Institutional Biosafety Committee
2/6/2026, 12:00PM – 1:15PM
Teleconference

Minutes

Voting Members Present: Brian Taylor, Marianne Cloeren, Alan Schmaljohn, Ron McNeil, Elizabeth Bramhall, J. Kristie Johnson, John O'Neill, Irina Luzina, Janna Barcelo, Matthew Frieman, Robert Ernst, Ciaran Skerry, Jessie Duggan, Matthew Fischer

Voting Members Absent: Ami A. Patel, Karen Scanlon, Melissa Morland, Anthony Kim, Joseph Gillespie, Sherry Bohn, Alfredo Garzino-Demo

Other Person(s) Present: Tonya Webb

Staff Present: Matthew Fischer, John O'Neill, Holda Ramos

1 Vote on Last Meeting's Minutes

Institutional Biosafety Committee meeting on 1/9/2026
Votes to approve minutes: 12, Disapprove: 0, Abstain: 0

2 New Business

This meeting of the IBC is open to the public pursuant to the NIH Guidelines, Section IV-B-2-a-(6).

- Disinfection protocol for Dental School ABSL-2 room is being revised.
- Representatives of the NIH Office of Science Policy are coming to UMB to interview us about the NIH Guideline modernization effort.
- A replacement US Government policy for Dual Use Research of Concern (or "Dangerous Gain of Function") is expected any day.
- Our next meeting is scheduled for Friday, March 6th.
- Member issues
    - ChABSA has a dinner meeting in Frederick on March 10th entitled "Modernization of Biosafety: Thoughts on Improving NIH Guidelines in a Deregulatory Environment"
    - ASM Maryland has a dinner meeting at IMET on February 23rd entitled "Out of the Endotoxin Box: Addressing Pyrogen Diversity Challenges Using the Monocyte Activation Test (MAT)"

3 Select Agent Program Oversight

- We received notification that our renewal inspection will be the week of March 1st.

4 Reportable Incidents

- On January 13th, we were notified that our incident report from September was closed with no further action required.

- A case of unapproved research (use of plasmid in an animal; see IBC-00008684 on this meeting's agenda) was reported on January 13th to the NIH Office of Science Policy.
- No other cases of reportable incidents occurred this month.

5 New IBC Submissions

Short Title:	IBC: CAR-T in Multiple Sclerosis
Investigator:	David Benavides
ID:	IBC-00008252
Analyst:	John O'Neill
VA-Related:	No
Discussion:	This protocol involves the use of allogeneic CAR-T cells in patients with multiple sclerosis. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-C-1 and is approved using universal practices.
Motion:	Approved
Vote:	For: 12, Against: 0, Abstained: 0, Recused: 0

Short Title:	IBC Submission: 2585GCCC: Cemacabtagene Ansegedleucel for MRD in LBCL Post First-Line Therapy (ALPHA3)
Investigator:	Jean Yared
ID:	IBC-00008458
Analyst:	John O'Neill
VA-Related:	No
Discussion:	This protocol involves the use of allogeneic CAR-T cells in Large B-cell Lymphoma patients. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-C-1 and is approved using universal precautions.
Motion:	Approved
Vote:	For: 13, Against: 0, Abstained: 0, Recused: 0

Short Title:	Exosomes as a drug delivery cargoes in neurodegenerative diseases
Investigator:	Wei-Bin Shen
ID:	IBC-00008684
Analyst:	John O'Neill
VA-Related:	No
Discussion:	This protocol involves the use of plasmids in human cells and *E. coli*. The DNA will be loaded into murine exosomes, which will be injected into animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-4-a using BSL-2/ABSL-1 facilities and practices. This work was reportedly performed prior to receiving approval and was submitted so that the committee could perform a review. As the research team does not plan on pursuing this work in the future, the committee decided to acknowledge and withdraw the proposal without granting approval.
Motion:	Withdraw Protocol

Vote: For: 14, Against: 0, Abstained: 0, Recused: 0

Short Title: Mechanisms of synaptic physiology and neurodegenerative diseases
Investigator: Leonardo Parra-Rivas
ID: IBC-00008690
Analyst: John O'Neill
VA-Related: No
Discussion: This protocol involves the use of lentiviral vectors in mammalian cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-1-a using BSL-2 facilities and practices with sharps precautions. This protocol also involves the use of AAV and plasmids in mammalian cells and animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-4-a using BSL-2/ABSL-2 facilities and practices for work with human cells and BSL-1/ABSL-1 facilities and practices for work with murine cells and animals. The following modifications are required to secure approval: 1) Add the animal-use protocol number; 2) Upload a spreadsheet of constructs; 3) Update language on the types of genes involved; 4) Acknowledge that lentivirus is not used in live animals; 5) Clarify the lentiviral backbones used; and 6) Define which, if any, procedures need to be conducted outside of a biosafety cabinet and update precautions accordingly.
Motion: RMSA
Vote: For: 14, Against: 0, Abstained: 0, Recused: 0

