CHILDREN'S HOSPITAL BOSTON
Meeting of Boston Children's Hospital Institutional Biosafety Committee
AGENDA
10/16/2025 11:30 AM to 1:00 PM
KARP 4th Floor, Conference Room

Members Present: DF, EC, DC, SG, IJ, MM, EG, BS, SD, SVH, CH, HD, PW, AR, TW, SL, KK, JM, LW

Members Absent: None

Guests: None

RLSO: DH, LA, JF

SD chaired this meeting.

1 IBC Meeting Minutes

Boston Children's Hospital Institutional Biosafety Committee meeting (08/06/2025)
Boston Children's Hospital Institutional Biosafety Committee meeting (09/18/2025)

IBC Meeting Minutes were unanimously approved by the committee.

- **Committee Decision:**
  - Motion: Approved
  - Majority (Approved): 18
  - Minority (Against): 0

2 Administrative Updates

- **IBC Public Meeting:** Scheduled for December 18th, 2025
- **RLSO Safety Fair:** October 23rd at 1:00 pm - 3:00 pm.
- **Cryostat & Microtome Survey**: The cryostat and microtome survey results were presented to the committee.
  - **Committee Discussion:**

    1. Evaluate different glove options to ensure proper sizing and maximize comfort and dexterity.

Many staff members are not aware of the glove options available.Update online training to clarify glove types and their availability, and efforts will continue to raise awareness that gloves are provided free of charge.

2. Provide each operator with a personal, properly sized pair of cut resistance gloves rather than relying on shared gloves.
3. The committee discussed establishing a Cryostat User Group to collect feedback and share best practices.

3	**New submission – Laboratory**

IBC-P00002136 Human Genetic variation and neuroinflammation

PI:	**MA**
Motion:	Modifications Required for Approval – Return to IBC Analyst
Discussion:	**IBC Discussion:** The lab is studying how common and rare human genetic variations affect neuroinflammatory responses. The lab will use CRISPR/Cas 9 to edit human iPSCs, which will then be differentiated into neural cells in vitro or on mouse glia. Genes of interest include NGN2, CASP7, CASP3, RANBP2, RNASEH2B, but they also anticipate a wide CRISPR screening across hundreds of genes. To simulate inflammation, cells will be introduced to cytokines, tetrodotoxin, APV, and depolarization with potassium chloride. Tissue culture using human iPSCs and mouse glia, including use of a toxin of biological origin and lentivirus will be performed at BSL-2 work practices. **Regulations Applicable to this Protocol:** The NIH Guidelines Section III-D, III-E, and the OSHA Bloodborne Pathogens Standard. **Motion: Modifications Required for Approval** • Majority (Approved): 18 • Minority (Against): 0 • Abstention: 0

Modifications Requested:

- Specify that genome engineering experiments are performed using E. coli.

- Describe how samples are transported and clarify whether materials have been transduced with lentivirus.
- Indicate the CRISPR delivery method (e.g., protein-based delivery, viral delivery, or transfection).
- Confirm whether iPSCs used are of human origin.
- Define APV.
- For neural differentiation and perturbation, specify whether glial cells are of mouse or human origin.
- Include the potential risks of aerosol generation associated with flow cytometry procedures.
- For Escherichia coli K12, include plasmid transfection details, including antibiotic resistance profiles.
- Update the biosafety level for lentivirus from BL2+ to BSL-2.
- In the Recombinant DNA section, list the plasmids and describe their intended use (e.g., transfection, electroporation).
- Confirm whether the lab will work with human primary cell lines or other cell lines; provide the IRB protocol number if applicable.
- Clarify whether flow cytometry or luminometry will be used to track fluorescence.
- Add mouse glial cell tissue culture to the BSL-1 entry.

4	3 year Lab Study Renewals	
IBC-RN00001722-1	Renewal 1 : Mechanistic Studies on COVID-19 pathogenesis	
	PI:	**TC**
	Motion:	Modifications Required for Approval – Return to IBC Analyst
	Discussion:	**IBC Discussion:** This laboratory investigates SARS-CoV-2 infection using infectious clone (icSARS-CoV-2-mNG) that encodes a Neon Green (NG) fluorescent reporter to infect target monocytes. Specifically, A549-ACE2 and Vero E6 cells will be employed to examine viral replication and cytopathic effects. Viral RNA will be introduced into cells via electroporation, followed by incubation and virus production. Viral titers will be measured using plaque assays and qPCR. This renewal includes an updated risk assessment reflecting the transition from BSL-3 to BSL-2 containment, in accordance with the NIH's current Biosafety Risk Considerations for SARS-CoV-2. All procedures involving the handling and processing of SARS-CoV-2 will be performed using BSL-2 work practices inside a biosafety cabinet. Similarly, all human-

derived samples will be processed under BSL-2 conditions within a biosafety cabinet.

