Institutional Biosafety Committee
Meeting Minutes

Tuesday, January 27, 2026 3pm Abigail Wexner Research Institute or Virtual via Teams

National Institutes of Health Office of Science Policy has provided guidance on Institutional Biosafety Committee (IBC) meetings and minutes to document and capture that the IBC has adequately fulfilled their responsibilities as defined in Section IV-B-2 of the NIH Guidelines. As described in the March 28, 2025, Guide Notice, NCH AWRI IBC is committed to complying with the transparency aims of the NIH Guidelines and IBC minutes are accessible to the public. Meetings and minutes will include application reviews with particular focus on the following items:

1. *Agent characteristics (e.g. virulence, pathogenicity, environmental stability)*
2. *Types of manipulations planned*
3. *Source of the nucleic acid sequences (e.g., species)*
4. *Nature of the nucleic acid sequences (e.g., structural gene, oncogene)*
5. *Host(s) and vector(s) to be used*
6. *Whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced*
7. *Containment conditions to be implemented (biosafety level and any special provisions)*
8. *Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.)*
9. *Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research*

Call to Order:	Call to order 3:00 PM; Meeting Adjourned at 4:00 PM.
Committee members in attendance:	Alex Brown, Kevin Cassady, Dakota Esterline, Sumit Ghosh, Amit Kapoor, Paul Martin, Christopher Montgomery, Addie Moore, Stefan Nicolau, Mark Peeples, Nizar Saad, Mary Walker, and Chack-Yung Yu
Members excused:	Carmen Arsuaga, Katie Campbell, McKayla Carlson, Tara Chinn, and Juan de Dios Ruiz Rosado
Guests in attendance:	Kelly Fallon
Approval of Minutes:	December 2025 IBC meeting minutes approved
Action Register:	The Action Register was reviewed and the following approved: Amendments Approved: Protocol # MS2_IBS00000738 -**Timothy Cripe "Clinical Research Office Laboratory"** Protocol # MS3_IBS00000906 -**Dean Lee "Development of a novel AAV9 gene replacement therapy "** Protocol # MS4_IBS00000921 -**Jenny Barker "Local management of MRSA"**

Protocol # MS5_IBS00000590 -**Dean Lee "CRISPR Gene Editing Using Viral Vectors, Plasmids and Electroporation in cancer cells and immune cells to enhance cancer immunotherapy"**

Protocol # MS8_IBS00000571 -**Dean Lee "CRISPR/Gene Editing Core Lab biosafety protocol"**

Protocol # MS2_IBS00000637 -**Nilsa Ramirez "Use of Human Source Material in the Biopathology Center"**

Protocol # MS9_IBS00000608 -**Karen McCoy "An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis"**

Contingencies Approved:

Protocol # IBS00001062 -**Bryce Kerlin "Investigation of Hemostasis in DTR Transgenic Rat and Mouse Models of Nephrosis"**

Protocol # IBS00001054 -**Amrik Singh Khalsa "Pathways2Prevention"**

Protocol # IBS00001067 -**Kevin Flanigan "Cell Line Engineering using Lentiviruses"**

Contingencies for Renewal:

New Business: Action Register Approved

Meeting Purpose: The IBC meeting was held as a closed session to ensure that only authorized individuals were present on the NCH campus, in order to uphold patient privacy and maintain the highest standards of safety and security.

Details:

Amendment # IBA11_IBS00000521 - Bline, Katherine - "Amendment 11 for IBCSC Protocol #IBS00000521"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of human source materials from patients with respiratory diseases.
2. **Types of manipulations planned:**
   The lab will be vortexing, pipetting, centrifuging and general processing of human source material samples to investigate Respiratory Syncytial Virus, Influenza, Pneumonia, Mycobacterium Tuberculosis and various other viruses that infect pediatric patients in our hospital in order to study the immune system, antibodies and genomics as well.
3. **Source of the nucleic acid sequences (e.g., species):**
   NA
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   NA
5. **Host(s) and vector(s) to be used:**
   NA
6. **Whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced:**
   NA
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL2

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8. **Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.):**
   Appendix G-II-B-1. Standard Microbiological Practices (BL2)
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   The PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification of where sample processing will occur and inclusion of the RNA extraction methodology

The Institutional Biosafety Committee has determined the status of the protocol to be: **Withheld with Contingencies – Minor.**

