# Institutional Biosafety Committee

# Meeting Minutes

Tuesday, February 24, 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*

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| **Call to Order:** | Meeting called to order at 3:01PM. Meeting adjourned at 3:49PM. |
| **Committee members in attendance:** | Carmen Arsuaga, Alex Brown, Kevin Cassady, Tara Chinn, Dakota Esterline, Sumit Ghosh, Amit Kapoor, Yusen Liu, Paul Martin, Christopher Montgomery, Stefan Nicolau, Nizar Saad, and Chack-Yung Yu |
| **Members excused:** | Katie Campbell, McKayla Carlson, Addie Moore, Mark Peeples, Juan de Dios Ruiz Rosado, and Mary Walker |
| **Guests in attendance:** | Kelly Fallon, and Jennifer Ramsey |
| **Approval of Minutes:** | January 2026 IBC meeting minutes approved |
| **Action Register:** | The Action Register was reviewed and the following approved:<br>Amendments Approved: |

Protocol # MS11_IBS00000608 -**Karen McCoy "An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis"**

Protocol # MS10_IBS00000608 -**Karen McCoy "An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis"**

Protocol # MS22_IBS00000530 -**Allison Bradbury "AAV delivery to the central nervous system "**

Contingencies Approved:

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

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

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

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

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

Contingencies for Renewal:

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**New Business:** Updates to IBC Conduct of Business SOP

**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 # IBA2_IBS00000801 - Isaacs, Albert - "Amendment 2 for IBCSC Protocol #IBS00000801"**

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Risk group 1 viral vectors: AAV replication defective serotype 9
2. **Types of manipulations planned:**
   AAV in vivo
3. **Source of the nucleic acid sequences (e.g., species):**
   The AAV vector expresses the genetically encoded calcium indicator jGCaMP8f, a chimeric protein derived from rat, chicken, and Aequorea victoria GFP domains.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Calcium reporter
5. **Host(s) and vector(s) to be used:**
   Mouse models

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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:**
   Syn-driven expression of ultrafast calcium sensor GCaMP8f.
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   Biosafety level 1.
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-A-1. Standard Microbiological Practices (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 PPE; inclusion of AAV risk; and clarification of AAV function.

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

**Protocol # IBS00001091 - Bharucha-Goebel, Diana - "RGX-202 for Duchenne Muscular Dystrophy (DMD)"**

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Risk group 1, non-replicating, recombinant adeno-associated virus serotype (AAV8) encoding a miniaturized-dystrophin gene for the treatment of Duchenne Muscular Dystrophy (DMD).
2. **Types of manipulations planned:**
   In this study, participants will receive a dose of 2 x 10^14 genome copies/kg, delivered during a one-time systemic injection.
3. **Source of the nucleic acid sequences (e.g., species):**
   Human
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   A muscle specific Spc5-12 promoter, microdystrophin transgene, SV40 polyadenylation signal
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:**
   Expression of specific microdystrophin transgene
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   Biosafety level 2 for human source material handling; Biosafety level 1 for study agent.

8. **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 study-agent and enrollment information; description of sample processes; disposal procedures; confirmation of BSL2 practices; and clarification of administration locations.

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

**Protocol # IBS00001097 - Hester, Mark - "Understanding Molecular Mechanisms of Pediatric Epilepsy"**

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Human source material, viral vectors, and recombinant DNA at Biosafety level 2
2. **Types of manipulations planned:**
   Study involves handling human source material, viral vectors, recombinant DNA, to understand the molecular mechanisms of disease pathology in vitro and in vivo.
3. **Source of the nucleic acid sequences (e.g., species):**
   human TSC2, AUTS2, and other neurodevelopmental genes.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   AUTS2 is a nuclear and cytoplasmic protein to regulate gene expression and RNA metabolism, TSC regulates cell-cycle progression, and ERCC5 encodes protein essential in transcription
5. **Host(s) and vector(s) to be used:**
   Cell lines and mouse models
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:**
   gene knock-out in human cell lines
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   Biosafety level 2.
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 non-technical abstract; inclusion of CRISPR/Cas9-related risks; update biosafety manual reference; specification of PPE; clarification of sample source and risks; procurement details of viral vectors; update of incident-reporting system name; confirmation of biosafety cabinet use; and addition of AAV bedding-handling procedures.

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. Human Source Material
2. **Types of manipulations planned:**
   Study involves handling human source material, viral vectors, recombinant DNA, to understand the molecular mechanisms of disease pathology in vitro and in vivo.
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:**
   Gene knock-out in human cell lines 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):**
   Biosafety Level 2
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 abbreviation definitions.

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

**Protocol # IBS00001089 - Stanton, Benjamin - "Understanding the epigenetic drivers of childhood cancers"**

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of risk group 2 viral vectors (SeV and LV) and human source material
2. **Types of manipulations planned:**
   In vivo and in vitro manipulations including knockout, or expression of exogenous alleles of epigenetic regulators.
3. **Source of the nucleic acid sequences (e.g., species):**
   Reporters (Firefly Luc and Jellyfish), Human Genes
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Oncogenes, chromatin regulatory protein, fluorescent protein, regulatory kinase
5. **Host(s) and vector(s) to be used:**
   In vitro cell modifications
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:**
   Genetic manipulation and expression of exogenous alleles of epigenetic regulators.
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   Biosafety Level 2
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-B. Biosafety Level 2 (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 questions; simplification of the non-technical abstract; inclusion of related safety issues; updates of decontamination procedures, biosafety-cabinet terminology, and emergency contacts; added sample processing and disposal practices; correction of typographical errors and outdated references; confirmation of viral-vector sources and documentation of replication incompetence; inclusion of CRISPR/Cas9 experiment information; description of potential environmental consequences if loss of containment; and listing of required trainings.

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

**Amendment # IBA8_IBS00000685 - Shimamura, Masako - "Amendment 8 for IBCSC Protocol #IBS00000685"**

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Staphylococcus enterotoxin B produced by Staphylococcus aureus and can cause non-specific activation of T-cells; this agent is managed under biosafety level 2 and quantities small enough to be excluded from select agent toxin requirements
2. **Types of manipulations planned:**
   Study involves handling in vitro experiments with cell lines and toxin
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):**
   Biosafety level 2
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 inclusion of toxicity data and quantities; methods for inactivation; and addition of enterotoxin-related work in the abstract.

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