Institutional Biosafety Committee

Meeting Minutes

Tuesday, April 28, 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 3pm; meeting adjourned 3:46pm.
Committee members in attendance:	Carmen Arsuaga, Alex Brown, Kevin Cassady, Tara Chinn, Dakota Esterline, Sumit Ghosh, Amit Kapoor, Yusen Liu, Paul Martin, Christopher Montgomery, Addie Moore, Stefan Nicolau, Mark Peeples, Nizar Saad, and Chack-Yung Yu
Members excused:	Katie Campbell, McKayla Carlson, Liubov Gushchina, Juan de Dios Ruiz Rosado, and Mary Walker
Guests in attendance:	Kelly Fallon
Approval of Minutes:	March Meeting Minutes and Action Register Approved
Action Register:	The Action Register was reviewed and the following approved: Amendments Approved: Protocol # MS1_IBS00001019 -**Brian Becknell "Biological Agents for Studies of Urinary Tract Infection and Peritonitis"** Protocol # MS1_IBS00001037 -**Ashley Jackson "Human Urothelium Culture and Organoid Formation"** Protocol # MS5_IBS00000921 -**Jenny Barker "Local management of MRSA"** Protocol # MS1_IBS00000986 -**Christopher Beatty "NGN-401 in Rett Synd"**

Protocol # MS2_IBS00001024 -**Vidu Garg "Analysis of human patient samples for the Heart Center"**

Contingencies Approved:

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

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

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

Protocol # IBS00001095 -**Vilmarie Rodriguez "EFC17905 - Phase 3 Fitusiran Prophylaxis in Children With Hemophilia A or B"**

New Business:

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 # IBS00001111 - Bedrosian, Tracy - "Molecular Mechanisms of Neurodevelopmental Disorders"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Risk group 1 adeno-associated viral vector (AAV) in vivo and human source material
2. **Types of manipulations planned:**
   In vivo administration of AAV via injections
3. **Source of the nucleic acid sequences (e.g., species):**
   Mouse
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   SLC35A2 gene, which encodes a protein involved in UDP-galactose (sugar) transport
5. **Host(s) and vector(s) to be used:**
   Mice and cultured cells, with AAV 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 mouse gene SLC35A2 and/or mCherry will be used under the control of different promoters within AAV vectors as gene therapy replacement in SCL35A2 knockout mice and in cell cultures. SLC35A2 is a protein involved in UDP-galactose transport.
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   Biosafety level 1 and 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-A Standard Microbiological Practices (BL1); 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; description of decontamination practices, PPE usage clarification, inclusion of AAV safety information, mitigation strategy clarification of centrifugation and biosafety cabinet usage, and inclusion of NIH references.

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

Protocol # IBS00001106 - King, Sam - "Studies of bacterial pathogenesis"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Risk group 1 and 2 bacteria, NHP and human source material
2. **Types of manipulations planned:**
   microbiological, cellular, molecular, immunological, and biochemical techniques (e. g. ELISAs, Western Blot analyses; protein purification; cellular fractionation studies; confocal and electron microscopy; QPCR; etc)
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 inclusion of IRB protocol number, clarification if flow core services will be used, and pathogen clarification.

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

Protocol # IBS00001112 - Lynch, Thomas - "Ferret viral challenge"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Agent characteristics (e.g. virulence, pathogenicity, environmental stability): Use of risk group 2 virus respiratory syncytial virus (RSV) in-vivo Stability for hours remains infectious in environment and passed by large droplets from infected individuals
2. **Types of manipulations planned:**
   Intranasal and intratracheal inoculation - part 1 harvest samples during peak viral

replication phase from animals - part 2 allow other animals to recover and then expose to allergens to evaluate airway reactivity post-infection.

3. **Source of the nucleic acid sequences (e.g., species):**
   RSV strains from Peeple's lab (no nucleic acid inserts) 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 according to biosafety review of training.

Major Points of Discussion: Withheld pending clarification of source material usage; identification of relevant safety issues with infectious materials; description of pertinent NIH guideline information, PPE usage regarding respiratory protection clarification, mitigation strategy for centrifugation usage and transportation.

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

Protocol # IBS00001086 - Bradbury, Allison - "Development of therapeutics for Central and Peripheral Nervous System disorders"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Risk group 1 adeno-associated viral vector (AAV) in vivo, Risk group 2 lentivirus and human source material
2. **Types of manipulations planned:**
   In vivo administration of AAV; cell line culture establishment, lentivirus in vitro
3. **Source of the nucleic acid sequences (e.g., species):**
   Human, canine, viral, non-mammalian derived sequences and synthetic
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Regulatory, reporter, functional/imaging, therapeutical and disease-relevant transgenes
5. **Host(s) and vector(s) to be used:**
   Mice and cultured cells
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 transgene expression will be actively pursued for reporter, imaging, therapeutic, and RNA-modulation studies.

7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   Biosafety level 1 and 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-A Standard Microbiological Practices (BL1); 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 title update; protocol formatting, viral vector safety clarification, where vector systems will be obtained from; description of pertinent NIH guideline information, inclusion of training and documentation practices.

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

Amendment # IBA11_IBS00000599 - Cripe, Timothy - "Amendment 11 for IBCSC Protocol #IBS00000599"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Risk group 1 adeno-associated viral vector (AAV) in vivo
2. **Types of manipulations planned:**
   Intravenous administration of AAV in vivo to test transgene expression in animals
3. **Source of the nucleic acid sequences (e.g., species):**
   Recombinant AAV
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Therapeutic transgene that encodes a bispecific T-cell engager (diabody), its function is to redirect T cells to CD19-positive B-cell malignancies.
5. **Host(s) and vector(s) to be used:**
   Swine and AAV
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:**
   expressing a transgene encoding a bispecific diabody termed GP101.
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 G-II-A Standard Microbiological Practices (BL1)
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 proposed experiment safety information; protocol formatting, decontamination practices, host information, dose information, risk mitigation strategies for sharps and disposal of materials.

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

Amendment # IBA6_IBS00000558 - Walker, Christopher - "Amendment 6 for IBCSC Protocol #IBS00000558"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Staphylococcal enterotoxin B (SEB) acute toxicity is associated with this toxin.
2. **Types of manipulations planned:**
   This reagent will be used as a positive control to stimulate human T cells for in-vitro immunology assays.
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:**
   Verified the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research

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

Amendment # IBA4_IBS00000499 - Walker, Christopher - "Amendment 4 for IBCSC Protocol #IBS00000499"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Staphylococcal enterotoxin B (SEB) acute toxicity is associated with this toxin
2. **Types of manipulations planned:**
   This reagent will be used as a positive control to stimulate human T cells for in-vitro immunology assays
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:**
   Verified the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research.

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