Protocol # IBS00001075 - Kopp, Benjamin - "Immune Research on Regulatory Mechanisms of Cystic Fibrosis"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   RG2 bacterial agents (bacteria used in the protocol cause disease in immune compromised such as people with Cystic Fibrosis, they are commonly found in the environment and have available antibiotic treatments) Human source material will also be used and bacteria will have genes deleted using CRISPR-CAS9.
2. **Types of manipulations planned:**
   Procedures involve a variety of microbiological, cellular, molecular, immunological, and biochemical techniques (e. g. western blot, confocal and electron microscopy, bacterial growth assays, flow cytometry assays, halide efflux, kinase assays, qRT-PCR, etc.) The CFTR gene will be deleted in cells using CRISPR-Cas9.
3. **Source of the nucleic acid sequences (e.g., species):**
   Human CFTR gene.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   CFTR (cystic fibrosis transmembrane conductance regulator), an ion channel with a role in regulating salt and water balance in epithelial cells.
5. **Host(s) and vector(s) to be used:**
   Human cell lines
6. **Whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced:**
   Knockout of gene in human monocyte derived macrophages, which are terminally differentiated cells that no longer divide.
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL2.
8. **Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.):**
   Appendix G-II-B-1. Standard Microbiological Practices (BL2)
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   The PI and lab staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification of appropriate disinfectant use; definition of BSL2+ practices; circumstances which work will be performed outside of a

biological safety cabinet; detailed description of CRISPR-Cas9 delivery to cells; eye protection requirements; and sharps disposal practices.

The Institutional Biosafety Committee has determined the status of the protocol to be: **Withheld with Contingencies – Minor.**

Protocol # IBS00001087 - Saad, Nizar - "Biomarkers of Neuromuscular Dystrophies"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of risk group 2 human source material samples specifically from patients with FSHD and some patients previously treated with AAV.
2. **Types of manipulations planned:**
   Serum or plasma samples will be processed to purify extracellular vesicles (EVs) through a number of steps including centrifugation, size exclusion chromatography, and density sedimentation. EVs will then be characterized by a variety of methods.
3. **Source of the nucleic acid sequences (e.g., species):**
   N/A
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   N/A
5. **Host(s) and vector(s) to be used:**
   N/A
6. **Whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced:**
   N/A
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL2
8. **Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.):**
   Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.): Appendix G-II-B-1. Standard Microbiological Practices (BL2)
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Verified the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification that AAV will not be directly handled (allowing removal of the Biological Agents section); safety glasses/goggle requirements; description of waste disposal for liquids and sharps; clarification regarding the use and processing of whole blood; and specification of bleach contact time for decontamination.

The Institutional Biosafety Committee has determined the status of the protocol to be: **Withheld with Contingencies – Minor.**

Protocol # IBS00001081 - Besner, Gail - "Evaluation and Treatment of NEC in Swine Model"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of risk group 1 probiotics and human body fluids, milk, at biosafety level 1 in vivo experiments.
2. **Types of manipulations planned:**
   Study involves in vivo inoculation of risk group 1 probiotics to study necrotizing enterocolitis (NEC) treatments.
3. **Source of the nucleic acid sequences (e.g., species):**
   N/A
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   N/A
5. **Host(s) and vector(s) to be used:**
   N/A
6. **Whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced:**
   N/A
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL1
8. **Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.):**
   Appendix B-I. Risk Group 1 (RG1) Agents; Appendix G-II-A. Biosafety Level 1 (BL1).
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Verified the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification of exemption of RG1 probiotics from IBC review and human breast milk from being classified as OPIM; personal protective equipment requirements; disinfectant use of EPA-approved tuberculocidal agent for work; and information regarding potential contaminants mentioned.

The Institutional Biosafety Committee has determined the status of the protocol to be: **Withheld with Contingencies – Minor.**

Protocol # IBS00001080 - Drissi, Rachid - "Targeting Telomeres and Telomerase, and Epigenetic Alterations in Pediatric Brain Tumors"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   1. Non-replicating retrovirus and lentivirus system
2. **Types of manipulations planned:**
   In vitro cell culture and in vivo injection.
3. **Source of the nucleic acid sequences (e.g., species):**
   Received from other investigators some prepared in the lab
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   1. Telomere modifying genes (e.g. hTERT telomerase reverse transcriptase) 2. proto-oncogenes (e.g. hDEK an AML associated gene that makes a protein that binds DNA to promote supercoiling and affects RNA splice site selection)
5. **Host(s) and vector(s) to be used:**
   LV and Retrovirus obtained from outside source "The Retro and Lentiviral vectors will

be purchased from an approved vendor, core at NCH/OSU or from collaborators (with an approved MTA in place)."

