

IBC Meeting Minutes
August 20, 2026 (Thursday) at 11:00 A.M.
via Zoom Conference
Bridge

IBC members present:

Tom Greenough (Chair)	X	Shaoguang Li		Mohan Somasundaran	X	Edward Jaskolski (alt)	X
Lisa Cavacini		Philip Tai	X	Eric Rouse		Timothy Kowalik (alt)	
Colleen Driskill	X	Robert Klugman		Regino Mercado-Lubo (alt)	X	Casey Moran (alt)	
Kris Giaya	X	Amelia Houghton	X	Sharone Green (alt)		Richard Ellison III (alt)	
Carol Schrader	X	Melissa Scannell		Jennifer Wang (alt)	X		

Non-members present: Patrice Rando (IACUC/IBC Office)

I. Introductory Remarks

- 1) NEBSA meeting; Sept 9th.
- 2) 07/20/2026: USG Policy for Stopping High-Risk Life Sciences Research (DGOF research and IROC) pursuant to section 5 of EO 14292 from 050525.
- 3) 08/19/2026: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards. The committee discussed emerging policies on dangerous gain-of-function research and a proposed broader NIH biosafety policy covering all biohazard research, public reporting, and institutional oversight.
- 4) The Chair brought to the attention of the Committee the meeting minutes from the previous IBC meeting. **Meeting Decision: Vote to approve July 16, 2026 Meeting Minutes**

II. Report on incidents/accidents from Employee Health Services (EHS)

Past incidents that remain open:
None.

Recent incidents:

- 1) 07/13/2026: Clean mouse bite
- 2) 08/14/2026: Clean rat scratch.

III. Protocols Reviewed Administratively

- 1) Investigator: Bosco, D
Title: Investigating the Effect of Mutant ALS-Linked Proteins on Neuronal Function to Determine Biological Causes of Amyotrophic Lateral Sclerosis (ALS)
IBC Registration: I-466-22, Amendment
Training Verification: **Acceptable pending completion of PI training**
Brief Summary: **Overview and Objectives:** to Identify the effects of mycotoxin-induced neurotoxicity in iPSC-derived motor vs cortical neurons and sALS vs controls patients cell lines.
Experimental approach: Dissolved mycotoxin will be added to the culture media of iPSC-derived cortical and motor neurons to compare neuronal subtype-specific susceptibility. In parallel, iPSC-derived motor neurons from sALS patients and healthy controls will be exposed to the same treatment to assess disease-specific susceptibility. Cells will undergo acute (24-hour) and chronic (up to 7-day) exposure to evaluate time-dependent neurotoxicity.

BSL/ABSL: BSL-2
NIH Guidelines: N/A

- 2) Investigator: Comeau, A
Title: New England Newborn Screening Program
IBC Registration: I-668-26, Renewal (Prev. Eaton)
Training Verification: Acceptable
Brief Summary: We request a Blanket Approval that will allow our clinical laboratory to participate in two major types of MA DPH-sanctioned research projects: 1) evaluation of the analytic and clinical validity and clinical utility of population based testing for newborn conditions and 2) development of technologies to identify newborn conditions. These research activities are required responsibilities of our ISA with the MA Department of Public Health.
The New England Newborn Screening Program is a licensed clinical laboratory that performs population-based testing mandated by Massachusetts Regulations in order to identify newborns who have treatable conditions. The assays used are varied (eg, biochemical, immunological, molecular), singleplex, multiplex and high throughput (hundreds to thousands of specimens per day). The clinical specimens are dried blood spot specimens >99.9% of the time. The laboratory space is mixed use: technical staff and instrumentation used for clinical services are also applied to research projects.
BSL/ABSL: BSL-2
NIH Guidelines: III-F
- 3) Investigator: Koupenova, M
Title: Role of Innate Immunity in Pathogen-Induced Inflammation
IBC Registration: 474-26, Amendment
Training Verification: Acceptable
Brief Summary: To add: poly I:C via Intraperitoneal- polyinosinic: polycytidylic acid route of administration and mCMV via Intraperitoneal, Intravenous route of administration. (ancillary review)
BSL/ABSL: BSL-2; ABSL-2
NIH Guidelines: III-F
- 4) Investigator: Reboldi, A
Title: B Cell Response at the Mucosal Interface
IBC Registration: I-666-26, Amendment
Training Verification: Acceptable
Brief Summary: To add: Candida parapsilosis, and E.coli.
BSL/ABSL: BSL-2; ABSL-2
NIH Guidelines: N/A

