CHILDREN'S HOSPITAL BOSTON
Meeting of Boston Children's Hospital Institutional Biosafety Committee AGENDA
7/17/2025 11:30 AM to 1:00 PM
KARP 4th Floor, Conference Room

Members Present: AR, MM, IJ, SG, DF, BS, KK, SVH, JM, TW, CH, SD, DC, PW, SC, HD,

Members Absent: SL, EC

Guests:

RLSO: JF, DH, AL

SD chaired the meeting.

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1 IBC Meeting Minutes

Boston Children's Hospital Institutional Biosafety Committee meeting (05/15/2025)

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

IBC Meeting Minutes were unanimously approved by the committee.

Committee Decision:

Motion: Approved

Majority (Approved): 16

Minority (Against): 0

2 Laboratory Events

1. **Non-compliant Shipment Event**

- **Incident summary:** A researcher incorrectly shipped a sample on dry ice. The package was missing the required UN1845 label, Class 9 hazard diamond, and dry ice details on the waybill. This resulted in a noncompliant shipment.
- **Root Cause:**
    - Failure to complete Biological Shipping and Dry Ice Training.
- **Corrective Actions:**
    - Staff involved in shipping research samples must complete the Shipping of

Biological Substances & Dry Ice Training initially and then every two years.

2. **IBC Non-compliant Event**

- **Event summary:** During a recent laboratory inspection, it was noted that work involving Staphylococcus aureus was being conducted without IBC approval. Additionally, a researcher actively working with biological materials noted on the labs IBC protocols was not listed on the current protocol. A letter of non-compliance was sent to the PI.

  Lab Response: The PI submitted an amendment to include Staphylococcus aureus and added the individual to the protocol.

- **Root cause:**
  - Failure to update the IBC protocol to include Staphylococcus aureus and to list the researcher actively working with the biological materials.
- **Preventative Actions:**
  - The lab submitted an amended to add Staphylococcus aureus and the researcher.
  - Review and update IBC protocols to ensure all biological materials and personnel are up to date.

3	**New submission – Laboratory**

IBC-P00002127 Molecular regulation of neurovascular retina

PI: ZF

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion**: The laboratory will investigate the molecular signals and mechanisms that regulate blood vessel growth and neural degeneration in eye diseases. This research will utilize a variety of human eye cell types, including human retinal microvascular endothelial cells (HRMECs), which will be cultured to assess cell proliferation, survival, and the formation of blood vessel-like structures. To manipulate gene expression, the lab will employ adeno-associated virus (AAV) and lentiviral vectors for gene knockdown and overexpression, focusing on targets such as ACOX1 and PHGDH in mouse models of retinopathy. All work involving human cells will be conducted using BSL-2 work practices. Experiments involving lentiviral and AAV vectors that target oncogenes or proto-oncogenes, including PHGDH, will also be performed at BSL-2 work practices and conditions. In addition, all animal work involving lentiviral vectors and AAV constructs expressing oncogenes will be performed under ABSL-2 (72 hours).

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

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Explain why both AAV and lentiviruses will be used in the proposed work to modify some of the same genes.
- Provide details on how retinas will be dissected and what instruments will be used. Indicate what protections will be taken to prevent injuries.
- Clarify what 'different reagents' will be used to treat the cells. Are these growth factors? Inhibitors? Any biological reagents?
- Provide a scientific explanation for why 8 different types of AAVs are needed to package the listed genes.
- Describe for the in vivo models of retinopathy what sharps will be used, how they will be disposed and what precautions will be taken to avoid injuries.
- Include hazards associated with working with the cryostat/microtome.
- Specify in the protocol that animal shedding will occur for 72 hours following lentivirus injections.
- Provide an IACUC protocol number.