6. **Whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced:**
   As described above they are expressing proto-oncogenes and hTERT as well as KD of genes regulating telomere length and other pro-carcinogenic factors to investigate the biology of these difficult to treat cancers.
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL2
8. **Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.):**
   NIH Guidelines Appendix G-II-B-1. Standard Microbiological Practices (BL2) (a-h) Appendix G-II-B-2. Special Practices (BL2) (a-m) Appendix G-II-B-3. Containment Equipment (BL2) (a-f)
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Verified the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification of xenograft practices; abstract revision; clarification of sample sources; CRISPR Core name update; removal of excess implantation detail; correction of biosafety cabinet type; clarification of safer sharps practices; removal of NHP selection and unintended biological agent questions; clarification of oncogene activity in xenografts; specification of storage conditions and vector use; description of BSL2+ practices; and update of the incident reporting system.

The Institutional Biosafety Committee has determined the status of the protocol to be: **Withheld with Contingencies – Major.**

Protocol # IBS00001083 - Tanaka, Ryuma - "Phase 2 Study of BCB-276 CAR T Therapy in DIPG"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   B7-H3-Specific CAR T Cell infusion in children and young adults with Diffuse Intrinsic Pontine Glioma (DIPG)
2. **Types of manipulations planned:**
   Study involves handling human source material donated from participants via apheresis to ship for manufacturing CAR T cells to be received by patients in an intraventricular administration every 14 days (+/- 2 days) for a maximum of 15 doses
3. **Source of the nucleic acid sequences (e.g., species):**
   BCB-276 is derived from autologous T cells genetically modified with a second-generation (4-1BBζ) B7-H3–specific chimeric antigen receptor (CAR). The product consists of autologous CD4+ and CD8+ T cells obtained from apheresis starting material that undergoes CD4 and CD8 immunomagnetic selection, activation with CD3/CD28 beads, and transduction with a self-inactivating (SIN) lentiviral vector encoding a B7-H3–specific second-generation (4-1BBζ) CAR and a dihydrofolate reductase double mutant (DHFRdm) conferring methotrexate (MTX) resistance, followed by cell expansion.

4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Binds the extracellular domain of human B7-H3 and exhibits strong differential reactivity to tumor tissue compared with normal tissue.
5. **Host(s) and vector(s) to be used:**
   Human research participants
6. **Whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced:**
   B7-H3 as a target to increase T cell binding to and activity on DIPG
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL2
8. **Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.):**
   Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.): Section III-C. Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation; Appendix G-II-B-1. Standard Microbiological Practices (BL2)
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Verified the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification of General Protocol Question 6.1; clarification of disposal practices and cellular therapy product handling; resolution of inconsistencies regarding viral-free manufacturing; and confirmation that replication-defective lentiviral vectors are tested for replication-competent virus.

The Institutional Biosafety Committee has determined the status of the protocol to be: **Withheld with Contingencies – Minor.**

Protocol # IBS00001072 - Harper, Scott - "AAV-mediated Gene Therapy for Dominant Myopathies and Neurodegenerative Diseases"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   1. Lentivirus (BSL2) using VSV pseudotyping (gen 2 or 3?) 2. AAV (BSL1) 3. Primate blood/ tissue exposure - not defined but interested in neurologic disease so assume nervous system tissue 4. Porcine blood and tissue 5. Human Blood and Tissue (blood borne pathogen risk).
2. **Types of manipulations planned:**
   siRNA based gene knockdown (animal-injection of AAV) siRNA and Gene overexpression LV based cell culture
3. **Source of the nucleic acid sequences (e.g., species):**
   Lab generated clones and gene mutations
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   reporters (luc and fluorescent) U6 promoter driven miRNA Some structural proteins (e.g. MYOT) Enzymes (e.g. glycyl tRNA synthetase) Transcription factor (DUX4) Dynamin 1 (DNM1) gene involved in Neurotransmitter recycling by endocytosis. No oncogenes
5. **Host(s) and vector(s) to be used:**
   E coli: Plasmids propagation DH5alpha or DH10B or TOP10 cells. AAV vectors are

used in vivo, primarily in mice. Lentiviral vectors are only delivered to cells in vitro. (propagated in Hek293 cells using split plasmid system).

6. **Whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced:**
   Yes: one structural proteins (e.g. MYOT) Enzymes (e.g. glycyl tRNA synthetase) Transcription factor (DUX4) Dynamin 1 (DNM1) gene involved in Neurotransmitter recycling by endocytosis.
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL2 No info on Blood borne
8. **Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.):**
   Appendix G-II-B-1. Standard Microbiological Practices (BL2)
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Verified the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification of study staff; vector source and replication-defective status; personnel and environmental risks; required training; clarification of work locations, centrifugation controls, PPE, safer sharps practices, and agent administration procedures; waste disposal and disinfection practices.

The Institutional Biosafety Committee has determined the status of the protocol to be: **Withheld with Contingencies – Minor.**

Old Business: