Institutional Biosafety Committee

Meeting Minutes

Tuesday, October 28, 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:	IBC meeting called to order 3:00pm. IBC meeting adjourned at 3:32pm.
Committee members in attendance:	Allison Bradbury, McKayla Carlson, Kevin Cassady, Dakota Esterline, Amit Kapoor, Paul Martin, Christopher Montgomery, Addie Moore, Mark Peeples, Juan de Dios Ruiz Rosado, Mary Walker, and Chack-Yung Yu
Members excused:	Carmen Arsuaga, Alex Brown, Katie Campbell, Tara Chinn, Sumit Ghosh, Stefan Nicolau, and Nizar Saad
Guests in attendance:	Kelly Fallon, and Jennifer Ramsey
Approval of Minutes:	September meeting minutes approved
Action Register:	The Action Register was reviewed and the following approved: Amendments Approved:

Protocol # MS9_IBS00000584 -**Rolf Stottmann "Genetic Analysis of Mouse Models of Human Congenital Malformations"**

Protocol # MS4_IBS00000590 -**Meisam Naeimi Kararoudi "Naeimi Kararoudi Lab to Perform CRISPR Gene Editing Using Viral Vectors, Plasmids and Electroporation in cancer cells and immune cells to enhance cancer immunotherapy"**

Protocol # MS1_IBS00001024 -**Vidu Garg "Analysis of human patient samples for the Heart Center"**

Protocol # MS20_IBS00000530 -**Allison Bradbury "AAV delivery to the central nervous system "**

Protocol # MS5_IBS00000558 -**Christopher Walker "Immunity in Hepatitis C Virus Infection and Vaccination"**

Protocol # MS1_IBS00000866 -**Sarah O'Brien "Clinical Research Services Laboratory"**

Contingencies Approved:

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

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

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

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

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

Contingencies for Renewal:

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 # IBS00001041 - Sribnick, Eric - "Bacterial Inoculation of Rodents"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):** Streptococcus pneumoniae, a bacteria that frequently colonizes humans asymptomatically but can also cause infections such as pneumonia.
2. **Types of manipulations planned:** In vivo inoculation of RG2 bacteria to study pneumonia at biosafety level 2.
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:**
   No
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.):**
   Biosafety Level 2 (BL2) NIH Guidelines - Appendix G-II-B 1 to 4
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 minor contingencies including clarification of PPE selection and procedural details, confirmation that aerosol-generating procedures will be conducted within a biosafety cabinet, and updates to the online incident reporting software names and disinfectant utilized.

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

Protocol # IBS00001044 - Bishop, Alex - "Bishop Lab General Protocol "

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of risk group 2 agent at biosafety level 2.
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):**
   EWS, EWS RNA Binding Protein 1, Fli-1 Proto-Oncogene, ETS Transcription Factor (FLI-1), BRCA1 DNA Repair Associated (BRCA1), RNA polymerase II subunit RPB1 (POLR2A), Senataxin (SETX), DExH-Box Helicase 9 (DHX9), Nuclear factor erythroid 2-related factor 2 (NRF2), Kelch Like ECH Associated Protein 1 (KEAP1), Poly(ADP-Ribose) Polymerase 1 (PARP1), Tumor protein 53 (P53/TP53)
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Gene associated with oncoprotein, multifunctional proteins, and transcriptional factors.
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
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: Major Points of Discussion: Withheld pending minor contingencies including updating the title, confirming whether core facilities will be used for cell sorting, simplifying the non-technical abstract, specifying the exact location of work, and providing updated details on disinfectant and decontamination procedures.

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

Protocol # IBS00001046 - Liu, Yusen - "Regulation of host defense against bacterial infection"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Bacteria with the potential to cause infection (S. pneumoniae, L. monocytogenes, E. coli). Viral replication vectors including lentivirus, sendai virus, and adenovirus.
2. **Types of manipulations planned:**
   Deletion or overexpression of immune genes.
3. **Source of the nucleic acid sequences (e.g., species):**
   Human, non-human primates, or mice.
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Immune genes
5. **Host(s) and vector(s) to be used:**
   Lentivirus, adenovirus, sendai virus. Plasmid-based CRISPR/Cas system will be used in adenoviruses or lentivirus. Plasmids are commercially purchased or constructed onsite. All viruses are replication defective.
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:**
   Several immune genes will be overexpressed.
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 1-4
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 confirming use of sealed safety rotors during centrifugation, ensuring agents are transported in secondary containment, correcting typographical errors, verifying staff completion of the required vector training, and updating the name of the online incident reporting system.