IBC-P00002125 Mechanisms and treatability of disorders of chromatin biology

PI: MH

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion:** This protocol focuses on understanding how genetic variation affects neurodevelopment through iPSC-derived neuron studies. Neurons will be generated from iPSCs obtained from biobanks and used for characterizing how genetic differences, specifically chromatic-related genes, affect epigenomic and transcriptomic regulation. CRISPR will be used to introduce NGN2 into iPSCs cells via electroporation. Growth factors and chemical inhibitors will be used for directing differentiation to specific cell types. Cells will then be harvested and analyzed using CUT&Tag and RNA-seq. The second part of this protocol will use CRISPR/Cas9 or nuclease-inactive Cas9 to identify pathways that alter the effects of chromatin gene disruption, delivered by second generation lentiviral vectors. E. Coli K12 will be used to propagate plasmids at BSL-1 work practices and procedures. Work with iPSC, lentivirus and human cell lines will be performed at BSL-2. Fixed cells with 4% formaldehyde will be handled at BSL-1.

Regulations Applicable to this Protocol: NIH guidelines III-D, III-E and Bloodborne Pathogens.

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Note that pipettes and other plastics can be disposed of directly into the red bin after producing second generation lentivirus.
- Ensure all research personnel complete the shipping training prior to shipping biological materials.
- Check off shipping training
- Add *Escherichia coli* K-12 and specify the genes/plasmids to be propagated.
- Select 'yes' to allow for ultracentrifugation.
- Uncheck 'Bleach'.
- Update to 10% fresh bleach solution. 70% ethanol is not effective for BBPs.
- Replace 'razor blades' with 'plastic/ceramic' cutting tools.
- Confirm that the collaborating lab is within walkable distance of the lab.
- Additional biosafety enhancements are not necessary per this protocol.

IBC-A00000191-5: Amendment 5 : Gastrointestinal Organoid Culture and Implantation into Mice

PI: DB

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion**: The lab uses patient-derived gastrointestinal biopsies to develop model systems for in vitro studies. The objective is to gain novel insights and treatment strategies for diseases such as IBD, diabetes and celiac. The amendment adds three new lentiviral vectors to assess their role in the expression of proteins such as OSMR (Oncostatin M Receptor - oncogenic in several contexts), PERCC1 and CXXC4 potentially involved in regulating enteroendocrine formation using the lab's intestinal organoid systems. Work with primary human cell lines, lentivirus and adenovirus will be done at BSL-2 work practices and procedures and transplant of transduced organoids into mice will be performed at ABSL-2 followed be ABSL-1 housing.

Regulations Applicable to this Protocol: NIH guidelines III-D.

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Clarify whether adenovirus type 5 and HIV-2 are used; If so, detail the manipulations. If only derived vectors are used remove them from this section.
- Include the physiological function of the proteins.
- Specify the generation of the stated plasmids and the tropism of the viral vector.
- Update to "less than (<1/2)" of the viral genome.

- Respond to the questions in the Gene Drives section, accordingly.
- Remove the reference to gastrointestinal biopsies from patients, as this information is already included in the Human Materials section.
- Update to include the purpose of transporting animals outside of ARCH.
- Describe measures used to prevent aerosol exposure and contamination.
- Specify whether the materials sectioned by the cryostat will be fixed or unfixed.
- Update to include the transport of biopsy specimens from the clinic to the lab.
- Provide responses in the Dual Use of Concern section.

IBC-A00001929-1 Amendment 1 : Virulence determinants of Bacterial pathogens and the emergence of antimicrobial resistance

PI: TVO

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion**: The lab is currently updating protocols to include Staphylococcus aureus USA300, which is a Methicillin –Resistant Strain, to broaden investigations into genotype-phenotype relationships and bacterial adaptation under varying environmental conditions, such as antibiotic exposure. All work involving Staphylococcus aureus, will be conducted at BSL-2 work practices and procedures. Mouse infections will be carried out at ABSL-2, with subsequent housing also maintained at ABSL-2. Handling and processing of all human cell lines will be conducted at BSL-2 work procedures and practices.

Regulations Applicable to this Protocol: NIH guidelines III-D.

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- State the antibiotic resistance determinants introduced into the bacteria and the antibiotics for Tn-seq and CRISPRi studies.
- The protocol indicates that sorting of human cells will be performed. Describe the related experiments, including whether cells will be infected with bacteria, whether they will be fixed prior to sorting, the location of sorting (BSC), and any potential risk of aerosol exposure to personnel.

IBC-A05-228-4 Amendment 4 : Drosophila as a Model Host of Vibrio Cholerae

PI: PW

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion**: The amendment expands on the lab's ongoing studies on host-pathogen interactions in the context of Vibrio cholerae infection of Drosophila melanogaster and human organoids by introducing the aquatic invertebrate Daphnia magna as a new infection model. Daphia magna is a water flea that inhabits freshwater environments in the northern hemisphere and South Africa. It ranges between 2 mm (male) to 5 mm (female) in size. Daphnia magna will be orally inoculated with recombinant Vibrio cholerae strains expressing fluorescent markers to study colonization dynamics and host responses. Infections will be conducted in 24-well plates using saline solutions not exceeding 10^8 CFU/mL Vibrio cholerae. Colonization will be assessed via fluorescence microscopy and selective plating. Gut dissection, homogenization, and qRT-PCR will be performed to evaluate host gene expression changes. Work with human organoids, Drosophila melanogaster, and Daphnia magna infected with Vibrio cholerae will be done at BSL-2 and Vibrio cholerae infection of Drosophila melanogaster will be conducted at ACL-2 work practices and procedures.

Regulations Applicable to this Protocol: NIH guidelines III-D.

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Include information on the method of disposal for liquid waste generated from V. cholerae-infected fleas.
- Specify the antibiotics and their concentrations that will be used to render *Daphnia* germ-free.
- Clarify whether the water fleas are also being handled in the same facility. It is mentioned that drosophila will be contained in vials and anesthetized prior to removal. Specify how water fleas will be contained in 24-well plates.
- Remove the statement "recently renovated Arthropod Containment Level 2 facility".
- Include fluorescence microscopy and RT-PCR.
- Include information on how *V. cholerae* is transported between BSL-2 (culture/manipulation) and ACL-2 (infection of *Drosophila*) labs.

IBC-RN3a-5 Renewal 5 : Transgenic and ES Cell Derived Mouse Models to Study Immunologic and Oncogenic Processes

PI: FA

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion**: The lab studies the molecular mechanisms involved in the generation of B and T cell receptor genes using a combination of molecular, high-throughput, cellular, and animal-based studies. One aspect of the lab's methods involves the use of viral vectors (MSCV, AAV,

and lentivirus) as tools to study in vitro stimulated primary murine B and T cells, as well as established human cell lines. In this renewal, the lab is incorporating the use of mouth pipetting to isolate murine cells and pre-implantation murine embryos. Risk of accidental aspiration will be minimized by using a 1-foot-long tubing alongside a 0.2 µm in-line filter. Work with adenoviral, lentiviral, MSCV, and human cell lines will be done at BSL-2 and injection of altered murine embryonic stem cells into mouse blastocysts to generate genetically modified mice will be done following ABSL-1 work practices and procedures.

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Review and revise this summary using layman's terms so that it may be understood by nonscientific members of the committee.
- Provide more specific information regarding the types of constructs that will be used for gene targeting. Specify the intended effect of these constructs on the target gene (e.g., knockout, knock-in) and the gene editing technology that will be used, such as CRISPR/Cas9 or other methods.
- Clarify the statement: 'Examples include pX330, pX335 (Cas9/CRISPR modifying plasmids) into mouse, rat, or human cell lines, in order to genetically modify these lines' by specifying the plasmids that will be used rather than providing examples.
- Describe the work involving human blood and other potentially infectious materials (OPIM)
- Clarify that Expi293 cells are a human embryonic kidney cell line.
- Clarify what specific experiments will be performed using mouse–rat chimeras, including any downstream procedures.
- Specify the cell types transfected with the plasmids mentioned in the statement, 'To generate CRISPR/Cas9 plasmids, we purchase the pX330 and pX335 vector backbones from Addgene. The CRISPR sgRNA sequences are cloned into the vector backbones, amplified in bacteria, and the resulting purified plasmids are used to transfect cells.'
- Specify the studies or experiments that will be conducted after mice are inoculated with AAV.
- Provide a description of the procedures involving baculovirus and specify whether sf9 cells will be used.
- Remove the "e.g." and "etc." phrases (e.g., viral vectors and cell lines) and specify the viral vectors and cell lines that will be used.
- Check off section III-D-4.
- Specify the promoters contained in pUC and pBR322 expression plasmids.
- Provide responses in the Gene Drives section.
- Include the source of blood and how it will be obtained
- Confirm that the lab is not shipping biological agents.
- Uncheck the selected entries. Enhancements are not required for ABSL-1.

