildtype Plasmodium cynomolgi in NHPs at BSL-2 and in mosquitoes at ACL-2. In vitro they work with human and nonhuman primate source material at BSL-2 and with rDNA in vitro at BSL-1.
- The lab was inspected, and no deficiencies were noted.
- All required trainings are complete.
- A medical management plan is in place for work with Risk Group 2 Plasmodium species.
- 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. Shears.
- The Committee voted unanimously to approve the draft BUA for Dr. Shears.

p. Sniadecki, Nate, renewal, *Studies on Cell Mechanics and Mechanotransduction with Engineered Systems*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Sniadecki lab studies cell mechanical behaviors and uses engineered tools to measure their behavior and properties.
- The lab works with Streptococcus gordonii and human source material in vitro at BSL-2.
- 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. Sniadecki.
- The Committee voted unanimously to approve the draft BUA for Dr. Sniadecki.

q. Theberge, Ashleigh, change, *Studying cell signaling and cell-microenvironment interactions with new analytical tools*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Theberge lab is adding work with wildtype uropathogenic E. coli, E. faecium, K. pneumoniae, P. mirabilis, P. aeruginosa, and S. saprophyticus, and human source material in vitro 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. Theberge.
- The Committee voted unanimously to approve the draft BUA for Dr. Theberge.

r. Veesler, David, change, *Expression of recombinant proteins using mammalian cell lines*

- NIH Guidelines Sections III-D
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Veesler lab is adding work with a chimeric, replication competent vesicular stomatitis virus pseudovirus that encodes the Marburg virus glycoprotein and to lower the containment level of in vitro SARS-CoV-2 to BSL-2.
- There are occupational health requirements for work with SARS-CoV-2.

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

9. SUBCOMMITTEE REPORTS:

s. Greninger, Alex, renewal, *Isolation, propagation, and characterization of clinically relevant human viral pathogens*

- NIH Guidelines NIH Guidelines Sections III-D
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The Greninger performs work to support detection assay development and isolate sequencing for avian influenza viruses and Mpox.
- The lab works with high and low pathogenic avian influenza viruses, including one strain generated via reverse genetics, and with Mpox Clade I and II in vitro at BSL-3. They also work with human and NHP cell lines in the BSL-3.
- BSL-3 labs are inspected quarterly and not in association with BUAs/projects.
- All required trainings are complete.
- A medical management plan is in place for Mpox and HPAI.
- Work with Mpox Clade I is regulated by the Federal Select Agent Program (FSAP). FSAP approval has been obtained.
- 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.

t. Shah, Javeed A, renewal, *Immunology and Genetics of Infectious Diseases and Vaccines*

- NIH Guidelines NIH Guidelines Sections III-D, III-E and III-F
- Four members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The Shah lab studies the pathogenesis and host response of respiratory bacterial infections, such as Mycobacterium tuberculosis.
- The lab works with M. tuberculosis in vitro at BSL-3, with L. pneumophila and Risk Group 2 species of Mycobacterium, third generation lentiviral vectors with oncogenes, and human source material in vitro at BSL-2. Several species of Risk Group 2 bacteria, including Pseudomonas, Legionella, and Staphylococcus, are administered to mice at BSL-2.
- BSL-3 labs are inspected quarterly and not in association with BUAs/projects.
- Non-BSL-3 labs were inspected, and all deficiencies have been corrected.
- All required trainings are complete.
- A medical management plan is in place for M. tuberculosis. There are occupational health requirements for work with M. tuberculosis H37Ra strains and Streptococcus pneumoniae.
- 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. Shah. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Shah, pending review of the IACUC protocol, with one member not voting.

u. Venur, Vyshak, new, *The CAROLYN Trial: Lisocabtagene Maraleucel as First-Line Therapy for Primary Central Nervous System Lymphoma (PCNSL) in Transplant-Ineligible Patients*

- 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 company-sponsored, multi-site, non-first-in-humans clinical trial targeting B-cell lymphoma.
- A CAR T-cell study product will be administered to human study participants.
- A discussion occurred regarding information about testing of master stock of the viral vector prior to transduction of patient samples. The reviewers are waiting for clarification from the PI of the study.
- 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. Venur. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Venur, pending clarification of reviewer questions, with one member not voting.

v. Wuliji, Natalie, new, *Phase 1b/2 Study of AZD0120, a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and B-cell Maturation Antigen (BCMA) in Subjects with Refractory Systemic Lupus Erythematosus (SLE)*

- 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, non-first-in-humans clinical trial targeting Refractory Systemic Lupus Erythematosus.
- A CAR T-cell 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. Wuliji. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Wuliji.

10. FOR YOUR INFORMATION:

- IBC Meeting Open to the Public via Zoom

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

12. MEETING ADJOURNED AT APPROXIMATELY 12:02 p.m.