

Institutional Biosafety Committee

7/11/2025, 12:00PM – 12:45PM

Teleconference

Minutes

Voting Members Present: Marianne Cloeren, Karen Scanlon, Alan Schmaljohn, J. Kristie Johnson, John O'Neill, Irina Luzina, Janna Barcelo, Matthew Frieman, Sherry Bohn, Robert Ernst, Ciaran Skerry, Matthew Fischer

Voting Members Absent: Brian Taylor, Ami A. Patel, Ron McNeil, Melissa Morland, Elizabeth Bramhall, Anthony Kim, Theresa Marth, Joseph Gillespie, Alfredo Garzino-Demo

Other Person(s) Present: No other persons were present at the meeting.

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

1 Vote on Last Meeting's Minutes

Institutional Biosafety Committee meeting on 6/6/2025

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).

- NIH NOT-OD-25-127 gave institutions 12 days to review their entire research portfolio for what EO 14292 defines as "Dangerous Gain of Function." No NIH-funded studies met this definition.
- The USDA reached directly out to an IMET PI regarding "Dangerous Gain of Function" review. As they are UMBC faculty, that institution took the lead for a response.
- Our next meeting is scheduled for Friday, August 1st.
- Member issues
 - EHS is hiring for a lab inspector.

3 Select Agent Program Oversight

- We received the results from our select agent inspection. We had one request for more information, but no findings at this time.

4 Reportable Incidents

- No reportable events occurred this month.

5 Modification Discussions

Short Title: Engineering adenoviral vectors as vaccines for infectious disease

Investigator: Lynda Coughlan

ID: IBC-00005922
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of plasmids in non-pathogenic *E. coli* and mammalian 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-2 facilities and practices.
Motion: Approve the Modification
Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: Electrical Signaling at the Mitochondrion in Health and Disease
Investigator: Vivek Garg
ID: IBC-00005962
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of a lentiviral vector in mammalian 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.
Motion: Approve the Modification
Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: Role of Cacna1c in mood disorder related behaviors in the mouse using AAV Cre to delete Cacna1c in Floxed Cacna1c mice.
Investigator: Todd Gould
ID: IBC-00002171
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the addition of new recombinant AAV constructs in animals. This work is classified by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules as III-D-4-a using BSL-1 and A-BSL-1 facilities and practices. The following modification is required to secure approval: Update the IACUC information.
Motion: RMSA
Vote: For: 11, Against: 0, Abstained: 0, Recused: 0

Short Title: Translational Laboratory Shared Service (TLSS)
Investigator: Rena Lapidus
ID: IBC-00001298
Analyst: Holda Ramos
VA-Related: No

Discussion: This modification involves the addition of previously transduced human cells in animals. 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/ABSL-2 facilities and practices.

Motion: Approve the Modification

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

Short Title: Xenotransplantation of genetically engineered porcine hearts in baboons

Investigator: Muhammad Mohiuddin

ID: IBC-00006063

Analyst: John O'Neill

VA-Related: No

Discussion: This modification involves the use of lentiviral vectors in murine and porcine 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-1-a and is approved using BSL-2 facilities and practices with sharps precautions for the lentiviral transduction and ABSL-1 for the engraftment in animals.

Motion: Approve the Modification

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

Short Title: Adeno-associated viral (AAV) gene insertion to manipulate neural activity during drug craving and social behaviors

Investigator: Marco Venniro

ID: IBC-00006148

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 using ABSL-1 facilities and practices. The following modification is required to secure approval: Explicitly add DREADD to the genes of interest.

Motion: RMSA

Vote: For: 12, Against: 0, Abstained: 0, Recused: 0

Short Title: Development and evaluation of novel nanotherapies for glioblastoma in clinically relevant animal models

Investigator: Graeme Woodworth

ID: IBC-00002350

Analyst: John O'Neill

VA-Related: No

Discussion: This modification involves the use of lentiviral vectors 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-1-a and is approved using BSL-2/ABSL-2 facilities and practices with sharps precautions.

Motion: Approve the Modification
Vote: For: 12, Against: 0, Abstained: 0, Recused: 0

Short Title: Maintenance of transgenic and wild type zebrafish for molecular endocrinology and developmental biology studies.
Investigator: Yonathan Zohar
ID: IBC-00002423
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of plasmids for the creation of 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 Crispr/Cas9 technology without a vector 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. The following modification is required to secure approval: Update the personnel.
Motion: RMSA
Vote: For: 12, Against: 0, Abstained: 0, Recused: 0

6 RMSA Follow Up

Short Title: Molecular Imaging Mouse
Investigator: Vikas Kundra
ID: IBC-00006585
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of adenovirus, retrovirus, and lentiviral vectors used in *E. coli* and 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-1-a and is approved using BSL-2/ABSL-2 facilities and practices with sharps precautions. This modification also involves the use of AAV in *E. coli* and 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 and is approved using BSL-1/ABSL-1 facilities and practices. The following modification was made to secure approval: Recombinant DNA entries which were made redundant by the latest modification have been removed.
Status: Approved

Short Title: Development and evaluation of novel nanotherapies for glioblastoma in clinically relevant animal models
Investigator: Graeme Woodworth
ID: IBC-00002350
Analyst: John O'Neill

VA-Related: No
Discussion: This protocol was previously approved for use of recombinant tumor cell lines in animals. This work is classified by the NIH Guidelines for Recombinant or Synthetic Nucleic Acid Molecules as III-D-4-b and is approved using BSL-2 and ABSL-2 facilities and practices. It has been modified to change committee-approved precautions to administer tumor cell lines to animals outside of a biosafety cabinet. PPE described includes eye protection and masks as outlined in the OSHA bloodborne pathogen standard. The following modification was made to secure approval: Removed the sentence that stated injection is not an aerosol producing procedure.
Status: Approved

Short Title: Xenotransplantation of genetically engineered porcine kidneys and livers in baboons
Investigator: Raphael Meier
ID: IBC-00008213
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the xenotransplantation kidneys and livers from genetically engineered 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. The following modification was made to secure approval: Removed mention of modified mesenchymal stem cells.
Status: Approved

Short Title: Target validation studies in lung pathogenesis
Investigator: Alison Scott
ID: IBC-00008240
Analyst: Holda Ramos
VA-Related: No
Discussion: This protocol involves the use of SARS-CoV-2-infected cells and is approved using BSL-2 facility and practices. The following modifications were made to secure approval: 1) Provided references for fixation methods, 2) Updated the medical monitoring plan, 3) Updated the health risk factors, and 4) Provided detailed procedures for the pre-fixation stage.
Status: Approved

Short Title: Anti-Cancer Therapies
Investigator: Joseph P Stains
ID: IBC-00006568
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the use of previously transfected murine carcinoma cells in animals. This work is classified by the NIH Guidelines for Research Involving

Recombinant or Synthetic Nucleic Acid Molecules as III-D-4-a and is approved using BSL-1/ABSL-1 facilities and practices. The following modification was made to secure approval: Corrected risk group and vector information.

Status: Approved

Short Title: Target Validation and Screening (CBT) and Therapeutic Working Group (TWG)
Investigator: David Weber
ID: IBC-00004265
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of previously transduced murine cells 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. The following modification was made to secure approval: Elaborated further for the experimental design.

Status: Approved

7 Non-Exempt Protocols with Periodic Reviews

Short Title: IBC Submission: Malaria CVD 35000; BNT165-02
Investigator: Matthew Laurens
ID: IBC-00007459
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Role of trkB in Descending Pain Modulation
Investigator: Susan Dorsey
ID: IBC-00001192
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IBC Submission: i-LIVER
Investigator: Lydia Tang
ID: IBC-00007631
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Animal models with increased RBC turnover
Investigator: Elizabeth Rochon
ID: IBC-00006924

Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Effect of gene transfer of anti thrombotic factors on the formation and resolution in mouse inferior vena cava (IVC) thrombus
Investigator: Rajabrata Sarkar
ID: IBC-00000993
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IBC: 2091GCCC: GMCI plus Standard of Care Immune Checkpoint Inhibitor for Stage III/IV NSCLC Patients (HP-00094281)
Investigator: Ranee Mehra
ID: IBC-00006005
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Neural mechanisms of allergic symptoms in rhinosinusitis
Investigator: PANG-YEN TSENG
ID: IBC-00007547
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Animal Models in Cortical Dysplasia
Investigator: Peter Crino
ID: IBC-00003858
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Assessment of sex differences and estrogen effects on sleep regulating cells in preoptic brain regions
Investigator: Jessica Mong
ID: IBC-00005329
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IBC Submission: DMID 23-0015; Lassa Fever CVD 1000
Investigator: Justin Ortiz
ID: IBC-00007865
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Opioid withdrawal and depression comorbidity
Investigator: Gregory Elmer
ID: IBC-00006937
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IBC: 2259GCCC: Axicabtagene Ciloleucel vs SOC Therapy in Participants with R/R Follicular Lymphoma
Investigator: Jean Yared
ID: IBC-00007027
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Specific cell protein depletion using small inhibitory RNA species
Investigator: Stephen Thom
ID: IBC-00003564
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: L platin-a novel target for intervention in the treatment of osteoporosis
Investigator: Meenakshi Chellaiah
ID: IBC-00002812
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Recombinant Hemoprotein Creation and Testing
Investigator: Jason Rose
ID: IBC-00006979
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: IBC: 2339GCCC: Ph I/IIa of BNT142 in patients with CLDN6-positive advanced solid tumors
Investigator: Heather Mannuel
ID: IBC-00007420
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Gene transfer in mouse hindlimb ischemia.
Investigator: Rajabrata Sarkar
ID: IBC-00000618
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Co-transplantation of MMP-9 enhanced Mesenchymal Stem Cells and Pancreatic Islets for the Treatment of Type 1 Diabetes
Investigator: Raphael Meier
ID: IBC-00007965
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Animal Models in Cortical Dysplasia
Investigator: Peter Crino
ID: IBC-00003858
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Recombinant Anthrax Toxin Studies
Investigator: Bryan Krantz
ID: IBC-00002947
Analyst: Holda Ramos
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IBC Submission: CMV CVD 2000; mRNA-1647-P104
Investigator: James Campbell
ID: IBC-00006870
Analyst: John O'Neill

VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Immunopathogenesis of Infectious Diseases
Investigator: Joao Pedra
ID: IBC-00002247
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Ultrasound-Mediated Microbubble Coupled Plasmid sFlt-1 or VEGF Gene Delivery in the Pregnant Baboon and offspring.
Investigator: Eugene Albrecht
ID: IBC-00001512
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Animal models with increased RBC turnover
Investigator: Elizabeth Rochon
ID: IBC-00006924
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Lentivirus transduction into cells for virus trafficking experiments and CRISPR-CAS9 gene targeting
Investigator: Matthew Frieman
ID: IBC-00002935
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Stem cell therapy for brain injury and peripheral nerve injury
Investigator: Xiaofeng Jia
ID: IBC-00002658
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Role of Drug Transporters in Xenobiotic Disposition and Transporter Physiology
Investigator: Yan Shu

ID: IBC-00000213
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Investigation of SARS-CoV-2 and related coronaviruses
Investigator: Matthew Frieman
ID: IBC-00005484
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: IL-1(beta) regulation of perinatal brain injury
Investigator: Irina Burd
ID: IBC-00007015
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for work with non-recombinant HIV in tissue culture using BSL-2 and A-BSL-2 facility and practices with sharps precautions.

Short Title: Comprehensive Analysis of Polycystin Related Endothelial Cell Signaling Pathways
Investigator: Terry Watnick
ID: IBC-00002098
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of plasmids in 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.

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 has been administratively approved for the removal of experiments that are no longer being performed.

Short Title: Automated Stem Cell Radiolabeling via 3D Microprinting-Enabled Microfluidics
Investigator: Mirosław Janowski
ID: IBC-00005346
Analyst: John O'Neill

VA-Related: Yes
Discussion: This modification has been administratively approved for the change of title.

Short Title: Interferon stimulated gene screening for inhibition of Coronavirus replication
Investigator: Matthew Frieman
ID: IBC-00002073
Analyst: John O'Neill
VA-Related: Yes
Discussion: There have been no substantive changes to this protocol submission.

Short Title: In vitro and In vivo analysis of the SARS Coronavirus
Investigator: Matthew Frieman
ID: IBC-00000711
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: This protocol has been administratively approved for changes in personnel.

Short Title: Molecular and Cellular Physiology of HERG K channels
Investigator: Matthew Trudeau
ID: IBC-00001397
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Evolution of pathogenic Aeromonas species
Investigator: David Rasko
ID: IBC-00007713
Analyst: Holda Ramos
VA-Related: No
Discussion: This protocol has been administratively approved for changes in work location.

Short Title: Lipid A modification of BSL-3 Gram-negative bacteria
Investigator: Robert Ernst
ID: IBC-00000133
Analyst: John O'Neill

VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: In vitro and In vivo analysis of the MERS Coronavirus
Investigator: Matthew Frieman
ID: IBC-00002089
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Investigation of SARS-CoV-2 and related coronaviruses
Investigator: Matthew Frieman
ID: IBC-00005484
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for the removal of experiments that are no longer being performed.

Short Title: Molecular and Cellular Physiology of HERG K channels
Investigator: Matthew Trudeau
ID: IBC-00001397
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for a change in personnel.

Short Title: Breeding of Genetically Deficient Mice
Investigator: Toni Antalis
ID: IBC-00001180
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Recombinant Hemoprotein Creation and Testing
Investigator: Jason Rose
ID: IBC-00006979
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes 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 the removal of experiments that are no longer being performed.

Short Title: Expression of Viral Proteins in Yeast for Function Identification and Drug Screens
Investigator: Matthew Frieman
ID: IBC-00003326
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission.

Short Title: Cyclic nucleotide signaling in memory and social behaviors
Investigator: Michy Kelly
ID: IBC-00005947
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for work with human and NHP tissue using BSL-2 facilities and practices.