



# NATIONWIDE CHILDREN'S

*When your child needs a hospital, everything matters.™*

## Institutional Biosafety Committee

### Meeting Minutes

Monday, December 8, 2025 3pm Abigail Wexner Research Institute or Virtual via Teams

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*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:**

IBC meeting called to order at 3:00PM. IBC meeting adjourned at 3:30PM.

**Committee members in attendance:**

Carmen Arsuaga, Alex Brown, McKayla Carlson, Kevin Cassady, Sumit Ghosh, Amit Kapoor, Paul Martin, Christopher Montgomery, Stefan Nicolau, Mark Peeples, Juan de Dios Ruiz Rosado, and Nizar Saad

**Members excused:**

Allison Bradbury, Katie Campbell, Tara Chinn, Dakota Esterline, Addie Moore, Mary Walker, and Chack-Yung Yu

**Guests in attendance:**

Kelly Fallon

**Approval of Minutes:**

October meeting minutes approved.

**Action Register:**

The Action Register was reviewed and the following approved:

Amendments Approved:

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Protocol # MS3\_IBS00000575 -Rajan Thakkar "Burn Infection"

Protocol # MS21\_IBS00000530 -Allison Bradbury "AAV delivery to the central nervous system "

Protocol # MS3\_IBS00000921 -Jenny Barker "Local management of MRSA"

Protocol # MS1\_IBS00000804 -Kevin Flanigan "Center for Gene Therapy Clinical Trial Sample Handling Source Material Registration"

Protocol # MS10\_IBS00000599 -Timothy Cripe "Novel Biologic and Small Molecule Therapies for the Treatment of Pediatric Solid Tumors"

Protocol # MS3\_IBS00000829 -David Brigstock "Fibrosis modulation by extracellular vesicles"

Protocol # MS2\_IBS00000514 -Sam King "Studies of bacterial and viral pathogenesis"

Protocol # MS9\_IBS00000559 -Katherine Miller "Research handling of human tissues in the Institute for Genomic Medicine"

Protocol # MS7\_IBS00000582 -Masako Shimamura "CMV in Immunocompromised Host"

Protocol # MS4\_IBS00000594 -Megan Waldrop "ssAAV9.P546.IGHMBP2 Clinical Trial"

Protocol # MS4\_IBS00000524 -Kevin Mason "Haemophilus pathogenesis: microevolution, adaptation and persistence "

Protocol # MS2\_IBS00000796 -Kevin Flanigan "A Study of SGT-003 Gene Therapy in Duchenne Muscular Dystrophy (SOLID)"

Contingencies Approved:

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Protocol # IBS00001041 -Eric Sribnick "Bacterial Inoculation of Rodents"

Protocol # IBS00001044 -Alex Bishop "Lentivirus and human tissue culture protocol for Ewing sarcoma research"

Protocol # IBS00001046 -Yusen Liu "Regulation of host defense against bacterial infection"

Protocol # IBS00001039 -Genevieve Kendall "Therapeutic Strategies for Pediatric Sarcomas"

Contingencies for Renewal:

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**New  
Business:**

**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 # IBA1\_IBS00001044 - Bishop, Alex - "Amendment 1 for IBCSC Protocol #IBS00001044"**

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**  
Non-integrating mRNA used for transient transfection of cells and gene overexpression Risk group 1 at biosafety level 1
2. **Types of manipulations planned:**  
Electroporation of mRNA into cells and intravenous injection of cells in mice.
3. **Source of the nucleic acid sequences (e.g., species):**  
murine genes Gpx4 and Fsp1
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**  
Genes associated with preventing programmed cell death
5. **Host(s) and vector(s) to be used:**  
Murine tumor and primary cells
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 Gpx4 or Fsp1, to prevent programmed cell death.
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. 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:**  
The PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.

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Major Points of Discussion: Withheld pending clarification of recombinant DNA modification of mouse cells, the biosafety level for these procedures, and a complete description of materials and methods.

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

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

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**  
Diphtheria toxin - a biological toxin that can be lethal in high doses. It has the potential to persist in the environment.
  2. **Types of manipulations planned:**  
None.
  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
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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:**  
No
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. Biosafety Level 2 (BL2) NIH Guidelines = Appendix M-II-B. Biosafety Level 2 - Animals (BL2-N)
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.

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Major Points of Discussion: Withheld pending minor contingencies including clarification of in vivo procedures, waste disposal practices, immunization requirements, engineering controls, and protocol reformatting for software compliance.

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

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

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**  
Replication incompetent (non-replicating) lentivirus vector for gene delivery and expression
  2. **Types of manipulations planned:**  
Transduction of Primary Muscle cells from patients. Using hTert & CDK4 to render the cells immortalized to establish a persistent cell line. For Fibroblasts MyoD
  3. **Source of the nucleic acid sequences (e.g., species):**  
human sequences
  4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**  
Oncogenic human Telomerase Reverse Transcriptase (hTERT) cyclin-dependent kinase 4 (CDK4) MyoD
  5. **Host(s) and vector(s) to be used:**  
Lentivirus Vectors (commercial source)
  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:**  
1) Function is to immortalize these primary skeletal muscle cells (hTERT to maintain telomere ends or CDK4 to drive cell cycle). 2) A second infection involving fibroblasts from the tissue samples with a second lentivirus coding an
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inducible MyoD to activate the myogenic program and force myogenesis of the fibroblasts to form multinucleated myotubes

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-II. Risk Group 2 (RG2) Agents Appendix G-II-B. Biosafety Level 2 (BL2) Appendix G-II-B-1a-h Appendix G-II-B-2-a-m Appendix G-II-B-3-a
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.

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Major Points of Discussion: Withheld pending minor contingencies including clarification of cell line procedures, safety risks from lentiviral vectors and human materials, identification of lentiviral vector source, validation of replication incompetence, assessment of antibiotic resistance, and waste disposal practices.

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

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