IBC-RN00001089-2 Renewal 2 : Retinal vascular and degenerative diseases

PI: JC

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion**: The lab studies the molecular mechanisms underlying degenerative diseases caused by abnormalities in retinal blood vessels and specialized neuronal cells, with the goal of identifying critical molecular pathways and therapeutic targets to mitigate vision loss. The renewal includes the addition of procedures to isolate primary peritoneal macrophages from mice for downstream proliferation, metabolic, and transcriptomics assays. Genes such as Abca1, Nrf2, Klf4, and Prkaa2 will be targeted in these primary macrophages via siRNA (using lipofectamine-mediated transfection) or viral vectors (AAV and lentivirus). Work involving AAV and lentiviral vectors carrying oncogenes, proto-oncogenes, or tumor suppressor genes in human and murine cells will be conducted at BSL-2 and administration of these viral vectors to mice will be performed at ABSL-2 (72 hours) work practices and procedures.

Regulations Applicable to this Protocol: NIH guidelines III-D.

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Detail the experiments that will be performed with L cells.
- Clarify whether the DNA plasmids listed in the transfection section are viral vector plasmids and specify the studies in which they will be used.
- Clarify what is being subcloned in the Bacteria Transformation section and specify the studies in which it will be used.
- Clarify whether a safety syringe will be used for the extraction of macrophages from the peritoneal cavity.
- Clarify the rationale for using different AAVs and remove “etc.” by providing a complete list of the specific AAV vectors to be used.
- Clarify whether any cells or tissues will be collected from animals after viral shedding has occurred and specify the timing of collection.
- Clarify which animals in the mouse studies will receive viral vectors versus siRNAs and revise the text if only the sub-retinal injections involve viral administration.
- Include IP injections in the descriptions of Project I and/or Project II.
- Specify the purpose of the CRISPR/Cas9 system, which is listed but not included in Projects I and II and include the use of shRNA studies in the projects.
- Update the protocol to include the risk of integration into the host cell genome and insertional mutagenesis when working with lentiviruses.
- Note that personnel are due for the annual refresher safety training.
- Indicate that siRNA oligonucleotides will be used for mouse genotyping and select Section III-F-1.
- Indicate that the adenovirus vector is replication incompetent.

- Update the scientific description to indicate where and how the overexpression and reporter plasmids listed will be used in Projects I and II.
- Confirm and reconcile the injection volumes noted in the Animal Research Study summary with the information provided in the scientific description.
- Update the BSL-2 entry to include viral production in the list of work performed at this biosafety level.

IBC-RN00000632-4 Renewal 4 : Circadian Rhythms in Health and Disease

PI: JL

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion**: The aim of the study is to investigate the fundamental relationship between circadian timekeeping mechanisms and neurological diseases of both the developing and adult brain using in vitro and animal-based models. The renewal adds primary fibroblasts obtained from de-identified Kleefstra Syndrome patients and Large T-antigen promoter. Primary fibroblasts will either be expanded or immortalized by viral inoculation with the Large T-antigen promoter and used for downstream protein expression studies. The renewal also added E. coli BL21 used to propagate plasmids expressing BMAL1, CLOCK, CaMK2A and mutants of these proteins. All work with lentivirus for use with human cell lines will be conducted at BSL-2 and Lentiviral injections in mice will be performed at ABSL-2 (72 h) work practices and procedures.

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

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Specify whether “primary cell lines or mammalian cells” refers to primary mammalian cells and indicate the cell type and source.
- Include that fibroblasts will be obtained from Kleefstra Syndrome patients and provide a brief description of Kleefstra Syndrome.
- Clarify whether 3rd generation lentivirus is being used to express the Large T antigen to immortalize cells, as the plasmids are also described as containing TAT protein, which would be second generation.
- Clarify whether stereotactic injections are occurring within a biosafety cabinet.
- Reverse the spill procedure order for work with primary neurons, as the protocol lists 70% ethanol before 10% bleach.
- Clarify: the Recombinant DNA summary states Large T is made from an MMLV, but the scientific description mentions lentivirus.
- Change the response regarding amplifications of vectors.

- List the risk relevant to the specific AAV, which should be none.
- Do not list the clinical manifestations of HIV as vector-associated risks; instead, specify risks relevant to the gene inserts, including Large T oncogenic potential, insertional mutagenesis, and other oncogenic genes such as METTL3/4, PTEN, and mTOR.
- Per Lentivirus human immunodeficiency virus 1, change the answer to 'Yes'.
- Ensure that bleach should be used for surface deactivation of plasmids and siRNA.
- Verify whether human red blood cells are used in this study, in the Exposure Control Plan. If they are, include this information in the scientific description and Human Materials section.
- Change answer to 'Yes' in the Animal Research study section (Mice AAV entry).
- Verify whether the syringes used for stereotactic injections are included in the Laboratory Procedures section.
- Clarify whether safety needles are being used for brain injections. Note that the volume may be too low to permit their use.
- Describe cell sorting of human blood in the scientific description.
- Remove the statement '...and does not result in aerosolization.'
- Indicate whether the mouse brain will be fixed.
- Include how AAVs will be transported.
- Note that additional biosafety enhancements are not necessary for any of the categories.
- Combine the two *E. coli* sections and the two BSL-2 sections, as they present the same biosafety risks.

IBC-RN10-343-4 Renewal 4 : Manipulation of Neuronal Activity in vivo and in vitro

PI: BS

Motion: Modification Required for Approval – Return to IBC Analyst

Discussion: **IBC Discussion**: The laboratory investigates how the production and function of complement proteins influence neuronal activity and synaptic refinement using both in vitro and in vivo models. Viral plasmids are amplified in thermocompetent E. coli K12 and used to generate AAV vectors encoding various transgenes including mScarlet, DDC, and scrambled shRNAs targeting MAOB and COMT (all newly added in this renewal). The AAV vectors are administered to mice via intraperitoneal, intravenous, stereotaxic, or retro-orbital injection. In vitro work involving AAVs targeting oncogenes will be conducted at BSL-2 and injection of AAV targeting oncogenes into mice will be done at ABSL-2 (72 hours) work practices and procedures.

Regulations Applicable to this Protocol: NIH Guidelines III-D

Motion: Modifications Required for Approval

- Majority (Approved): 16
- Minority (Against): 0
- Abstention: 0

Modifications Requested:

- Indicate if AAV will be generated in the lab or elsewhere. If in the lab include the cell line used for generating the virus.

- Indicate whether AAVs will express human or mouse genes. Indicate which genes are oncogenic and specify if the shRNAs will be used to target tumor suppressor genes, including the timing of tissue collection after AAV injection.
- Describe the cell culture studies using AAVs, including the cell lines to be used and whether they are human cell lines.
- Check off section III-E-1 and uncheck III-F-2 under the NIH Guidelines section.
- Indicate which genes are human in the AAV section (Recombinant DNA).
- Reconcile with the IACUC protocol, as several modes of administration noted there (e.g., in utero, temporal vein of neonates) are not listed in this protocol.
- List all the routes of administration. For neonates, this encompasses temporal vein or jugular vein.
- Indicate in the scientific description which modified mice will be used for these studies.
- Reconcile with the IACUC protocol to ensure all relevant locations are included.
- Include instruments used for survival surgery.
- Include a description of how viral vectors are transported between the lab, core facility and local institutions.
- Clarify whether viral vectors will be shipped to the viral cores mentioned as sources of AAV production.
- Reconcile the BSL-1 entries, as the risks are the same.
- Revise to indicate “Standard ARCH PPE” with the additional use of safety glasses.
- Clarify what is meant by “in vitro targeting of oncogenes,” and specify whether this refers to cell culture experiments.
- Include AAVs containing human genes under BSL-2.