Short Title: Engineering Plasmodium parasites to study malaria biology and host responses
Investigator: Janna Armstrong
ID: IBC-00008704
Analyst: John O'Neill
VA-Related: No
Discussion: This protocol involves the use of lentiviral vectors in human and murine cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-1-a using BSL-2 facilities and practices with sharps precautions. This protocol also involves the use of plasmids and CRISPR/Cas9 technology in *Falciparum spp*. which are used in animals and human cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-1-a using BSL-2/ABSL-2 facilities and practices. The following modifications are required to secure approval: 1) Change the PI to a faculty member and 2) Remove or define qualifying language for precautions in the risk assessment.
Motion: RMSA
Vote: For: 14, Against: 0, Abstained: 0, Recused: 0

6 Modification Discussions

Short Title: Therapeutic modulation of comorbid pain conditions
Investigator: Richard Traub

ID:	IBC-00008261
Analyst:	Holda Ramos
VA-Related:	No
Discussion:	This modification involves the addition of an AAV construct which will be used in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-4-a using ABSL-1 facilities and practices. The following modification is required to secure approval: Add the control virus described in the IACUC protocol.
Motion:	RMSA
Vote:	For: 14, Against: 0, Abstained: 0, Recused: 0

Short Title:	Molecular and Functional Studies of Depression and Addiction on Brain
Investigator:	Mary Kay Lobo
ID:	IBC-00001687
Analyst:	John O'Neill
VA-Related:	No
Discussion:	This modification involves the use of AAV in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-4-a and is approved using ABSL-1 facilities and practices.
Motion:	Approve the Modification
Vote:	For: 14, Against: 0, Abstained: 0, Recused: 0

Short Title:	Cytoskeletal Regulation of Lung Endothelial Cell Barrier Function
Investigator:	Konstantin Birukov
ID:	IBC-00004000
Analyst:	John O'Neill
VA-Related:	No
Discussion:	This modification involves the use of previously transduced pathogenic *E. coli* in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-4-b using ABSL-2 facilities and practices. The following modifications are required to secure approval: 1) Complete the personnel profiles for two laboratory members; 2) Update the IACUC protocol information; 3) Change the routes of administration to match the IACUC protocol; and 4) Explicitly add *E. coli* Seattle 1946 to the risk assessment pages.
Motion:	RMSA
Vote:	For: 14, Against: 0, Abstained: 0, Recused: 0

Short Title:	Development and preclinical evaluation of novel therapeutic delivery strategies
Investigator:	Jung Soo Suk
ID:	IBC-00007510
Analyst:	John O'Neill
VA-Related:	No

Discussion: This modification involves the addition of previously transduced murine cells which will be used in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-4-a using ABSL-1 facilities and practices. The following modifications are required to secure approval: 1) Include procedures and training missing for a laboratory member and 2) Remove the superfluous CpG entry from the Recombinant DNA Questions page.
Motion: RMSA
Vote: For: 14, Against: 0, Abstained: 0, Recused: 0

Short Title: Investigation of SARS-CoV-2 and related coronaviruses
Investigator: Matthew Frieman
ID: IBC-00005484
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of bacterial artificial chromosomes to express recombinant, but naturally occurring, coronaviruses in mammalian cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-2-b using BSL-3 facilities and practices. The following modifications are required to secure approval: 1) Explicitly add the new bat coronaviruses to the risk assessment, even if they are the same as the previously included bat coronaviruses and 2) Include a risk/benefit analysis document.
Motion: RMSA
Vote: For: 13, Against: 0, Abstained: 0, Recused: 1 (Matthew Frieman)

7 RMSA Follow-Up

Short Title: Imaging brain cell morphology and activity with genetically encoded reporters
Investigator: Yajie Liang
ID: IBC-00006780
Analyst: John O'Neill
VA-Related: No
Discussion: This protocol was previously approved for work with AAV constructs in animals. It has been modified to add new AAV constructs. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-4-a and is approved using BSL-1 and ABSL-1 facilities and practices. The following modifications were made to secure approval: 1) Specified personnel procedures and 2) Updated IACUC protocol number.
Status: Approved

Short Title: Novel mechanisms and interventions of vascular remodeling in lung injury
Investigator: Kelly Schweitzer
ID: IBC-00008530
Analyst: John O'Neill

VA-Related: No

Discussion: This protocol has been approved for the use of lentiviral vectors and AAV in human cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-1-a using BSL-2 facilities and practices with sharps precautions for work with lentiviral vectors and III-E-1 Appendix C1 using BSL-2 facilities and practices for work with AAV. The following modifications were made to secure approval: 1) Rewrote the abstracts to make them congruent with the work described in the protocol; 2) Added personnel; 3) Changed mistaken reference to "adenovirus" to "AAV"; 4) Removed the unrelated AUP number; 5) Clarified Cas9 expression; 6) Corrected the NIH Guideline classification for plasmid and AAV entries; 7) Discussed consideration of off-target effects for gene editing; 8) Changed "10% bleach" to "a 1:10 dilution of household bleach"; and 9) Changed the infectious dose of lentivirus to "unknown".

Status: Approved

8 Periodic Reviews of Protocols with Recombinant or Synthetic Nucleic Acid Moledules

Short Title: Molecular genetics of a complement factor H homolog
Investigator: Bruce Vogel
ID: IBC-00000821
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Novel drug delivery strategies for treatment of breast cancer brain metastases
Investigator: Anthony Kim
ID: IBC-00006475
Analyst: John O'Neill
VA-Related: Yes
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IBC: 2407GCCC: CARTITUDE-6
Investigator: Mehmet Kocoglu
ID: IBC-00007758
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IBC: 2080GCCC: (EAP) for Subjects Receiving Lisocabtagene Maraleucel that is Nonconforming for Commercial Release
Investigator: Nancy Hardy
ID: IBC-00005911
Analyst: John O'Neill
VA-Related: No

Discussion: There have been no substantive changes to this protocol submission.

Short Title: Restoration of tumor suppressor activity in malignant melanoma
Investigator: David Weber
ID: IBC-00000406
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: The roles of BASP1 and autophagy in cocaine abuse
Investigator: Maged Harraz
ID: IBC-00007153
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Lipid Metabolism and Metabolic Disease
Investigator: Liqing Yu
ID: IBC-00004718
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IBC: 2517GCCC: Expanded Access Program for OOS Obe-cel (HP-00113710)
Investigator: Jean Yared
ID: IBC-00008220
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Developing an inducible sterilization technology in fish
Investigator: Ten-Tsao Wong
ID: IBC-00003820
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Modulation of nociceptive ion channels
Investigator: Man-Kyo Chung
ID: IBC-00000817
Analyst: John O'Neill
VA-Related: No

Discussion: There have been no substantive changes to this protocol submission.

Short Title: Mechanisms of antimicrobial and anticancer activities of Interferon-stimulated genes.
Investigator: Saumendra Sarkar
ID: IBC-00008070
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Genomic specification of heme in nutrition and development
Investigator: Iqbal Hamza
ID: IBC-00006944
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Novel Mechanisms of Beta-lactam Resistance in Staph aureus
Investigator: Som Chatterjee
ID: IBC-00004995
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: AAV-mediated modulation of neuronal activity related to spatial navigation in mice
Investigator: Emily Aery Jones
ID: IBC-00008579
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for a change in personnel.

Short Title: Screening of BSL2 viruses with anti-viral compounds
Investigator: Matthew Frieman
ID: IBC-00002948
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for addition of a new wild type influenza strain using BSL-2 facilities and practices.

Short Title: Genomic specification of heme in nutrition and development
Investigator: Iqbal Hamza
ID: IBC-00006944
Analyst: Holda Ramos

VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Generating an *E. coli* mutant for the education of first-year graduate students
Investigator: Ciaran Skerry
ID: IBC-00008654
Analyst: John O'Neill
VA-Related: No
Discussion: This protocol involves the use of plasmids in K12 *E. coli.* This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-F-8, Appendix C-2 using BSL-1 facilities and practices.
Motion: Approved

Short Title: Screening of BSL2 viruses with anti-viral compounds
Investigator: Matthew Frieman
ID: IBC-00002948
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for the addition of a new influenza strain which will be used in animals using ABSL-2 facilities and practices.

Short Title: Calcium and Reactive Oxygen Species in Muscle
Investigator: Christopher Ward
ID: IBC-00002669
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

9 Standard Operating Procedures

Short Title: IBC Charter
Contact: Matthew Fischer
ID: IBC-2026
Discussion: The IBC charter was added to the meeting for routine annual review. Changes made in 2025 for compliance with the 2024 US Government Policy on the Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential, which was rescinded by Executive Order, have been removed. This was not discussed, but tabled until the next meeting because of time.