Institutional Biosafety Committee

Meeting Minutes

Tuesday, June 30, 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*

Call to Order:	Meeting called to order at 3:01pm meeting adjourned at 3:43pm
Committee members in attendance:	Carmen Arsuaga, Alex Brown, Tara Chinn, Sumit Ghosh, Liubov Gushchina, Amit Kapoor, Yusen Liu, Paul Martin, Christopher Montgomery, Stefan Nicolau, Mark Peeples, Nizar Saad, and Chack-Yung Yu
Members excused:	Katie Campbell, McKayla Carlson, Kevin Cassady, Dakota Esterline, Addie Moore, Juan de Dios Ruiz Rosado, and Mary Walker
Guests in attendance:	Kelly Fallon, and Jennifer Ramsey
Approval of Minutes:	April Meeting Minutes and Action Register Approved
Action Register:	The Action Register was reviewed and the following approved: Amendments Approved:

Protocol # MS4_IBS00000729 -**Michelle Wedemeyer "Genomic and In Vitro Analysis of Pediatric Brain Development, Brain Tumors, and Vascular Malformations"**

Protocol # MS1_IBS00001086 -**Allison Bradbury "Development of therapeutics for Central and Peripheral Nervous System disorders"**

Protocol # MS4_IBS00000695 -**Zongdi Feng "Study of hepatitis virus life cycle and pathogenesis"**

Protocol # MS1_IBS00001016 -**Alisa Mo "Identification of genes and disease mechanisms involved in neurodevelopmental disorders"**

Protocol # MS2_IBS00001037 -**Ashley Jackson "Human Urothelium Culture and Organoid Formation"**

Protocol # MS1_IBS00000600 -**Oluyinka Olutoye "Olutoye Human and Large Animal IBC Protocol"**

Contingencies Approved:

Contingencies for Renewal:

New Business: OSHA recordable injury reported to committee regarding needlestick involving human source material.

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 # IBS00001113 - Breuer, Christopher - "Materials Testing to Determine Hemocompatibility"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   NHP and human source material
2. **Types of manipulations planned:**
   Tissue engineering vascular grafts and implants
3. **Source of the nucleic acid sequences (e.g., species):**
   Not applicable
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Not applicable
5. **Host(s) and vector(s) to be used:**
   Not applicable
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:**
   Not applicable

7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   Biosafety level 2 (BSL-2)
8. **Applicable section of the NIH Guidelines the research falls under (e.g. Section III-D-1, Section III-E-3, etc.):**
   Standard Microbiological Practices (BSL2)
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 study staff, clarification of source material usage; identification of relevant safety risks for tissue and exposure response procedures.

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

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

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Lentiviral Vector and human source material
2. **Types of manipulations planned:**
   Knockdown efficiency and downstream effects on cellular phenotypes will be assessed using standard molecular and cellular assays.
3. **Source of the nucleic acid sequences (e.g., species):**
   Commercially available third-generation lentiviral vectors encoding short hairpin RNA (shRNA) sequences targeting each gene of interest will be utilized. For each target gene, three independent shRNA constructs will be tested alongside a non-targeting scrambled control vector. All vectors are replication-deficient and carry a puromycin resistance cassette to enable selection of successfully transduced cells.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Genes involved in idiopathic nephrotic syndrome that include CD-93, PIEZO1, and MCP1
5. **Host(s) and vector(s) to be used:**
   Glomerular endothelial cells
   Human podocytes
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:**
   Knockdown efficiency and downstream effects on cellular phenotypes will be assessed using standard molecular and cellular assays.
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-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 biosafety cabinet use, if lentivirus is third-generation, PPE usage, and cell line types.

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

Protocol # IBS00001118 - Bline, Katherine - "Respiratory Syncytial Virus"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Respiratory syncytial virus (RSV) is a common human respiratory pathogen that is especially dangerous for the very young and the elderly in whom it can cause pneumonia and death. Its infectivity is unstable in the environment.
2. **Types of manipulations planned:**
   Frozen (-80C) vials of RSV will be thawed and diluted for use in a neutralization assay in which a constant amount of RSV will be mixed with serial dilutions of human sera and the amount of remaining infectivity determined by inoculation of a cultured human cell line (A549). The RSV used in this assay is strain A2 with a luciferase gene added. The luciferase is secreted from the infected cells and quantified by its ability to release photons from luciferin. Plotting the release of photons enables quantification of the remaining non-neutralized RSV.
3. **Source of the nucleic acid sequences (e.g., species):**
   The RNA genome of RSV.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   The RSV genome is a negative (anti-sense) RNA genome. In a cell, it The RSV construct used here also expresses the luciferase gene for quantitation purposes.
5. **Host(s) and vector(s) to be used:**
   The human cell derived immortalized cell line, A549.
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 transgene in this RSV was luciferase which releases photons detectable by a luminometer.
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.):**
   NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Section III-D-1.
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 laboratory specific procedures, vaccine guidance, safer sharp handling methods, waste disposal, protocol formatting, and inclusion of relevant NIH guidelines.

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

Amendment # IBA3_IBS00000719 - Chiang, Tendy - "Amendment 3 for IBCSC Protocol #IBS00000719"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Potentially pathogenic bacteria (S. aureus and P. aeruginosa) Lentivirus
2. **Types of manipulations planned:**
   Bacteria: Culture and inoculation into cultured cells and animals. Lentivirus: used to label cells with tdTomato or GFP.
3. **Source of the nucleic acid sequences (e.g., species):**
   Bacteria: N/A Lentivirus: not stated
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Bacteria: N/A Lentivirus: genes for fluorescently labelled proteins
5. **Host(s) and vector(s) to be used:**
   Bacteria: N/A Lentivirus: VSV-G 3rd generation, replication defective AAV6
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:**
   Bacteria: N/A Lentivirus: used to label cells with tdTomato or GFP for fluorescent protein identification
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL2/RG2
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 (bacteria) and G-III-D-E (lentivirus)
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 clarification of bacteriophage usage, plasmid details of lentivirus vector, dosing ranges, biosafety cabinet use, and PPE use.

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

Amendment # IBA2_IBS00001044 - Bishop, Alexander - "Amendment 2 for IBCSC Protocol #IBS00001044"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   This amendment includes and human NK cell products.
2. **Types of manipulations planned:**
   The proposed amendment includes the use of primary human NK cells derived from healthy human donors to complement parallel work in murine NK cells.
3. **Source of the nucleic acid sequences (e.g., species):**
   recombinant DNA/RNA: mRNA encoding a KEAP1-binding-deficient human NRF2 mutant (achieved by point mutations in ETGE and/or DLG motifs) mRNA encoding wild type human NRF2 mRNA encoding GFP
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   mRNAs encoding transcription factor/proto-oncogene, tumor suppressor and a fluorescent reporter protein.
5. **Host(s) and vector(s) to be used:**
   Human NK cell products will be infused into mice
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:**
   Cells will be transiently transfected with mRNA to enable expression of wild type NRF2 or NRF2 binding mutants to evaluate resistance to chemotherapeutic treatment both in 2D tissue culture and in murine models (human NK cells will be infused into mouse donors).
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL-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 pending clarification of transportation, terminology edits, and clarification of source for materials.

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