

**CHILDREN'S HOSPITAL BOSTON**  
**Meeting of Boston Children's Hospital Institutional Biosafety Committee**  
**AGENDA**  
**3/19/2026 11:30 am to 1:00 pm**  
**Karp 4 Conference Room or Teams**

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**Members Present:** DF, RD, SG, EG, TW, SL, KK, IJ, CH, DC, SD, MM, HDL, SVH, BS, AR, JM

**Members Absent:** PW, EC

Guests:

RLSO: JF, DH, AL

SD chaired the meeting.

## 1 IBC Meeting Minutes

Boston Children's Hospital Institutional Biosafety Committee meeting (02/19/2026)

IBC Meeting Minute was unanimously approved by the committee.

**Committee Decision:**

Motion: Approved

Majority (Approved): 17

Minority (Against): 0

## 2 Administrative Updates

The IBC welcomed RD as a new member to the committee.

## 3 Laboratory Events

### 1. Puncture by Needle:

**Incident Summary:** A researcher sustained a needlestick injury to their finger while recapping an insulin syringe containing biotin during mouse inoculation.

**Root causes:**

- Recapping the needle.
- Lack of evaluation of safer sharps alternatives (e.g., retractable needles).
  - Rushing during procedure.

**Preventative Actions:**

- Never recap needles; dispose immediately after use in a red biohazard sharps container.
- Lab will evaluate safety-engineered syringes.

- Staff should ensure adequate time is allotted for procedures to avoid rushing and ensure safe practices.

## 2. Laceration by Blade:

**Incident Summary:** A researcher sustained a cut while sectioning isopentane-fixed mouse tissue after attempting to remove debris from the blade. The researcher was wearing nitrile gloves, a lab coat, and safety glasses.

**Root Cause:**

- Failure to wear cut-resistant gloves when working near the blade.

**Preventative Action:**

- Wear cut-resistant gloves when working near the cryostat blade.

## 3. Laceration by Blade:

- **Incident Summary:** A researcher sustained a laceration to the left index finger while using a Kimwipe to remove debris from a cryostat blade during sectioning of fixed mouse spinal cord tissue.

**Root Causes:**

- Failure to complete Cryostat Training.
- Failure to wear cut-resistant gloves when working near the cryostat blade.
- Fatigue

**Preventative Actions:**

- Complete the required Cryostat training. Obtain hands on specific cryostat training by a knowledgeable lab member.
- Implement a buddy system or task-sharing approach for long sectioning procedures to reduce fatigue.
- Do not use Kimwipes to clean debris from the blade. Tools such as brushes are available for this purpose.

## 4. Cryostat Updates – RLSO presented updates on cryostat and sectioning equipment safety training for personnel.

**RLSO Updates:**

- Hands-on training materials were revised.
- The updated cryostat/sectioning equipment training has been posted on the intranet, including instructions on how to access it through the new platform.
- A Teams channel has been created for users to share best practices and safety resources amongst cryostat users.
- New resources include A9 cut-resistant gloves with improved dexterity for the research community.

- Updated signage has been posted on each sectioning unit.

**Committee Discussion:**

- The Committee recommended emphasizing cryostat training requirements and use of cut-resistant gloves in the annual refresher safety training.
- The IBC recommended that the PI attests that users in their lab have completed cryostat training prior to using the equipment.

**4 New submission – Clinical**

**IBC-P00002152**

ENDEAVOR: ETX101

PI: AR

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion:** This protocol describes a multi-site, randomized, double-blind, sham-controlled, delayed-treatment, dose-finding clinical study evaluating ETX101, a one-time gene therapy in 18 pediatric participants (6 months to 4 years) with Dravet syndrome. ETX101 is a non-replicating recombinant AAV9 vector designed to enhance expression of the SCN1A gene through a GABAergic cell-selective regulatory element and engineered transcription factor. The study's primary objectives are to assess the safety, tolerability, and efficacy of ETX101, and to determine an appropriate therapeutic dose for future development. The gene therapy product will be prepared and stored in BCH Pharmacy and transported to OR for administration.