Regulations Applicable to this Protocol: The NIH Guidelines Section III-D and the OSHA Bloodborne Pathogens Standard.

Motion: Modifications Required for Approval

- Majority (Approved): 18
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Specify whether lab personnel are performing blood collection from patients. If they are not, remove references to blood draws and needle use.
- Describe how media used for culturing live cells and PFA used for cell fixation will be processed or disposed of after media change and fixation.
- Include the potential biohazard risks to research personnel conducting experiments. Specify the risks of isolating various cell types from human blood.
- Describe how the biohazard bag containing solid waste from the biosafety cabinet will be disinfected before transferring to the red biohazard bin.
- Remove reference to wearing PAPRs or enhanced PPEs, including a disposable gown, double nitrile gloves, foot covers, and the use of respiratory protection.
- Remove the reference to autoclave.
- Clarify that human blood samples will be received from another institution or drawn at Boston Children's Hospital. Specify the location where the blood will be drawn.
- Specify whether primary and secondary rigid containers are used for transporting samples from the lab to the FACS Core.

IBC-RN00001035-2 Renewal 2 : Role of Notch4 in Allergic Airway Inflammation

PI:	**TC**
Motion:	Modifications Required for Approval – Return to IBC Analyst
Discussion:	**IBC Discussion:** The lab studies the role of human immune cells in the context of allergic airway inflammation using cell- and animal-based models. The renewal adds work with influenza virus (H1N1) to support these studies. Mice will be intranasally challenged with

2×105 PFU of the virus, and weight changes and survival will be monitored daily for up to 33 days post-infection. All Influenza virus culture and handling will be done at BSL-2, with animal inoculations at ABSL-2 work practices and procedures.

Motion: Modifications Required for Approval

- Majority (Approved): 18
- Minority (Against): 0
- Abstention: 0

Modification Requested:

- Clarify that influenza virus will not be amplified in the lab.
- Ensure that staff have completed the research safety training.
- Provide the source of the biological agent.
- Add influenza virus to the animal research model.
- Include how the influenza virus is transported from the lab to the animal facility.
- Specify storage of influenza virus in the lab under BSL-2 entry.
- Uncheck laboratory standard PPE for ABSL-2 entry.

5	Human Study Annual Reconfirmation

IBC-P00002020 Recode RCT2100

PI:	**RP**
Motion:	Approved
Discussion:	The study is active and open to enrollment.

IBC-P00001545 Pilot and Feasibility Trial: Hematopoietic Stem Cell BCL11A Enhancer Gene Editing for Severe β-Hemoglobinopathies

PI:	**EE**
Motion:	Approved
Discussion:	No DSMB meetings have taken place as no patients have been enrolled in this study.

6	Administrative Reviews

IBC-RN00001163-2 Renewal 2 : Study of RELiZORB in Children with Short Bowel Syndrome Dependent on Parenteral Nutrition

PI:	**MP**
Motion:	Administrative Approval

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

IBC-RN06-125-5 Renewal 5 : Analysis of Erythropoiesis and Globin Gene Regulation in Primary Human Erythroid Progenitors

PI: **SO**

Motion: Administrative Approval

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

IBC-RN87-388-5 Renewal 5 : Tissue Specific Expression in Transgenic Mice

PI: **SO**

Motion: Administrative Approval

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

IBC-A04-253-9 Amendment 9 : Characterization of Mutant Mouse Strains and Human Genetic Diseases

PI: **MF**

Motion: Administrative Approval

Discussion: The lab includes commercially sourced LLC-PK1 (porcine kidney) for signaling assays studies, and Hep 1-6 and AML12 (murine hepatocyte) cell lines for iron metabolism studies. These procedures will be conducted at BSL-1 work practices.

IBC-RN00001635-1 Renewal 1 : Cellular and pseudovirus assays

PI: **WW**

Motion: Administrative Approval

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

IBC-A00001775-1 Amendment 1 : A phase II trial to evaluate the safety and efficacy of oral encapsulated Microbiota Transplantation Therapy in peanut allergic patients.

PI: **RR**

Motion: Administrative Approval

Discussion: The amendment adds a new open-label Phase II arm combining microbial transplantation therapy (MTT) with oral immunotherapy (OIT) maintenance and antibiotic pretreatment to assess sustained unresponsiveness after OIT cessation. It also introduces two capsule formulations targeting different regions of the small intestine, replacing the single-capsule approach without concurrent OIT. The Protocol, Informed Consent, and

inclusion/exclusion criteria were updated, with no updates or changes to the risk assessment of the investigational product.

