Institutional Biosafety Committee

Meeting Minutes

Tuesday, August 26, 2025 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:	Meeting called to order by chair at 3:01pm. Meeting adjourned 3:36pm.
Committee members in attendance:	Allison Bradbury, Alex Brown, Kevin Cassady, Tara Chinn, Sumit Ghosh, Amit Kapoor, Paul Martin, Christopher Montgomery, Addie Moore, Stefan Nicolau, Mark Peeples, Juan de Dios Ruiz Rosado, Nizar Saad, and Chack-Yung Yu
Members excused:	Carmen Arsuaga, Katie Campbell, McKayla Carlson, Dakota Esterline, and Mary Walker
Guests in attendance:	
Approval of Minutes:	July 29, 2025 meeting minutes approved
Action Register:	The Action Register was reviewed and the following approved: Amendments Approved:

Protocol # MS10_IBS00000521 -**Katherine Bline "Use of Human Source Material in Bline Laboratory"**

Protocol # MS1_IBS00000996 -**Kevin Flanigan "INS1201-101 (ASCEND)"**

Protocol # MS2_IBS00000906 -**Meisam Naeimi Kararoudi "Development of a novel AAV9 gene replacement therapy "**

Protocol # MS6_IBS00000582 -**Masako Shimamura "CMV in Immunocompromised Host"**

Protocol # MS6_IBS00000685 -**Masako Shimamura "Immunocompromised Host Responses to Pathogens in Translational Research"**

Protocol # MS9_IBS00000599 -**Timothy Cripe "Novel Biologic and Small Molecule Therapies for the Treatment of Pediatric Solid Tumors"**

Contingencies Approved:

Protocol # IBS00001006 -**Nina Mann "Genetic landscape of childhood kidney disease"**

Protocol # IBS00001008 -**Mark Peeples "Human respiratory viruses and primary human respiratory cell culture"**

Protocol # IBS00001012 -**Anup Patel "ETX-DS-002 in Dravet"**

Contingencies for Renewal:

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_IBS00000848 – Stacy, Mitchel - "Amendment 2 for IBCSC Protocol #IBS00000848"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of human source material at biosafety level 2 without animals.
2. **Types of manipulations planned:**
   Study involves using human source material and isotopes
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
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 including clarification of waste disposal plans.

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

Protocol # IBS00001004 - Zhao, Mingtao - "Human Induced Pluripotent Stem Cells (iPSCs) Derivation and Differentiation"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of a low-risk RNA virus modified so that each virus can only infect one cell and express its genes, but the infection cannot spread to other cells. The genes inserted in this virus expresses factors that reprogram white blood cells to become stem cells.
2. **Types of manipulations planned:**
   Infection of white blood cells in the laboratory with virus that cannot leave these cells.
3. **Source of the nucleic acid sequences (e.g., species):**
   Human transcription factor genes.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Genes expressing transcription factors.
5. **Host(s) and vector(s) to be used:**
   Primary human white blood cells will be infected with this RNA 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:**
   The transgenes expressed in this system are human transcription factors.
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-D, Appendix G-II-B; section III-D-3.
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 including updates to the technical abstract, clarification of disinfectant, centrifuge safety procedures, personal

protective equipment, waste disposal plans, potential environmental impacts, and a description of the vectors involved.

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

Protocol # IBS00001019 - Becknell, Brian - "Biological Agents for Studies of Urinary Tract Infection and Peritonitis"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of risk group 2 viral and bacterial agents at biosafety level 2.
2. **Types of manipulations planned:**
   Study involves in vitro and in vivo procedures to study bacteria and immune systems.
3. **Source of the nucleic acid sequences (e.g., species):**
   Antimicrobial peptides, green fluorescent protein.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Immune system defense involved in antimicrobial activity.
5. **Host(s) and vector(s) to be used:**
   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:**
   Expression or down regulation of genes of interest (antimicrobial peptides and green fluorescent protein).
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, section III-D.
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 research.

Major Points of Discussion: Withheld with minor contingencies including updates to the technical abstract, inclusion of procedure descriptions, possible occupational consequences, personal protective equipment use, waste disposal plans, and accidental spill release mitigation availability.

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

Protocol # IBS00001016 - Mo, Alisa - "Identification of genes and disease mechanisms involved in neurodevelopmental disorders"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of risk group 2 agent at biosafety level 2 without animals.

2. **Types of manipulations planned:**
   Study involves in vitro delivery of non-replicating, recombinant RG2 vector
3. **Source of the nucleic acid sequences (e.g., species):**
   SHANK3, NRXN1, EHMT1, REST, CHD2
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Gene associated with genetic mutations
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:**
   Genetic manipulation to generate mutations of interest in cell lines and correction of known mutations.
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; section III-D-3
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: All previously identified contingencies have been satisfactorily addressed.

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