**Regulations Applicable to this Protocol:** NIH Guidelines III-C and OSHA Bloodborne Pathogens Standard.

**Motion: Modifications Required for Approval**

Majority (Approved): 17

Minority (Against): 0

Abstention: 0

**Modifications Requested:**

- Revise the lay summary so it is understandable to committee members without a scientific background.
- Define Dravet syndrome and SCN1A-positive Dravet syndrome.
- The protocol specifies that a designated individual will retrieve the investigational product from the research pharmacy and deliver it to the operating room; the committee recommends generalizing this statement to accommodate for other personnel should the specified individual be unavailable.

- Include details on how the drug will be transported to the OR. Specify that the drug will be placed in a primary container within a rigid self-sealable secondary container.
- Include the building and room number where samples will be processed at BCH.
- All personnel listed on the IBC protocol must complete protocol-specific training with an experienced lab member; update the protocol to include training completion dates for all team members.
- Include BCH Gene Therapy Committee review documentation.

## 5 New submission – Laboratory

**IBC-P00002145** Biomarker Core IBC Protocol

PI: ES

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion:** The Biomarker Core aims to validate assays that measure novel biomarkers related to psychiatric disorders and transdiagnostic risk. These biomarkers include indices of stress, trauma, aging, growth, and maturation in children and adolescents. Biospecimens such as hair, saliva, and blood will be used to assess hormones (e.g., cortisol) and molecular markers using ELISA and multiplex quantitative PCR. Work with human blood will be performed at BSL-2 work practices and procedures.

**Regulations Applicable to this Protocol:** NIH Guidelines, III-F and OSHA Bloodborne Pathogens Standard.

### **Motion: Modifications Required for Approval**

Majority (Approved): 17

Minority (Against): 0

Abstention: 0

### **Modifications Requested:**

- Rewrite this section in plain language so it can be easily understood by non-scientific members of the committee. Define all scientific terminologies used.
- Describe when and how stool will be handled on the bench.
- Clarify whether CRISPR-Cas9 will be used to modify genes in cells. If so, describe how the CRISPR-Cas9 components (e.g., Cas9 guide RNA) will be delivered, including the method of introduction (e.g., transfection, lipid nanoparticles, electroporation). Specify the intended gene targets.
- Indicate NIH Guidelines section III-E if CRISPR work is used to gene edit.
- Clarify whether bacteria (e.g., *E. coli* K12 ) will be used for cloning and propagation of CRISPR-Cas9 constructs.

- Clarify whether blood samples will be collected by the lab, obtained from external sources, or both. If collected by the lab, specify the location, method, and device used for collection. If obtained from external sources, indicate the source and how the samples will be acquired.
- Specify all samples obtained from external sources by the core, including urine sample preparation, blood collection, and aliquoting of saliva, urine, and blood samples as components of work performed at BSL-2.
- Include room locations for blood collection, including clinical exam room numbers, if blood collection will be performed by the core.
- Specify the source and location of blood draws.
- Note that none of the samples indicated in the scientific description are known to contain pathogens.
- Include the oligonucleotides and CRISPR-Cas9 sequences used.
- Clarify whether samples may contain infectious agents and specify any restrictions on the types of samples accepted and processed given that this is a fee-for-service core.
- Include aerosol-generating procedures when using human samples as possible occupational exposure risks.
- Include the use of a face shield when aliquoting blood, urine, and saliva samples on the open bench to protect personnel from aerosols.
- Indicate the equipment used and the types of samples that will be aliquoted on the open bench.

## 6 Laboratory Amendments

**IBC-A06-114-5** Amendment 5 : Recombinant DNA Constructs encoding proteins involved in synaptic and neurodevelopmental proteins

**PI:** **TS**

**Motion:** Approved

**Discussion:** **IBC Discussion:** The lab studies the molecular mechanisms that regulate synapse formation and mitochondrial movement in neurons to better understand brain development and learning. This amendment adds a dominant-negative SARM1 construct to the already approved procedures involving AAV-mediated expression in mouse studies. The proposed work involving AAV inoculation in mice will be conducted at ABSL-1.

