Institutional Biosafety Committee
Meeting Minutes

Tuesday, September 30, 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:	Call to order by chair at 3pm. Meeting adjourned at 3:51pm.
Committee members in attendance:	Allison Bradbury, Alex Brown, Kevin Cassady, Tara Chinn, Dakota Esterline, Sumit Ghosh, Amit Kapoor, Paul Martin, Christopher Montgomery, Addie Moore, Stefan Nicolau, Mark Peeples, Mary Walker, and Chack-Yung Yu
Members excused:	Carmen Arsuaga, Katie Campbell, McKayla Carlson, Juan de Dios Ruiz Rosado, and Nizar Saad
Guests in attendance:	Kelly Fallon
Approval of Minutes:	August meeting minutes approved
Action Register:	The Action Register was reviewed and the following approved: Amendments Approved:

Protocol # MS7_IBS00000571 -**Meisam Naeimi Kararoudi "CRISPR/Gene Editing Core Lab biosafety protocol"**

Protocol # MS2_IBS00000895 -**Jonathan Slaughter "ECHO Study"**

Protocol # MS8_IBS00000608 -**Karen McCoy "An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis"**

Protocol # MS19_IBS00000530 -**Allison Bradbury "AAV delivery to the central nervous system "**

Contingencies Approved:

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

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

Contingencies for Renewal:

Protocol # MS2_IBS00000848 -**Mitchel Stacy "Imaging of Skeletal Muscle Perfusion and Vascular Remodeling in Cardiovascular Diseases"**

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:

Protocol # IBS00001035 - Wang, Ruoning - "Metabolic regulation in immune response and tumorigenesis"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   The laboratory uses several different BSL2 approaches - Replication incompetent Lentivirus & retroviral gene delivery - Human Primary immune cells - CRISPR/CAS cell line modifications (using electroporation of gRNA and Cas)
2. **Types of manipulations planned:**
   Please see above
3. **Source of the nucleic acid sequences (e.g., species):**
   Commercial human and mouse targets
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   metabolic but also oncogenic (e.g. BCL2)
5. **Host(s) and vector(s) to be used:**
   replication incompetent Lentivirus and retroviral delivery
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 they are using LV, retrovirus, and Crispr systems to modify cell gene expression.
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: Section III-D-2, Section III-D-3, Section III-E-1. BMBL: Section VIII-E.
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 minor contingencies, including clarification of disinfectant and disposal procedures, exposure response and containment strategies, incorporation of applicable NIH guidelines, availability of occupational vaccines, door signage requirements, and confirmation of human cell line modifications and vector characteristics.

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

Protocol # IBS00001025 - Sahenk, Zarife - "Gene Therapy for Inherited Neurological Disorders"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of RG1 virus at biosafety level 1 in vivo.
2. **Types of manipulations planned:**
   Study involves using RG1 defective virus in vivo.
3. **Source of the nucleic acid sequences (e.g., species):**
   The genes that will be utilized in this study include NT-3, CAPN3, eGFP, micro-dystrophin, and BAG3 genes.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   The human/mouse genes associated with inherited neurological disorders.
5. **Host(s) and vector(s) to be used:**
   Rodent 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:**
   The transgenes expressed in this system are associated with inherited neurological disorders and are proteins that function in controlling and stimulating neurons to grow and differentiate.
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 B-I, 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 pending minor contingencies including clarification of experimental procedures, disposal and disinfection protocols, administration route, training and exposure response measures, and details regarding serotype, transgene, and promoter.

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

Protocol # IBS00001027 - Zhao, Mingtao - "Human Induced Pluripotent Stem Cells (iPSCs) Derivation and Differentiation-iPSC Core"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of human source material and RG2 virus at biosafety level 2 in vitro.
2. **Types of manipulations planned:**
   Study involves using human source material and RG2 defective virus
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 non-transmissible RNA virus vectors
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 pending minor contingencies including clarification of disinfectant and disposal procedures, correction of typographical errors, confirmation human cell line modifications, and an updated description of vector transmission.

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

Protocol # IBS00001031 - Bakaletz, Lauren - "experimental otitis media in the chinchilla"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Multiple pathogens including bacteria and viruses that could cause disease and 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
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.):**
   Appendix G-II-B and G-III-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.

Major Points of Discussion: Withheld pending minor contingencies including clarification of disinfectant and disposal procedures, worksite locations, potential aerosol generation, and availability of vaccines for study agents.

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

Protocol # IBS00001024 - Garg, Vidu - "Analysis of human patient samples for the Heart Center"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Human Source Material
2. **Types of manipulations planned:**
   Pipetting, Centrifugation, RNA Isolation and Plasma collection for ELISA's
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):**
   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.):**
   Section III. However, the work does not involve work with recombinant DNA and Synthetic nucleic acid molecules.
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Yes, the lab members have completed the required training as per institutional policy.

Major Points of Discussion: Withheld pending minor contingencies including clarification of procedures, material shipment details, use of respiratory protection, source of patient-derived specimens, and planned cell line modifications.

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

Protocol # IBS00001032 - Liu, Yusen - "Immune Response to Microbial Infections"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   A variety of pathogens (viral, bacterial, fungal) that have the capability of persisting in the environment and causing different disease processes. Also AAV particles that will be used to restore defective gene products.
2. **Types of manipulations planned:**
   Use of CRISP/Cas9 and AAV particles to restore gene function.
3. **Source of the nucleic acid sequences (e.g., species):**
   Human
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Protection from oxidative stress
5. **Host(s) and vector(s) to be used:**
   E. coli (host) and AAV6 (vector), replication deficient
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:**
   Protection from oxidative stress
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 B-II-A
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   PI and lab staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending minor contingencies including clarification of disposal and disinfectant procedures, use of personal protective equipment, exposure response practices, material transportation processes, and mitigation strategies for containment.

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

Protocol # IBS00001037 - Jackson, Ashley - "Human Urothelium Culture and Organoid Formation"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Human Source Material
2. **Types of manipulations planned:**
   Centrifugation and Culturing of Cell lines and Human Source Material.

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):**
   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.):**
   Section III (However, the work does not involve recombinant and Synthetic nucleic acids)
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Yes, the lab has completed the required trainings as per Institutional Policy.

Major Points of Discussion: Withheld pending minor contingencies including clarification of the source and screening of human cell lines, use of recombinant technologies, inclusion of relevant safety considerations, and a detailed description of the proposed studies.

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