



NATIONWIDE CHILDREN'S

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Institutional Biosafety Committee

Meeting Minutes

Tuesday, August 25, 2026 3pm Abigail Wexner Research Institute or Virtual via Webex

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:

Mark Peeples called meeting to order at 3:01pm, meeting adjourned at 3:43pm

Committee member attendance:

Alex Brown, McKayla Carlson, Kevin Cassady, Tara Chinn, Dakota Esterline, Sumit Ghosh, Liubov Gushchina, Yusen Liu, Paul Martin, Christopher Montgomery, Stefan Nicolau, Mark Peeples, Nizar Saad, and Mary Walker

Members excused:

Carmen Arsuaga, Katie Campbell, Amit Kapoor, Addie Moore, Juan de Dios Ruiz Rosado, and Chack-Yung Yu

Guests in attendance:

Kelly Fallon

Approval of Minutes:

June 2026 Meeting Minutes Approved

Action Register:

The Action Register was reviewed and the following approved:

Amendments Approved:

Protocol # MS6_IBS00000729 -**Katherine Miller "Genomic and In Vitro Analysis of Pediatric Brain Development, Brain Tumors, and Vascular Malformations"**

Protocol # MS1_IBS00001025 -**Kevin Flanigan "Gene Therapy for Inherited Neurological Disorders"**

Protocol # MS4_IBS00000863 -**Stefan Nicolau "Gene editing and gene therapy in neuromuscular disorders"**

Protocol # MS1_IBS00001012 -**Anup Patel "ETX-DS-002 in Dravet"**

Protocol # MS2_IBS00000996 -**Kevin Flanigan "INS1201-101 (ASCEND)"**

Protocol # MS2_IBS00001086 -**Allison Bradbury "Development of therapeutics for Central and Peripheral Nervous System disorders"**

Protocol # MS2_IBS00001039 -**Genevieve Kendall "Therapeutic Strategies for Pediatric Sarcomas"**

Protocol # MS4_IBS00000719 -**Tendy Chiang "Experimental Model Systems for Tracheal Replacement"**

Protocol # MS1_IBS00000926 -**Kevin Flanigan "AAV facilitated treatment of VCP Associated Inclusion Body Myopathy"**

Protocol # MS1_IBS00000898 -**Lawrence Gazda "Biologics Manufacturing Resource"**

Protocol # MS1_IBS00000693 -**Katherine Miller "Human Developmental Brain Atlas "**

Protocol # MS5_IBS00000729 -**Katherine Miller "Genomic and In Vitro Analysis of Pediatric Brain Development, Brain Tumors, and Vascular Malformations"**

Contingencies Approved:

Protocol # IBS00001113 -**Christopher Breuer "Materials Testing to Determine Hemocompatibility"**

Protocol # IBS00001122 -**Gabriel Cara Fuentes "Role of CD93 in Idiopathic Nephrotic Syndrome"**

Contingencies for Renewal:

New Business: Institutional Biosafety Officer update OSHA recordable injury reported to committee regarding sharps injury involving human source material. Discussion of USG Policy for Stopping High-Risk Life Sciences Research and Request for Comment on Draft NIH Biosafety Policy for Research Involving Biohazards

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 # IBA5_IBS00000620 - Kapoor, Amit - "Amendment 5 for IBCSC Protocol #IBS00000620"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
Japanese Encephalitis Virus (JEV) vaccine strain SA14-14-2.
 2. **Types of manipulations planned:**
live-attenuated vaccine strain, to study viral replication, host-cell interactions, and immune responses in human cell lines and mouse models.
 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:**
Human cell lines and rodents
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
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: The Kapoor Lab will begin studying a vaccine strain of Japanese Encephalitis Virus in mice. This is an attenuated strain of the virus developed to vaccinate and protect humans from Japanese Encephalitis. The vaccine strain does not cause disease in humans. It is a well written amendment, recommend approval.