6	**Human Study Annual Reconfirmation**	
IBC-P00001674	A Phase 1/2 Study Evaluating the Safety and Efficacy of a Single Dose of Autologous CD34+ Base Edited Hematopoietic Stem Cells (BEAM-101) in Patients with Sickle Cell Disease and Severe Vaso-Occlusive Crises (BEACON Trial)	
	PI:	**MH**
	Motion:	Approved
	Discussion:	The study is active and closed to enrollment.
IBC-P00000423	Bridge-Enhanced ACL Repair Study	
	PI:	**LM**
	Motion	Approved
	Discussion:	The study is active collecting data after engraftment. Results indicate statistically significant improvement in hamstring strength.
7	**Administrative Reviews**	
IBC-RN00001115-2	Renewal 2 : Study of normal and malignant blood formation	
	PI:	**RR**

Motion	Administrative Approval
Agenda Notes:	This is a three-year renewal with no changes or updates to the risk assessment.

IBC-A00001865-2 Amendment 2 : Immune evaluation of Clostridium difficile vaccines.

PI:	**DD**
Motion:	Administrative Approval
Discussion:	The lab is proposing to add an additional source of inactivated C. difficile Toxin B, derived from a different strain (VPI10463). All work will be conducted under BSL-2 and ABSL-2 work practices within a BSC. This addition does not change the risk assessment.

IBC-RN00000931-2 Renewal 2 : Roles for lipid-derived small molecules in the regulation of pulmonary inflammation and injury

PI:	**BR**
Motion	Administrative Approval
Discussion:	This is a three-year renewal with no changes or updates to the risk assessment.

IBC-RN00000159-4 Renewal 4 : CT adjuvant to protein based vaccines

PI:	**RM**
Motion:	Administrative Approval
Discussion:	This is a three-year renewal with no updates or changes to the risk assessment.

IBC-RN00001026-2 Renewal 2 : Pulmonary Biobank Initiative.

PI:	**BR**
Motion:	Administrative Approval
Agenda Notes:	This is a three-year renewal with no changes to the risk assessment.

IBC-RN00001358-1 Renewal 1 : Botulinum Neurotoxins

PI:	**MD**
Motion:	Administrative Approval
Discussion:	This is a three-year renewal with no changes to the risk assessment.

IBC-RN01-206-5 Renewal 5 : Innate and Acquired Immune Responses to Pneumococci

PI:	**RM**
Motion:	Administrative Approval
Discussion:	This is a three-year renewal with no changes to the risk assessment.

IBC-RN00000987-2 Renewal 2 : Understanding Polymorphisms in Growth Plate Chondrocytes

PI:	**JH**
Motion:	Administrative Approval
Discussion:	This is a three-year renewal with no changes to the risk assessment.

IBC-A00001844-2 Amendment 2 : Translational gene-based therapies

PI:	**MA**
Motion:	Administrative Approval
Discussion:	The amendment includes the use of primary human cells obtained from biorepositories, and the non-viral delivery of mRNA, DNA, and proteins using lipid-based nanoparticles. All work will be conducted under BSL-2 conditions. There are no changes to the risk assessment.

IBC-RN00000681-3 Renewal 3 : Expression of blood vessel regulators in mice and endothelial cells

PI:	**TH**
Motion:	Administrative Approval
Discussion:	In this renewal, CAS9-expressing mice will receive intravenous administration of AAV8 encoding guide RNAs to edit endothelial genes. The effect of these gene modifications on lung vascular permeability will be assessed using Evan's Blue dye perfusion. This update does not change the risk assessment.

IBC-RN00001691-1 Renewal 1 : Human Liver Cell Processing for IRB "Single Cell Atlas of Human Pediatric Livers Across Diverse Ancestry"

PI:	**AC**
Motion:	Administrative Approval
Discussion:	This is a three-year renewal with no updates or changes to the risk assessment.