**Regulations Applicable to this Protocol:** NIH Guidelines III-E

**Motion: Approved**

Majority (Approved): 17

Minority (Against): 0

Abstention: 0

**IBC-RN00000750-3**Renewal 3 : Vaccine development against Group B streptococcus  
(*Streptococcus agalactiae*)

PI:

YL

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion:** This laboratory renewal studies Group B Streptococcus (GBS), or *Streptococcus agalactiae*, a bacterial pathogen associated with neonatal and adult infections. The lab develops and evaluates vaccine-based approaches using in vitro models. This renewal adds procedures for culturing GBS from clinical isolates in an enclosed 5-liter bioreactor, harvesting bacteria by centrifugation, and purifying capsular polysaccharide (CPS) from the supernatant. Bacterial pellets are inactivated with sodium hydroxide, and the supernatant is chemically disinfected, filtered, and processed through diafiltration and gel filtration to isolate CPS. Protein and DNA levels will be assessed, and additional enzymatic treatment may be applied if necessary. All Group B Streptococcus procedures will be performed at BSL-2 work practices and procedures.

**Regulations Applicable to this Protocol:** NIH Guidelines III-E**Motion: Modifications Required for Approval**

Majority (Approved): 17

Minority (Against): 0

Abstention: 0

**Modifications Requested:**

- Clarify the proteins used to generate the MAPS fusion construct, including expression and purification of GBS proteins in *E. coli*.
- Indicate whether any proteins are known toxins and provide a brief description of the proteins being purified.
- Clarify whether breaking the stem of the vaginal swab to fit into an Eppendorf tube constitutes a sharps hazard; consider cutting the swabs instead of breaking them.
- Clarify whether homogenization of mouse vaginal samples containing bacteria will be performed in a biosafety cabinet or on the open bench.
- Clarify which procedures are considered non-aerosol-generating and will be conducted at the bench versus in a biosafety cabinet.
- Clarify all procedures involving HL-60 cells.
- Indicate shipping, specify materials to be shipped, and clarify whether shipping is domestic or international. Ensure designated personnel complete required training prior to shipping.
- Note that additional safety enhancements are not necessary at ABSL-2 per this protocol.
- Include culture of human cell lines to procedures performed at BSL-2.
- Include the use of *E. coli* BL21 strain for growing expression plasmids at BSL-1.

## 8 Human Study Annual Reconfirmation

**IBC-P00000718** Autologous Mitochondrial Transplant (Human Clinical Study)

PI: SE

Motion: Approved

Discussion: The study is active and open to enrollment.

**IBC-P00001436** A Multi-Center, Phase 2 Gene Transfer Study Inducing Fetal Hemoglobin in Sickle Cell Disease

PI: ES

Motion: Approved

Discussion: The study is active and closed to enrollment. No adverse events related to the study product have occurred.

## 9 Administrative Reviews

**IBC-RN00001200-2** Renewal 2 : Study of SARS-CoV-2

PI: JK

Motion: Administratively Approved

Discussion: This is a three-year renewal with no changes to the risk assessment.

**IBC-A10-275-7** Amendment 7: Molecular Basis of Cancer

PI: SP

Motion: Administratively Approved

Discussion: The amendment adds HCC827-G, a lung cancer cell line to conduct cell proliferation and survival assays. These studies will evaluate how treatment with pharmacological inhibitors can limit oncogenic signaling within cells. There are no changes to the risk assessment.

**IBC-RN00000325-4** Renewal 4: Generation of pluripotent mouse and human stem cells.

PI: GD

Motion: Administratively Approved

Discussion: This is a three-year renewal with no changes to the risk assessment.

**IBC-RN00001844-1** Renewal 1: Translational gene-based therapies

PI: MA

Motion: Administratively Approved

Discussion: This is a three-year renewal with no changes to the risk assessment.

**IBC-A00001515-2** Amendment 2 : Research involving human biological samples

PI: MG

Motion: Administratively Approved

Discussion: The amendment adds THP-1, a human monocytic cell line and HeLa cells to validate ongoing experiments. This update does not change the risk assessment.