The Institutional Biosafety Committee has determined the status of the protocol to be:
Approved

Amendment # IBA4_IBS00000649 - Vaidyanathan, Sriram - "Amendment 4 for IBCSC Protocol #IBS00000649"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
Adding Lentiviral vector systems
 2. **Types of manipulations planned:**
Transfection of cells with lentiviral vector
 3. **Source of the nucleic acid sequences (e.g., species):**
human
 4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
Cystic fibrosis transmembrane conductance regulator, Green fluorescent protein, mCherry, Turbo GFP, Nitric oxide synthase 3, Akaluc luciferase reporter, truncated CD19, synthetic epidermal growth factor receptors
 5. **Host(s) and vector(s) to be used:**
Human or mouse 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:**
Transgene expression for cystic fibrosis transmembrane conductance regulator, Green fluorescent protein, mCherry, Turbo GFP, Nitric oxide synthase 3, Akaluc luciferase reporter, truncated CD19, synthetic epidermal growth factor receptors
 7. **Containment conditions to be implemented (biosafety level and any special provisions):**
Biosafety level 2.
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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.

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 with minor contingencies to include applicable safety risks associated with lentiviral vector; revise protocol formatting; add vector concentration/titer information; safer sharps practices; document required institutional lentiviral educational sheet for personnel, and clarify waste disposal procedures.

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

Amendment # IBA1_IBS00001008 - Peeples, Mark - "Amendment 1 for IBCSC Protocol #IBS00001008"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**

The attachment (G) glycoprotein, only, from Andes virus (ANDV).

2. **Types of manipulations planned:**

Experiments will use non-replicating pseudotyped viral particles expressing the ANDV G protein and reporter transgenes to assess cell-type-specific binding and transduction.

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:**

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:**

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.

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: The amendment is to use a "pseudotype" virus to test the human airway epithelial cell tropism of the ANDV G protein. The pseudotype virus used, VSVΔG-GFP(ANDV G), is based on a vesicular stomatitis virus (VSV) mutant that lacks its G (glycoprotein) gene and has in its place the gene for the green fluorescent protein (GFP). The amendment is well written, provides appropriate justification and discusses the

relevant risk and safety issues. Considering that only non-infectious virus will be generated, biosafety risks are minimal. No concerns. Recommend approval.

The Institutional Biosafety Committee has determined the status of the protocol to be: **Approved**

Protocol # IBS00001038 - Cripe, Timothy - "A two-part phase I study of Intratumoral (ITu) M032 in patients with treatment refractory progressive or recurrent sarcomas (The IGNITE Trial)"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
M032 HSV is a conditionally replicating herpes simplex virus type 1 containing attenuating mutations that has also been genetically engineered to express the human cytokine, Interleukin-12 (IL-12).
2. **Types of manipulations planned:**
This research study is testing a new treatment for people with Ewing sarcoma or osteosarcoma whose cancer has returned, progressed, or did not respond to standard treatments. Participants will receive M032 by direct injection into their tumor. Researchers will monitor participants closely for side effects and collect blood samples, imaging scans, and tumor biopsy samples to learn how the treatment affects the cancer and the immune system.
3. **Source of the nucleic acid sequences (e.g., species):**
Human interleukin-12 (IL-12).
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
Interleukin-12 (IL-12). IL-12 is a heterodimeric cytokine.
5. **Host(s) and vector(s) to be used:**
HSV-1 oncolytic virus
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:**
Interleukin-12 (IL-12). IL-12 is a heterodimeric cytokine with documented antitumor properties in multiple models. Its antitumor effects include enhancing antitumor Th1 responses, increasing lymphocyte cytotoxicity, stimulating NK, NKT and T cells, and producing antiangiogenic effects.
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
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 with major contingencies. Return to the committee with clarification on exposure implications; viral shedding precautions; vector replication competency; any restrictions for immunocompromised or pregnant individuals; instructions regarding contact with injection sites; PPE and equipment used during study procedures; and biosafety training provided to healthcare personnel.

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

**Old
Business:**