Institutional Biosafety Committee

Meeting Minutes

Tuesday, March 31, 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 3pm. Meet adjourned at 4:14pm.
Committee members in attendance:	Carmen Arsuaga, Alex Brown, Kevin Cassady, Tara Chinn, Dakota Esterline, Sumit Ghosh, Liubov Gushchina, Amit Kapoor, Yusen Liu, Paul Martin, Addie Moore, Stefan Nicolau, Mark Peeples, Juan de Dios Ruiz Rosado, and Chack-Yung Yu
Members excused:	Katie Campbell, McKayla Carlson, Christopher Montgomery, Nizar Saad, and Mary Walker
Guests in attendance:	Kelly Fallon
Approval of Minutes:	February 2026 IBC meeting minutes approved
Action Register:	The Action Register was reviewed and the following approved: Amendments Approved:

Protocol # MS1_IBS00001031 -**Steven Goodman "experimental otitis media in the chinchilla"**

Protocol # MS6_IBS00000590 -**Dean Lee "CRISPR Gene Editing Using Viral Vectors, Plasmids and Electroporation in cancer cells and immune cells to enhance cancer immunotherapy"**

Protocol # MS15_IBS00000672 -**Karen McCoy "A Phase 1/2 Dose-escalation Study Evaluating the Safety, Tolerability, and Efficacy of VX-522 in Subjects 18 Years of Age and Older With Cystic Fibrosis and a CFTR Genotype Not Responsive to CFTR Modulator Therapy"**

Contingencies Approved:

Protocol # IBS00001091 -**Diana Bharucha-Goebel "RGX-202 for Duchenne Muscular Dystrophy (DMD)"**

Protocol # IBS00001097 -**Mark Hester "Understanding Molecular Mechanisms of Pediatric Epilepsy"**

Protocol # IBS00001089 -**Benjamin Stanton "Understanding the epigenetic drivers of childhood cancers"**

Contingencies for Renewal:

New Business: IBSO update regarding OSHA recordable sharp related injury

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_IBS00000902 - Hu, Yan - "Amendment 1 for IBCSC Protocol #IBS00000902"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Risk group 2 bacteria including Staphylococcus aureus and Pseudomonas aeruginosa
2. **Types of manipulations planned:**
   In-vitro procedures including inoculation of precision-cut lung slices (PCLS) generated from ferret and pig lungs with laboratory bacterial strains to evaluate host–pathogen interactions and bacterial clearance in this ex vivo airway model of cystic fibrosis (CF).
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-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:**
   The PI and lab staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification of relevant safety considerations; identification of tissue sources; description of which planned experiments will be conducted inside the biological safety cabinet; details on transportation routes and locations for agent movement; specification of required PPE; information on potential consequences of accidental release; and clarification of where training documentation will be maintained.

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

Protocol # IBS00001103 - Bline, Katherine - "Use of Human Source Material in Bline Laboratory"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Human source material from patients with respiratory viruses.
2. **Types of manipulations planned:**
   Processing samples from infected patients - serum will be frozen for future analysis of antibody assays. Manipulations could include vortexing, pipetting, and centrifuging the samples
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.):**
   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 relevant safety risks; definition of BSL-2+ practices; and clarification of procedures for working with potentially infectious diagnostic samples, including aerosol-mitigation methods, containment practices, transport procedures, virus-inactivation steps, and PPE requirements.

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

Protocol # IBS00001102 - Hall, Mark - "Use of COVID19 positive human source material"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Human source material (blood) from COVID-19 positive patients
2. **Types of manipulations planned:**
   Blood processing and assays to assess immune function
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-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 protocol formatting; identification of relevant safety issues; removal of materials exempt from review; description of sample transport procedures; and definition of BSL-2+ practices.

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

Protocol # IBS00001105 - Mason, Kevin - "Haemophilus pathogenesis: microevolution, adaptation and persistence "

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Risk group 2 viruses and bacteria with the potential to cause infections in humans and human source materials.
2. **Types of manipulations planned:**
   In-vitro and in-vivo procedures are planned with a wide variety of microbiological, cellular, molecular, immunological, and biochemical techniques (e. g. ELISAs, Western Blot analyses; cellular fractionation studies; confocal and scanning electron microscopy; RT-PCR; etc) in the studies.
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.):**
   Applicable sections of the NIH Guidelines to 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:**
   The PI and lab staff performing the research have been appropriately trained in the safe conduct of the research.

Major Points of Discussion: Withheld pending clarification of vivarium selection and use of core services; identification of relevant safety issues for all biological agents; description of downstream sample processing; clarification of PPE requirements; inclusion of applicable NIH Guideline information; updates to emergency-response procedures; and clarification of the disinfectant used.

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

Amendment # IBA2_IBS00000819 - Lynch, Thomas - "Amendment 2 for IBCSC Protocol #IBS00000819"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of risk group 2 virus respiratory syncytial virus (RSV) in-vivo. This differs from the

original scope of the approved IBCSC protocol and therefore was rejected by the committee who recommended an independent protocol for this project.

2. **Types of manipulations planned:**
   Intranasal and intratracheal inoculation
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-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: The amendment was tabled. The Principal Investigator was instructed to withdraw the amendment and resubmit the changes as a new protocol, as the scope of the proposed modifications exceeds that of the original approved protocol.

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

Protocol # IBS00001092 - Theisen, Emily - "Defining and targeting novel vulnerabilities in genome regulation and metabolism in pediatric cancers"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Retrovirus, lentivirus, CRISPR-Cas9
2. **Types of manipulations planned:**
   Transfection cells in-vitro via electroporation
3. **Source of the nucleic acid sequences (e.g., species):**
   synthetic constructs (shRNA, sgRNA, tags, fusion junctions), bacterial CRISPR components (Cas9 from S. pyogenes*), mammalian promoters (hU6, EFS), human cDNAs (e.g., LSD1, CoREST, EWSR1 fusions, ISC genes), engineered reporter/tag sequences (GFP, mCherry, HaloTag, NanoLuc), and retroviral vector backbones (pMSCV)

4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   cancer cell mRNA or human protein coding genes for mRNA
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:**
   Transfection into HEK293-EBNA cells for viral production, collect virus, and transduce our cancer cell lines to either deplete genes of interest (shRNA-knockdown or CRISPR-knockout) or express a cDNA.
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-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 if materials used are commercially available; waste disposal practices; the source and replication deficiency of vector systems; anticipated off-target effects; protocol formatting updates; information on potential consequences of accidental release, particularly involving oncogenes; and inclusion of institutional training requirements.

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

Protocol # IBS00001095 - Rodriguez, Vilmarie - "EFC17905"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Fitusiran (SAR439774) is a synthetic siRNA
2. **Types of manipulations planned:**
   Phase 3, parallel-arm, open-label study will evaluate the efficacy and safety of fitusiran prophylaxis in male pediatric participants
3. **Source of the nucleic acid sequences (e.g., species):**
   Fitusiran is a chemically synthesized small interfering RNA (siRNA) ovalently linked to a ligand containing three N-acetylgalactosamine (GalNAc) residues.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Fitusiran is designed to specifically bind and promote degradation of SERPINC1 mRNA in hepatocytes, thereby reducing antithrombin production.
5. **Host(s) and vector(s) to be used:**
   Male Pediatric Participants

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.):**
   Section III-C. Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation; 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 a more descriptive title; identification of who will be storing, preparing, transporting, and handling the study agent; specification of the dose and frequency of administration; clarification of disposal practices; confirmation of PPE use; and removal of the vector-encoded term, which is not applicable to this study agent.

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

Old Business: