

Institutional Biosafety Committee

August 7, 2026

12:00PM – 1:00PM

Teleconference

Minutes

Voting Members Present: Ami A. Patel, Marianne Cloeren, Alan Schmaljohn, Jennifer Johnson, John O'Neill, Irina Luzina, Janna Barcelo, Matthew Frieman, Sherry Bohn, Jessie Duggan, Matthew Fischer

Voting Members Absent: Brian Taylor, Karen Scanlon, Ron McNeil, Melissa Morland, Elizabeth Bramhall, Anthony Kim, Joseph Gillespie, Robert Ernst, Ciaran Skerry, Alfredo Garzino-Demo

Other Person(s) Present: Ikechukwu Enenmoh

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

1 Vote on Last Meeting's Minutes

Institutional Biosafety Committee meeting on 7/10/2026

Votes to approve minutes: 11, 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).

- A replacement US Government policy for "Dangerous Gain of Function" (or Dual Use Research of Concern) was released on July 28th. Funding agencies have 120 days to figure out logistics and then entities will have 60 days after that to get into compliance.
- Our next meeting is scheduled for Friday, September 11th. This is the second Friday to avoid Labor Day weekend.
- Member issues
 - None reported.

3 Reportable Incidents

- No reportable incidents occurred this month.

4 New IBC Submissions

Short Title: The Effects of Anesthetic and Sedative Exposure on Brain Development

Investigator: Cyrus Mintz

ID: IBC-00008968

Analyst: John O'Neill

VA-Related: No

Discussion: This protocol involves the use of recombinant MMLV in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-

1-a using ABSL-2 facilities and practices. The following modifications are required to secure approval: 1) Update the laboratory locations section; 2) Revise the statement regarding pathogenicity of MMLV; and 3) Add a link to VectorBuilder.

Motion: RMSA

Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: Role of 12/15-Lipoxygenase and CLOCK in Subarachnoid Hemorrhage

Investigator: Rashad Hussain

ID: IBC-00008966

Analyst: Holda Ramos

VA-Related: No

Discussion: This protocol involves the use of recombinant 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

Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

5 Modification Discussions

Short Title: Delivery of Pleckstrin Homology Domains in Breast Cancer Cells

Investigator: Aikaterini Kontrogianni-Konstantopoulos

ID: IBC-00007240

Analyst: John O'Neill

VA-Related: No

Discussion: This modification involves the use of adenoviral vectors in human cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-1-a and is approved using BSL-2 facilities and practices.

Motion: Approve the Modification

Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: Endocrine Actions of Sclerostin

Investigator: Ryan Riddle

ID: IBC-00006696

Analyst: Holda Ramos

VA-Related: Yes

Discussion: This modification involves the use of recombinant 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: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: Long-term Inhibition of HIV transcription by targeting cellular CDK9 in vivo

Investigator: Alonso Heredia

ID: IBC-00003501
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of recombinant AAV in HIV-infected 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-2 facilities and practices.
Motion: Approve the Modification
Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: In vitro and In vivo analysis of the MERS Coronavirus
Investigator: Matthew Frieman
ID: IBC-00002089
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the use of recombinant VSV in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-1-a using ABSL-2 facilities and practices. The committee discussed the appropriate answer to "Is the host range or tropism altered?" on the Dual Use Research of Concern page. Replacing VSV glycoprotein with a coronavirus spike protein would result a more limited range of cells that could be infected, but question is phased as altered, not increased. The committee settled on an answer of yes with an explanation that this VSV would actually be expected to be safer. The following modifications are required to secure approval: 1) Update personnel, 2) Replace outdated documents, 3) Add a description of this VSV backbone to the experimental design, and 4) Update DURC questions to reflect the new work.
Motion: RMSA
Vote: For: 10, Against: 0, Abstained: 0, Recused: 1 (Matthew Frieman)

Short Title: The functional role of Akt on dopamine release
Investigator: Joseph Cheer
ID: IBC-00000335
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of recombinant 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: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: Mechanisms of antimicrobial and anticancer activities of Interferon-stimulated genes.
Investigator: Saumendra Sarkar
ID: IBC-00008070

Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the use of plasmids in mammalian cells which will be engrafted 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-2 facilities and practices. The following modification is required to secure approval: Add the biosafety cabinet used in the animal facility.
Motion: RMSA
Vote: For: 11, 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: Holda Ramos
VA-Related: No
Discussion: This modification involves the use of recombinant 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: 11, Against: 0, Abstained: 0, Recused: 0

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 involves the use of recombinant MHV in mammalian cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-3-a using BSL-2 facilities and practices. The following modification is required to secure approval: Confirm that the existing MHV biosecurity statement is true.
Motion: RMSA
Vote: For: 10, Against: 0, Abstained: 0, Recused: 1 (Matthew Frieman)

Short Title: Development, Validation, and Manufacturing of genetically modified human T- and CD34+ cells
Investigator: Kim Hankey
ID: IBC-00006199
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the use of recombinant lentivirus 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. The following modification is required to secure approval: Rewrite the lay abstract so that it can be understood by non-scientists.

