

Institutional Biosafety Committee

10/6/2025, 12:05PM – 12:50PM

Teleconference

Minutes

Voting Members Present: Karen Scanlon, Ron McNeil, 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, Marianne Cloeren, Alan Schmaljohn, Melissa Morland, Elizabeth Bramhall, Anthony Kim, J. Kristie Johnson, Theresa Marth, Joseph Gillespie, Sammy Almashat, Jessie Duggan, 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 9/5/2025

Votes to approve minutes: 10, 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 meeting of the DURC Institutional Review Entity was held today.
- October is Biosafety and Biosecurity month. Events include an FBI webinar on biosecurity as well as tabling events with things like trivia and treats.
- The NIH held a listening session on September 30th regarding the future of IBCs.
- 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, November 7th
- Member issues
 - ChABSA has a social event in New Market, MD on October 9th.
 - ASM Maryland has a meeting at UMBC on October 15th entitled "Landmarks in Clinical Microbiology: an Editor's Perspective"
 - ChABSA has a dinner meeting on November 12th in Ellicott City entitled "Rate of Errors During Routine Biological Manipulation"

3 Reportable Incidents

- A first report of injury was received that mentioned use of a recombinant Herpes Simplex Virus 1. Although interviews suggest a very low probability that illness was the result of a laboratory exposure, an incident report was submitted to the NIH Office of Science Policy.
- No other reportable events occurred this month.

4 Select Agent Program Oversight

- The annual select agent exercise is scheduled for October 22nd.
- Holda Ramos has been submitted as an Alternate Responsible Official.

5 New IBC Submission

Short Title: Molecular Drivers of Pulmonary Vascular Remodeling in PH-HFpEF
Investigator: Yen-Chun (Charly) Lai
ID: IBC-00008473
Analyst: John O'Neill
VA-Related: No
Discussion: This protocol 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. This protocol also involves the use of plasmids and siRNA in human 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 III-F-1, respectively, using BSL-2 facilities and practices. The following modifications are required to secure approval: 1) Re-write the Lay Abstract for non-scientists; 2) Add scrambled control AAV constructs; 3) Clarify AAV constructs for the expression or knock down of genes; 4) Clarify that CAT2 and hSLC7A2 are the same gene; 5) Add fluorescent molecule under genes to be expressed; 6) Correct the NIH Guideline for the use of siRNA to III-F-1; and 7) Fix the typo of the word "human."
Motion: RMSA
Vote: For: 10, Against: 0, Abstained: 0, Recused: 0

6 Modification Discussions

Short Title: Molecular Imaging Mouse
Investigator: Vikas Kundra
ID: IBC-00006585
Analyst: Holda Ramos
VA-Related: No
Discussion: This protocol was previously approved for work with AAV, retrovirus, and lentivirus vectors *in vitro*, and plasmids *in vitro* and *in vivo*. It has been modified to include all the work being done *in vivo* and *in vitro*, and the addition of new cell lines. 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 procedure rooms.
Motion: RMSA
Vote: For: 10, Against: 0, Abstained: 0, Recused: 0

Short Title: Mechanisms of fate determination in peripheral T cells
Investigator: Nevil Singh

ID: IBC-00002339
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the addition of new plasmids and cell lines in animals. This work is classified by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules as III-D-1-a and is approved using BSL-1 and A-BSL-1 facility and practices.
Motion: Approve the Modification
Vote: For: 10, 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: John O'Neill
VA-Related: No
Discussion: This modification involves an additional wild-type MERS-CoV strain which will be used in animals using ABSL-3 facilities and practices. The following modifications are required to secure approval: 1) Update the past statement that a strain will be acquired in the future, if necessary and 2) Update the biosafety cabinet certification date.
Motion: RMSA
Vote: For: 9, Against: 0, Abstained: 0, Recused: 1 (Matthew Frieman)

Short Title: Dissecting Neural Circuits of Learning and Emotion
Investigator: Barbara Juarez
ID: IBC-00007058
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the addition of new AAV constructs 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 and A-BSL-1 facilities and practices.
Motion: Approve the Modification
Vote: For: 10, Against: 0, Abstained: 0, Recused: 0

Short Title: The functional role of Akt on dopamine release
Investigator: Joseph Cheer
ID: IBC-00000335
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the addition of a new AAV construct 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 and ABSL-1 facilities and practices.

Motion: Approve the Modification
Vote: For: 10, Against: 0, Abstained: 0, Recused: 0

Short Title: Labeling glioma or neural stem cells with fluorescent reporters for multiplex single cell tracking
Investigator: Yajie Liang
ID: IBC-00006162
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the use of murine retroviral vectors in mammalian cells. This work is classified by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules as III-D-1-a using BSL-2 and A-BSL-2 facility and practices. The following modifications are required to secure approval: 1) Elaborate in the experimental design, 2) Add discussion of the tropism of the vector, and 3) Remove superfluous entry in the lentivirus table.
Motion: RMSA
Vote: For: 10, Against: 0, Abstained: 0, Recused: 0

Short Title: Animal Models in Cortical Dysplasia
Investigator: Peter Crino
ID: IBC-00003858
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the addition of plasmids and new genes of interest using CRISPR-Cas9 technology 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: 10, Against: 0, Abstained: 0, Recused: 0

Short Title: Mechanism of Rickettsia-Host-interaction (BSL-2)
Investigator: Mohammed Rahman
ID: IBC-00007650
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the addition of previously transposed *R. parkeri* mutants in animals. They also added a new gene of interest to all previously approved work in the rDNA table. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-D-1-a using BSL-2 and ABSL-2 facilities and practices. The following modifications are required to secure approval: 1) Update IACUC protocol number, 2) Clarify the use of antibiotic resistance, and 3) Update BSC certification date.
Motion: RMSA

Vote: For: 10, Against: 0, Abstained: 0, Recused: 0

Short Title: Ion channel dysfunction in neuromuscular disorders and aging
Investigator: Christopher Ward
ID: IBC-00005450
Analyst: John O'Neill
VA-Related: No
Discussion: This modification involves the use of AAV and plasmids 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: 10, Against: 0, Abstained: 0, Recused: 0

Short Title: ProSAAS-mediated neuroprotective mechanisms in Alzheimer's and Parkinson's diseases
Investigator: Iris Lindberg
ID: IBC-00004821
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the addition of a lentivirus and AAV in animals. This work is classified by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules as III-D-1-a and using BSL-2 and ABL-2 facilities and practices. The following modification is required to secure approval: Update the IACUC number.
Motion: RMSA
Vote: For: 10, Against: 0, Abstained: 0, Recused: 0

7 RMSA Follow Up

Short Title: Therapeutic applications of focused ultrasound
Investigator: Pavlos Anastasiadis
ID: IBC-00008237
Analyst: John O'Neill
VA-Related: No
Discussion: This protocol involves the use of a sindbis viral vector 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. The following modifications were made to secure approval: 1) Corrected the typo in the title; 2) Removed extraneous details from the Scientific Abstract; 3) Clarified in the experimental design what is happening in this laboratory versus that of the collaborator; 4) Clarified the funding source; 5) Corrected the risk groups of the host and vector; 6) Added a pathogenicity statement for Sindbis virus; and 7) Explicitly listed all PPE to be used.
Status: Approved

Short Title: Develop a DNA based vaccine for *Mycobacterium marinum* in fish

Investigator: Nili Zmora
ID: IBC-00008482
Analyst: John O'Neill
VA-Related: No
Discussion: This protocol involves the use of plasmids 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 modifications were made to secure approval: 1) Corrected the typo in the title; 2) Added the IACUC Principal Investigator to this IBC protocol; and 3) Described the precautions used to prevent accidental needlesticks when injecting fish.
Status: Approved

Short Title: Sex differences in osteoarthritis pain model
Investigator: Joyce Teixeira da Silva
ID: IBC-00008443
Analyst: Holda Ramos
VA-Related: No
Discussion: This protocol involves the use of AAV 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 facilities and ABSL-1 practices. The following modifications were made to secure approval: 1) Updated IACUC information and 2) Listed equivalent names of the AAV genes of interest used.
Status: Approved

Short Title: Fetal Gene Delivery Using Low-Intensity Focused Ultrasound
Investigator: Whitney Parker
ID: IBC-00007792
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification involves the addition of plasmids and CRISPR technology 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: Updated personnel.
Motion: Approved

Short Title: Understanding the molecular mechanisms driving pulmonary fibrosis
Investigator: Konstantin Tsoyi
ID: IBC-00008472
Analyst: John O'Neill
VA-Related: No
Discussion: This protocol involves the use of lentiviral vectors in murine and 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 with sharps precautions. The following modifications were made to secure approval: 1) Removed extraneous chemical procedures from the abstract; 2) Defined disinfection method; and 3) Added sharps precautions related to work with lentiviral vectors.

Status: Approved

Short Title: Determine the efficacy of morpholino oligonucleotides in a rodent models of myotonic dystrophy

Investigator: Joseph P Stains

ID: IBC-00006467

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. This modification also involves the use of morpholinos and mRNA in animals. This work is classified by the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acids as III-F-1 and is approved using ABSL-1 facilities and practices. The following modifications were made to secure approval: 1) Updated personnel and 2) Removed expired animal-use documents.

Status: Approved

7 Non-Exempt Protocols with Periodic Reviews

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: 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: Tissue-specific delivery of nitroxide imaging probes for Electron Paramagnetic Resonance Imaging (EPRI)

Investigator: Joseph Kao

ID: IBC-00003567

Analyst: John O'Neill

VA-Related: No

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

Short Title: Cytoskeletal proteins in striated muscle pathophysiology

Investigator: Aikaterini Kontrogianni-Konstantopoulos

ID: IBC-00001018

Analyst: Holda Ramos

VA-Related: No

Discussion: There have been no substantial 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: Development of Small Molecules for Cancer Therapy

Investigator: Vincent Njar

ID: IBC-00002284

Analyst: John O'Neill

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: 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: Production of ETEC and Salmonella antigens from non-pathogenic *E. coli* expression vectors, and *S. aureus* capsule polysaccharides from wild-type strains

Investigator: Scott Baliban

ID: IBC-00003044

Analyst: Holda Ramos
VA-Related: No
Discussion: This protocol has been administratively approved for changes in personnel.

Short Title: Disease mechanism of cortical malformations
Investigator: Philip Iffland
ID: IBC-00007254
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Cancer Biology and Novel Agents in Lung Cancer
Investigator: John Schmitz
ID: IBC-00007728
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

Short Title: Virotherapy for vaccine and oncology applications
Investigator: Bolni Nagalo
ID: IBC-00008432
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for a change in personnel.

Short Title: Mechanisms of Regulatory T Cell Function in Mouse Models of Tumor and Transplantation
Investigator: Xuefang Cao
ID: IBC-00004347
Analyst: Holda Ramos
VA-Related: No
Discussion: This modification has been administratively approved for update of personnel and addition of procedure room.

Short Title: Animal Models in Cortical Dysplasia
Investigator: Peter Crino
ID: IBC-00003858
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for a change in personnel.

Short Title: Animal Models in Cortical Dysplasia

Investigator: Peter Crino
ID: IBC-00003858
Analyst: John O'Neill
VA-Related: No
Discussion: This modification has been administratively approved for changes in personnel.

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: Rickettsia cell envelope glycoconjugates are derived from the host cell amino sugar biosynthesis pathway
Investigator: Joseph Gillespie
ID: IBC-00005814
Analyst: John O'Neill
VA-Related: No
Discussion: There have been no substantive changes to this protocol submission