**IBC-A00002041-1** Amendment 1: Molecular, Cellular and Animal Studies of Kidney Disease Genes, Proteins and Factors

PI: AM

Motion: Administratively Approved

Discussion: This amendment updates lab locations and adds new research staff. This change does not impact the risk assessment.

**IBC-A00000180-7** Amendment 7 : Genetics of Human Hematopoiesis

PI: VS

Motion: Administratively Approved

Discussion: This amendment updates shipping information; this change does not impact the risk assessment.

**IBC-A00000573-10** Amendment 10: Translation in neurodegenerative and neuroimmune disease

PI: JS

Motion: Administratively Approved

Discussion: This amendment updates the protocol to include the animal protocol number. The update does not change the risk assessment.

**IBC-RN00001147-2** Renewal 2: Genetics of Neural and Cardiovascular Disorders

PI: RD

Motion: Administratively Approved

Discussion: This is a three-year renewal with no changes to the risk assessment.

**IBC-RN00000328-4** Renewal 4: Mouse and human cancer cells

PI: GD

Motion: Administratively Approved

Discussion: This is a three-year renewal with no changes or updates to the risk assessment.

**IBC-A00002171-1** Amendment 1: Taysha 201 ASPIRE

PI: DL

Motion: Administratively Approved

Discussion: This amendment includes updates to the pharmacy manual. This change does not impact the risk assessment.

**IBC-A00002033-4** Amendment 4: Taysha REVEAL 101 Study

PI: DL

Motion: Administratively Approved

Discussion: This amendment updates the pharmacy manual. This change does not impact the current risk assessment.

**IBC-RN00000323-4** Renewal 4: The role of Staphylococcus aureus in atopic dermatitis model

PI: RG

Motion: Administratively Approved

Discussion: This is a three-year renewal with no changes to the risk assessment.

**IBC-RN00001821-1** Renewal 1: Genetic engineering of hematopoietic cells for therapeutic purposes

PI: CB  
Motion: Administratively Approved  
Discussion: This is a three-year renewal with no updates or changes to the risk assessment.

**IBC-RN00000709-3** Renewal 3: Human Immune Function Studies and The Genes Involved

PI: TC  
Motion: Administratively Approved  
Discussion: This is a three-year renewal with no updates or changes to the risk assessment.

**IBC-RN00-056-4** Renewal 4: Cell Differentiation in Tissue-Engineered Structures

PI: JB  
Motion: Administratively Approved  
Discussion: This is a three-year renewal with no changes or updates to the risk assessment.

**IBC-A00002148-1** Amendment 1: A Phase I/II Study of MVX-220 Gene Therapy in Participants with Angelman Syndrome

PI: NB  
Motion: Administratively Approved  
Discussion: The Informed Consent was updated. This update does not change the risk assessment of the investigational product MVX-220.

**IBC-A00002041-2** Amendment 2 : Molecular, Cellular and Animal Studies of Kidney Disease Genes, Proteins and Factors

PI: AM  
Motion: Administratively Approved  
Discussion: The lab updated their room locations; this change does not impact the risk assessment.

**IBC-A00000423-2** Amendment 2: Bridge-Enhanced ACL Repair Study

PI: LM  
Motion: Administratively Approved

Discussion: This amendment updates the PI ownership. This change does not impact the risk assessment.

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| 10 | Laboratory Study Annual Reconfirmation |
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| IBC-P00001087 | Investigation of Pathogenesis and Therapy of Ocular Diseases Using Murine Models |
| PI:           | YS   |

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| 96-187 | Investigation of the transcriptional regulation of genes by hypoxia |
| PI:    | SK  |

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| 01-007 | The Role of Heme Oxygenase-1 in Modulating the Inflammatory Response of the Lung to Bacterial Infection |
| PI:    | SK  |

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| 02-064 | Determination of Cell Identity in the Cerebral Cortex |
| PI:    | CW  |

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| IBC-P00001310 | Translational Hearing Genomics Research |
| PI:           | AS                                      |

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| IBC-P00000677 | Diphtheria toxin mediated cell ablation in the mice central nervous system |
| PI:           | ZH   |

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| IBC-P00001874 | Noninvasive imaging of immune responses |
| PI:           | MR                                      |

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| IBC-P00001923 | Immunization of mice with heat killed bacteria |
| PI:           | BS   |

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| 10-001 | Implantation of murine tumor cell lines in knockout and transgenic mice and elucidation of the mechanism through which NETs are involved in cancer progression |
| PI:    | DW   |

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| IBC-P00000419 | Cellular and molecular research studies using human and mouse peripheral blood samples |
| PI:           | DW   |

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| IBC-P00002043 | Thymic restoration through adenoviral encoded cytokines in an aged and metabolically distinct animal model |
| PI:           | OL   |

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| IBC-<br>P00001067 | Modeling Development and Disease with Sensory Organoids<br>PI: KK   |
| 11-107            | Prolonged duration nerve block<br>PI: DK  |
| IBC-<br>P00001986 | Understanding quantitative principles of gene regulation in development and disease<br>PI: SN                   |
| IBC-<br>P00000281 | Coagulation studies<br>PI: SE   |
| IBC-<br>P00000573 | Translation in neurodegenerative and neuroimmune disease<br>PI: JS  |
| IBC-<br>P00001575 | APP- and PS1-transferring adeno-associated viruses<br>PI: BS  |
| IBC-<br>P00001836 | Investigation of Molecular Developmental Biology and Neonatal Disease<br>PI: SM                                 |
| 02-203            | Effect of Heme Oxygenase-1 on Hypoxia Modulated Gene Expression and Signal Transduction<br>PI: SK               |
| IBC-<br>P00000009 | Animal models of skeletal disease<br>PI: MW   |
| 04-207            | Heme Oxygenase-1 Transfected Mesenchymal Stem Cells in Hypoxia Induced Pulmonary Hypertension in Mice<br>PI: SK |
| 10-040            | Biomimetic Microengineering of Tissues and Organs on a Chip<br>PI: DI   |
| 04-098            | Mouse Models of Insulin Resistance, Beta-cell Failure and Diabetes<br>PI: MW                                    |

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| IBC-<br>P00002058 | Understanding Vaccines in Newborns Through Characterizing of Early Life Immune Responses<br>PI: KS  |
| IBC-<br>P00001043 | Effects of HIF PHD Inhibition on Lung Growth<br>PI: MP  |
| IBC-<br>P00000042 | Regulation and Characterization of Adult Stem Cell Proliferation and Differentiation<br>PI: FC  |
| 09-059            | Characterization of adult stem cell proliferation and differentiation<br>PI: FC   |
| IBC-<br>P00001409 | Characterization of the molecular and functional roles of glycoRNAs<br>PI: RF   |
| IBC-<br>P00000315 | DNA, RNA, Plasma, Serum, and Cell Extraction from samples<br>PI: JH   |
| IBC-<br>P00001438 | Immune Studies in Human and Murine Samples<br>PI: PN  |
| 05-025            | Using Lentiviral and Adeno-associated Viruses (AAV) to Introduce Axon Regeneration Molecules in Neurons both in vitro and in vivo<br>PI: ZH |
| IBC-<br>P00000103 | Wnt and Orphan Gene Signal Transduction in Vertebrates<br>PI: AO  |
| 08-214            | Translational Lab (TransLab) IBC protocol<br>PI: MA   |
| IBC-<br>P00000867 | The development of stable transfected cell lines for in vitro study<br>PI: KY   |
| IBC-<br>P00000301 | Regulation of protease and protease inhibitors in a mouse model of inflammation.<br>PI: KY  |

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IBC- Genetics of Neonatal and Neurological Conditions

P00002075 PI: AD

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11-053 Molecular Genetic Basis of Cranial Neuron Development

PI: EE

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IBC- Use of AAV viral vectors in mice

P00000917 PI: MF

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11 Completions

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IBC- A Phase 1b/2, randomized, double-blind, placebo-controlled, multi-center study of  
P00001529 STMC-103H in neonates and infants at risk for developing allergic disease.

PI: RR

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