IBC-P00002150 Mapping translation in the brain

PI: **BK**

Motion: Administrative Approval

Discussion: The lab investigates the mechanisms of RNA translation in brain cell types to understand how translational regulation contributes to human brain evolution. Human and chimpanzee cell lines will be differentiated into neural progenitor cells, microglial, and astrocytes to model distinct cellular functions within the brain. Astrocytes will be stimulated with cytokines (IL-1α, TNF, and C1q), followed by downstream analyses including ribosome profiling and proteomics. Work with all human and chimpanzee cell lines will be done at BSL-2 work practices and procedures.

IBC-A00000221-7 Amendment 7 : Obesity, endoplasmic reticulum stress and type 2 diabetes

PI: **SWP**

Motion: Administrative Approval

Discussion: This amendment includes the addition of KEAP1 expression in already approved HEK293 cells. This modification does not impact risk assessment.

7 Laboratory Study Annual Reconfirmation

IBC-P00000027 Humanized mice and microbiome

PI: **SS**

IBC-P00000191 Gastrointestinal Organoid Culture and Implantation into Mice

PI: **DB**

IBC-P00001163 Study of RELiZORB in Children with Short Bowel Syndrome Dependent on Parenteral Nutrition

PI: **MP**

05-109 Expression of recombinant proteins for structural and functional studies

PI: **TS**

07-068 Neonatal vaccine adjuvant potential of Toll-like receptor 8 agonists

PI: **OL**

IBC-P00000482 Generation of stable cell lines for mechanistic studies on genes associated with IBD.

PI: **SS**

IBC-P00000488 Culturing of clinical bacteria of concern

PI: **DK**

00-056 Cell Differentiation in Tissue-Engineered Structures
PI: **JB**

09-102 Role of the Vasculature and the Complement Cascade in CNS Synapse Elimination During Development and Disease
PI: **BS**

IBC-P00001519 Biomarkers in human samples
PI: **SN**

IBC-P00000306 Labeling and Imaging Live Rodent Cells
PI: **HU**

IBC-P00000150 Manipulation of Zebrafish for studies of muscle function and disease
PI: **LK**

IBC-P00001844 Translational gene-based therapies
PI: **MA**

IBC-P00001996 Asthma Research Lab Processing Initiative
PI: **WP**

IBC-P00000764 Bariatric Surgery Mechanisms
PI: **MSR**

IBC-P00000101 Use of diptheria toxin (DTA) to ablate diptheria toxin receptors (DTR) expressing sensory neurons
PI: **CW**

IBC-P00000057 Blocking GPCR activation using Pertussis toxin
PI: **CW**

01-154 Animal Models for Human Vascular Anomalies.
PI: **JB**

IBC-P00001465 Modeling pediatric airway disease with induced pluripotent stem cells.
PI: **RW**

IBC-P00000644 Trans-Tympanic Drug Delivery for Treatment of Otitis Media
PI: **DK**

00-055 Biochemical and Genetic Basis of Vascular Anomalies

PI: **JB**

98-014 Role of HSP27 in Neuronal Survival
PI: **CW**

IBC-P00001943 Tissue Engineering of urogential tissues/organs
PI: **ZI**

IBC-P00000221 Obesity, endoplasmic reticulum stress and type 2 diabetes
PI: **SWP**

IBC-P00001330 Cystic Fibrosis Clinical Trials
PI: **BR**

IBC-P00001464 Assessment of AMPA Receptor Subunit Composition Using Philanthotoxin
PI: **CC**

IBC-P00000270 Mapping Neuronal Circuit Remodeling using Novel Trans-Synaptic tracing methods.
PI: **CC**

07-164 Understanding molecular, cellular and organismal basis of childhood neurological diseases
PI: **MS**

IBC-P00000113 Effect of Omega-3 Fatty Acids and GPR40 on Human Melanoma
PI: **MP**

IBC-P00001987 Modeling Down Syndrome Neurogenesis
PI: **BK**

11-059 Identification and characterization of anti-angiogenic natural products.
PI: **MR**

IBC-P00000173 Study of derived neurons
PI: **CW**

IBC-P00000978 Proteinopathy in ALS
PI: **CW**

IBC-P00000334 Global regulators converge to orchestrate metabolism, biofilm, and pathogenesis
PI: **PW**

01-105 IDDRC Mouse Gene Manipulation Facility (Transgenic Core Facility)
PI: **MB**

8	Completions

IBC-P00001968 Taysha REVEAL Pediatric Study

PI: **DL**