Motion: RMSA

Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: White matter repair by transplanted glial progenitors guided by multimodality imaging

Investigator: Piotr Walczak

ID: IBC-00007091

Analyst: John O'Neill

VA-Related: No

Discussion: This modification involves the use of recombinant AAV 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: Update the host species for the new experiment to match the animal protocol.

Motion: RMSA

Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

6 RMSA Follow-Up

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 recombinant AAV 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 were made to secure approval: 1) Updated IACUC information; 2) Saved and uploaded a current copy of the experimental design; and 3) Wrote a new experimental design that focuses on the current aims of the laboratory.

Status: Approved

Short Title: Automated Stem Cell Radiolabeling via 3D Microprinting-Enabled Microfluidics

Investigator: Mirosław Janowski

ID: IBC-00005346

Analyst: Holda Ramos

VA-Related: Yes

Discussion: This modification involves the use of mRNA and plasmids in animals and mammalian cells. This work is classified by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules as III-D-4-b and is approved using ABSL-1 facilities and

practices. The following modifications were made to secure approval: 1) Updated personnel list and 2) Updated IACUC information.

Status: Approved

Short Title: Immunopathogenesis of Infectious Diseases

Investigator: Joao Pedra

ID: IBC-00002247

Analyst: John O'Neill

VA-Related: No

Discussion: This modification involves the use of *Borrelia spp.* in animals and is approved using ABSL-2 practices and ABSL-1 facilities. The following modifications were made to secure approval: 1) Updated IACUC information and 2) Described biosecurity procedures for hypothetical animal escape.

Status: Approved

Short Title: Genetic studies of hearing and vision impairment

Investigator: Saima Riazuddin

ID: IBC-00002828

Analyst: John O'Neill

VA-Related: No

Discussion: This modification involves the use of CRISPR/Cas9 technology to create transgenic 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. This modification also involves the use of mRNA in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-F-1 using ABSL-1 facilities and practices. The following modifications were made to secure approval: 1) Updated IACUC information and 2) Clarified the genes of interest for the morpholino, CRISPR/Cas9, and mRNA entries.

Status: Approved

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 lentivirus 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 modification also involves the use of a BAC containing MHV-A59 in *E. coli*, *S. cerevisiae*, human cells, monkey cells, and mouse cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-3-a using BSL-2 facilities and practices. The following modifications were made to secure approval: 1)

Changed the NIH Guideline for the new construct to III-D-3-a; 2) Fixed the typo in MHV-A59; 3) Moved the statement for MHV-A59 from "Animal Data" to "Pathogenicity"; 4) Removed outdated documents; and 5) Updated the attached SOP to the 2026 version.

Status: Approved

Short Title: Regulation of canonical and non-canonical substrates of histone lysine methyltransferases

Investigator: Jia-Ray Yu

ID: IBC-00008935

Analyst: John O'Neill

VA-Related: No

Discussion: This protocol involves the use of lentivirus 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 and is approved using BSL-2 facilities and practices with sharps precautions. This protocol also involves the use of baculovirus in insect cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-E-1 and is approved using BSL-1 facilities and practices. Finally, this protocol involves the use of plasmids and CRISPR/Cas9 technology in human and murine cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-F-8 Appendix C-1 and is approved using BSL-2 facilities and practices. The following modifications were made to secure approval: 1) Completed the training, qualifications, and procedures sections for the PI; 2) Added new laboratory staff; and 3) Added the bacterial selection marker for the lentiviral vector and plasmid.

Status: Approved

Short Title: Translational Laboratory Shared Service (TLSS)

Investigator: Rena Lapidus

ID: IBC-00001298

Analyst: John O'Neill

VA-Related: No

Discussion: This modification involves the use of previously transduced cells in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-1-a using ABSL-2 facilities and practices. The following modification was made to secure approval: Added updated language for lentivirus post-exposure prophylaxis.

Status: Approved

Short Title: STRUCTURAL AND FUNCTIONAL INVESTIGATIONS OF PROTEINS AND COMPLEXES

Investigator: Syed Saif Hasan

ID: IBC-00004974

Analyst: Holda Ramos

VA-Related: No

Discussion: This modification involves the generation of recombinant MHV-A59 in mammalian cells. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-3-a using BSL-2 facilities and practices. The following modifications were made to secure approval: 1) Moved safety information from the experimental design to the risk assessment pages and 2) Updated virus risk group.

Status: Approved

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

Short Title: IBC Submission: 2050GCCC: DALY II USA/MB-CART2019.1 for DLBCL
Investigator: Nancy Hardy
ID: IBC-00006160
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Endoplasmic Reticulum Mediated Neuroprotection in Neonatal Hypoxia Ischemia
Investigator: Jaylyn Waddell
ID: IBC-00006431
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Regeneration and tracking of specific cells and tissues by bone marrow transplantation in mice
Investigator: Li Zhang
ID: IBC-00000474
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Inhibition of Semaphorin 4D in the treatment of bone homing malignancies
Investigator: John Basile
ID: IBC-00004453
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Transgenic mice for research of neurodegenerative disease
Investigator: Peixin Yang
ID: IBC-00007128
Analyst: John O'Neill
VA-Related: No

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

Short Title: Viral inducers for use in mice

Investigator: Phuoc Tran

ID: IBC-00006675

Analyst: Holda Ramos

VA-Related: No

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

Short Title: IBC: 1985GCCC: CTL019 Out of Specification MAP for ALL or DLBCL Patients (HP-00086681)

Investigator: Nancy Hardy

ID: IBC-00005201

Analyst: John O'Neill

VA-Related: No

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

Short Title: Sex differences in osteoarthritis pain model

Investigator: Joyce Teixeira da Silva

ID: IBC-00008443

Analyst: Holda Ramos

VA-Related: No

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

Short Title: Discovering new post-translational regulatory mechanisms in Leishmania

Investigator: Franck Dumetz

ID: IBC-00008076

Analyst: John O'Neill

VA-Related: No

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

Short Title: IBC: Understanding the mechanism of neurosensory disorders

Investigator: Zubair Ahmed

ID: IBC-00003271

Analyst: John O'Neill

VA-Related: No

Discussion: This modification has been administratively approved for the use of *Haemophilus influenzae* in animals using ABSL-2 facilities and practices.

Short Title: Regulation of canonical and non-canonical substrates of histone lysine methyltransferases

Investigator: Jia-Ray Yu

ID: IBC-00008935
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for the use of previously transfected human cells *in vitro*. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-F-8 Appendix C-1 using BSL-2 facilities and practices.

Short Title: Identification of growth deficiency in Osteogenesis Imperfecta
Investigator: Satoru Otsuru
ID: IBC-00004520
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes in laboratory location and biosafety cabinets certification dates.

Short Title: Cancer and Angiogenesis in Mice
Investigator: Toni Antalis
ID: IBC-00002240
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for clarification of the cell lines.

Short Title: Epigenetic and molecular signatures specific to transplantation and ex vivo perfusion
Investigator: Valeria Mas
ID: IBC-00005933
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Role of TLR4 signaling in Innate and Adaptive Responses to pathogens
Investigator: Stefanie Vogel
ID: IBC-00001187
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for the addition of Influenza 6:2-PR8 H5N1 which will be used in animals using ABSL-2 facilities and practices.

Short Title: Mechanisms of synaptic physiology and neurodegenerative diseases
Investigator: Leonardo Parra-Rivas
ID: IBC-00008690
Analyst: Holda Ramos

VA-Related:	No
Discussion:	This modification has been administratively approved for changes in personnel.
Short Title:	Protein NEDD9 in pulmonary arterial hypertension
Investigator:	Bradley Maron
ID:	IBC-00007440
Analyst:	John O'Neill
VA-Related:	No
Discussion:	This modification has been administratively approved for the use of siRNA in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-F-1 using ABSL-1 facilities and practices.
Short Title:	Cytoskeletal proteins in striated muscle pathophysiology
Investigator:	Aikaterini Kontrogianni-Konstantopoulos
ID:	IBC-00001018
Analyst:	John O'Neill
VA-Related:	No
Discussion:	This modification has been administratively approved for updates to personnel and the animal-use protocol.
Short Title:	Role of TLR4 signaling in Innate and Adaptive Responses to pathogens
Investigator:	Stefanie Vogel
ID:	IBC-00001187
Analyst:	John O'Neill
VA-Related:	No
Discussion:	This modification has been administratively approved for the addition of Influenza A/HKx31 (H3N2) which will be used in animals using ABSL-2 facilities and practices.