IBC-A05-130-6 Amendment 6 : Inhibition of Angiogenesis using Adenoviral Semaphorins

PI:	**DB**
Motion:	Administrative Approval
Discussion:	The lab is amending their protocol to include luciferase-labeled tumor cells in their mouse model. All listed tumor cell lines have already been approved under this project. This addition does not change the risk assessment.

IBC-A00001409-3 Amendment 3 : Characterization of the molecular and functional roles of glycoRNAs

PI:	**RF**
Motion:	Administrative Approval
Discussion:	This amendment updates the protocol to include the use of HUVEC cells (human umbilical vein endothelial cells). Additionally, staff involved in the

		shipping of biological materials have completed the required shipping training.

IBC-A00001912-3 Amendment 3 : Gene Therapy Trial for OTOF-mediated Hearing Loss

PI:	**AS**
Motion:	Administrative Approval
Discussion:	The amendment includes linking the IRB and IBC protocols in the new format.

8	**Laboratory Study Annual Reconfirmation**

IBC-P00001154 Elucidating the Biology of Inflammatory Bowel Disease

PI: **WL**

08-301 Investigation of the ER stress sensor IRE1b in gut homeostasis

PI: **WL**

06-114 Recombinant DNA Constructs encoding proteins involved in synaptic and neurodevelopmental proteins

PI: **TS**

10-269 Induction of murine atopic dermatitis by environmental antigens

PI: **RG**

IBC-P00000202 Lymphocyte development and function

PI: **DW**

IBC-P00000158 Virus production service at the Viral Core of Children's Hospital Boston

PI: **ZH**

IBC-P00000183 Biomarker Discovery

PI: **RL**

10-343 Manipulation of Neuronal Activity in vivo and in vitro

PI: **BS**

IBC-P00001801 Pseudoviruses and virus-like particles

PI: **MF**

IBC-P00001800 Engineering B cells for in vitro and in vivo use

PI: **MF**

IBC-P00001795 AAV vectors for use in mice
PI: **MF**

IBC-P00001821 Genetic engineering of hematopoietic cells for therapeutic purposes
PI: **CB**

04-055 Transplant Research Program Biosafety Protocol
PI: **DB**

IBC-P00000272 Molecular Analysis of Hollow Organs
PI: **RA**

IBC-P00000054 Biobank Core
PI: **AC**

IBC-P00000730 Impact of thrombocytopenia and platelet transfusions on neonatal inflammation and host defense
PI: **MS**

IBC-P00001091 Development of oculomotor circuits
PI: **MW**

IBC-P00001561 In vivo CRISPR screen of Adrenal Cancer Cells in Mice
PI: **DB**

01-008 Genetic Research Studies of Congenital Eye Movement Disorders
PI: **EE**

08-123 Signaling in oncogenic epithelial cell transformation
PI: **SH**

IBC-P00001935 CRH in Pregnant Women_IBC Protocol - 11/20/2023 5:53:02 PM
PI: **JM**

IBC-P00001155 Investigation of genes associated with autoinflammatory diseases
PI: **PL**

IBC-P00001218 Immune Phenotyping of COVID19 Subjects
PI: **TC**

IBC-P00002006 Evaluation of stool, urine and blood in patients with and without diarrhea_IBC Protocol - 8/9/2024 4:30:11 PM

	PI:	**JT**
IBC-P00000916	Diphtheria Toxin and Resiniferatoxin Use in Transgenic Mice	
	PI:	**MR**
IBC-P00001867	Working with Human Blood and Fecal Matter	
	PI:	**MR**
IBC-P00000427	Salmonella paratyphi vaccine	
	PI:	**YL**
10-279	Driving stem cells to Dorsal root ganglia-like nociceptor neurons	
	PI:	**CW**
08-152	Prolonged duration sciatic nerve blockade	
	PI:	**DK**

9	**Completions**	
IBC-P00001721	STRENGTH	
	PI:	**BD**
IBC-P00001823	Wedel Lab Biosafety Protocol	
	PI:	**JW**
09-310	Platelet Function Tests on Peripheral Blood of Normal Volunteers	
	PI:	**AF**
IBC-P00001346	AADC Gene Therapy Ventricular Cannula Safety Study	
	PI:	**SS**