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

Protocol # IBS00001039 - Kendall, Genevieve - "Therapeutic Strategies for Pediatric Sarcomas"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   1) Lentivirus (LV)-based gene overexpression of oncogenic drivers (efforts are used to restrict expression in zebrafish using lineage and specifies specific promoters) 2) Gene loss studies also using LV based CRISPR/Cas9 strategy in cell lines 3) Primary Human tumor cells (minimal risk because these tumor lines have been maintained in cell culture (most >20-30 passages) the infectious risk is minimal (potential for viable virus survival is low).
2. **Types of manipulations planned:**
   In vitro gene over expression in cell culture In vitro gene loss of expression (CRISPR-CAS9) In vivo injection in zebrafish embryos using microcapillary delivery).
3. **Source of the nucleic acid sequences (e.g., species):**
   null
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Oncogenic drivers are used in LV based systems in vitro - this is the principal risk. For the in vivo studies (efforts are used to reduce risk with the transposon system and restrict expression using lineage and specifies specific promoters).
5. **Host(s) and vector(s) to be used:**
   Lentivirus (3rd generation split system) - non-replicating is used in cell culture not in vivo Transposon based gene delivery is used for the in vivo studies.
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 lab is investigating gene combinations important for tumorigenesis (Fusion proteins and known oncogenes). They also use reporters to track the gene location in an effort to recapitulate tumor formation and the complex transcriptional cascade that leads to sarcoma development.
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: -Section III-D-1-a: Experiments involving the introduction of recombinant DNA into Risk Group 2 agents will usually be conducted at Biosafety Level (BSL) 2 containment. -Appendix G-II-B: (1) Standard Microbiological Practices (BSL-2); (2) Special Practices (BSL-2); (3) Containment Equipment (BSL-2); (4) Laboratory Facilities (BSL-2)
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Yes

Major Points of Discussion: Withheld pending minor contingencies including simplification of the non-technical abstract, confirmation that agents will be transported in secondary containment, updates to disinfection procedures, inclusion of additional CRISPR-Cas9 details, and revision of the online incident reporting system name.

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

Protocol # IBS00001048 - Khan, Sara - "Brain Tumor Registry and Biorepository (BT Biorepository)"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Human Source Material
2. **Types of manipulations planned:**
   Cell Culture
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 - BSL2 work
9. **Verification that the PI and laboratory staff performing the research have been appropriately trained in the safe conduct of the research:**
   Training needs to be completed before approval.

Major Points of Discussion: Withheld pending major contingencies including updating study staff and confirming completion of required training, simplifying the non-technical abstract, refining the technical abstract to focus on relevant safety concerns tied to specific procedures, clarifying PPE selection based on activity, listing work locations, and identifying procedures that will be conducted in a biosafety cabinet.

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

Amendment # IBA1_IBS00000801 - Isaacs, Albert - "Amendment 1 for IBCSC Protocol #IBS00000801"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Use of risk group 2 agent at biosafety level 2.
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):**
   Human inflammatory genes (GPNMB, IL6, TNF-a) or disease-causing genes (APP, PSEN1)
4. **Nature of the nucleic acid sequences (e.g., structural gene, oncogene):**
   Gene associated with human inflammatory genes of disease-causing
5. **Host(s) and vector(s) to be used:**
   Human cell lines or 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:**
   Genetic manipulation to overexpress existing genes in human cell lines or express new transgenes (dcas9 transcript into human iPSCs)
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 pending minor contingencies including adding associated IACUC protocol number, refining technical abstract to address added procedures, providing a description of in vivo procedures, clarifying the safety mechanisms of the commercial vector, confirming if sharps will be used, addressing occupational and environmental risks, ensuring sealed safety rotors are used during centrifugation, detailing safety considerations including outlining post-exposure response, clarifying waste disposal, and verifying staff completion of the required vector training.

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

Protocol # IBS00001050 - Goodman, Steven - "Gene regulation and DNA binding proteins in bacterial biofilms"

1. **Agent characteristics (e.g. virulence, pathogenicity, environmental stability):**
   Potentially infectious bacteria that do not 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:**
   no
7. **Containment conditions to be implemented (biosafety level and any special provisions):**
   BSL2, except for E. coli K12 which will be BSL1.
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, G-II-A. BMBL appendix B.

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 description of source material procedures and clarification of waste disposal.

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