IV. Protocols to Discuss

- 1) Investigator: Bolon, D
Title: Analysis of the distribution of fitness effects of mutations
IBC Registration: I-468-26, Renewal
Training Verification: Acceptable
Brief Summary: The goals of the project are to systematically generate mutations in genes and to measure the fitness effects of these mutated genes in different systems including attenuated lab strains of bacteria, budding yeast, and mammalian cells in culture. Currently we do not have any active projects involving viruses, and we do not nor have we in the past worked with infectious viruses in my lab. We have safety protocols for generating mutations in plasmid encoded viral genomes that we transfer to

collaborators and for analyzing virus free genetic material transferred to us from collaborators. Before initiating active collaborations or projects on viruses we will file additional IBC addendums or applications.

Overview and Objectives: The goals of the project are to systematically generate mutations in genes and to measure the fitness effects of these mutated genes in different systems. They will use attenuated lab strains of bacteria, budding yeast, and mammalian (not human) cells in culture. There is no work with viruses, however, they will be generating mutations in plasmid-encoded viral genomes, which are then transferred to collaborators for analysis. They will be analyzing virus-free genetic material transferred to them from collaborators. IBC addendum(s) will be filed prior to any active/infectious viral studies.

Experimental Approach: All genes are mutated on plasmids that are amplified and maintained in E. coli. Mutations are introduced using traditional molecular biology methods including PCR and ligation strategies. In some projects, viral genes are studied using yeast reporters (e.g. we have GFP based yeast reporters for viral proteases including HIV protease and mPro from SARS-CoV2). When viral genes are studied in these yeast reporters, the majority of the viral genome is missing including multiple genes essential for generating infectious viruses.

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IBC Discussion and Vote

Discussion: Reviewer discussed that this is a 5-year renewal that involves systematically generating mutations in genes and measuring the fitness effects of these mutated genes in different systems. The reviewer highlighted the lab is now expanding this study by adding genes that are potentially of concern because of the potential to introduce random mutations. Specifically adding proteases from various viruses, SARS-CoV-2, chikungunya virus, Norovirus, MERS, HIV-1, herpes virus, dengue virus. The reviewer discussed although they are not making mutant viruses, they are making mutations in genes of these viruses and some of their plasmids have full-length virus in them. A member of the committee asked if the lab is looking for ways of modifying the protease to make antivirals more effective, or are they modifying them in different ways to make the virus more effective? The reviewer also highlighted that there is no clear rationale for why they're even focusing on that particular gene of the virus so more information is needed.

Meeting Decision: Vote to approve upon completion of action items.

BSL/ABSL: **BSL-2; BSL-2 Flow Sorting**

NIH Guidelines: IIID, III-E, III-F

- 2) Investigator: Cavacini, L
Title: Functional Activity of Monoclonal Antibodies to Bacteria and Yeast
IBC Registration: **I-665-26, Renewal**
Training Verification: **Acceptable**
Brief Summary: We are developing monoclonal antibodies as potential therapeutics for bacterial and yeast infections. This may be particularly relevant for antibiotic resistant organisms. In this project, monoclonal antibodies will be selected for binding to live bacteria, yeast or bacterial or yeast proteins and then tested for functional activity using in vitro assays. As part of this, we will also be measuring the anti-bacteria or anti-yeast antibodies in the serum and secretions from infected and convalescent individuals.

Overview and Objectives: This project aims to develop monoclonal antibodies as potential therapeutics for bacterial and yeast infections, with particular relevance to infections caused by antibiotic-resistant organisms.

Experimental Approach: Monoclonal antibodies will be screened for pathogen binding and therapeutic activity, while antibody responses in infected and recovered individuals will also be assessed.

IBC Discussion and Vote

Discussion: The reviewer discussed that this is a 5-year renewal to develop monoclonal antibodies as potential therapeutics for both bacteria and yeast, specifically for *Bordetella pertussis* and *Klebsiella pneumoniae*. The protocol is focusing on two strains, *Candida auris* and *Candida albicans*. The lab is paying specific attention to infectious diseases caused by antibiotic resistance organisms. The reviewer highlights that the lab is getting samples from convalescent or sick humans and animals, but they do not mention the source of these samples.

Meeting Decision: Vote to approve upon completion of action items.

BSL/ABSL: **BSL-2; BSL-2 Enhanced Flow Sorting**

NIH Guidelines: III-D, III-F

- 3) Investigator: Humphries, F
Title: Regulation of innate immunity by post-translational modifications
IBC Registration: **832-22, Amendment**
Training Verification: **Acceptable**
Brief Summary: Amendment request to change SARS-CoV-2 work from BSL-3 to BSL-2. The CDC laboratory Biosafety Guidelines for working with SARS-CoV-2 mentions: "At a minimum, BSL-2 facilities, practices, and procedures are recommended for diagnostic research, anatomic pathology, environmental testing, and virus propagation utilizing SARS-CoV-2. At a minimum, ABSL-2 is recommended for work with these viruses in animal models." Centers for Disease Control and Prevention. (2025, September 5). *Laboratory biosafety guidelines for working with SARS-CoV-2*. <https://www.cdc.gov/covid/php/lab/index.html>

Overview and Objectives: To delineate how post-translational modifications can regulate the innate immune response and how these modifications can effect viral, bacterial and fungal infection. To understand how these post-translational modifications can impact autoimmune diseases, neurodegeneration and cancer. To examine basic cell signaling events that underpin the immune response to infection both in vitro and in vivo.

Experimental Approach: Amendment request to change SARS-CoV-2 work from BSL-3/ABSL-3 to BSL-2 with enhancements/ABSL-2. Use a combination of biochemical, molecular and genetic approaches to determine which signaling events (receptors, signaling molecules, cytokines etc.) can regulate the innate immune response. Utilize a combination of shRNA/siRNA approaches in human and murine cell lines as well as the ex-vivo use of cells from mice with targeted deletions in innate immune genes. Live or inactivated bacteria, viruses, fungi, and pathogen-derived products like lipopolysaccharide (LPS) will be used to stimulate cells in vitro. Following these stimulations, we will determine the activation of specific signal transduction pathways in vitro and focusing on how post-translational modifications can regulate these pathways. We will also utilize experimental models of disease to monitor the role these posttranslational modifications play in vivo. We will use the following pathogens in our studies: *Listeria monocytogenes*, *Salmonella typhimurium*, *Candida albicans*, Sendai Virus (in vitro only), Vaccinia Virus, mouse cytomegalovirus, Herpes Simples Virus-1, Influenza Virus, and Human Coronavirus SARS-CoV-2.

IBC Discussion and Vote

Discussion: The reviewer discussed that this is an amendment to downgrade SARS-CoV-2 work that they're doing to BSL-2 enhanced and ABSL-2, done previously for the for Dr. Bazzone in the Fitzgerald Lab group, and for Dr. Wang last month, and is straightforward. The reviewer emphasized the importance of making sure the appropriate training is in place because they are working with a variety of different other human coronaviruses, so there needs to be some training that ensures there isn't any potential cross contamination.

Meeting Decision: Vote to approve upon completion of action items.

BSL/ABSL: **BSL-2+; ABSL-2**

NIH Guidelines: N/A

- 4) Investigator: Imbalzano, A
 Title: Regulation of Chromatin Remodeling and Gene Expression in Development, Differentiation and Transformation
- IBC Registration:** **I-680-26, Renewal**
 Training Verification: **Acceptable**
 Brief Summary: Our studies examine factors and pathways that regulate chromatin structure and gene expression in the context of animal development, cellular differentiation and cell transformation.

Overview and Objectives: The lab examines factors and pathways that regulate chromatin structure and gene expression in the context of animal development, cellular differentiation and cell transformation.

Experimental Approach: Murine and human immortalized cell lines and mouse primary cells are propagated using standard cell culture techniques. Plasmids and BACs will be propagated in standard laboratory strains of E. coli. BACS will be purchased from BACPAC Resources at Children's Hospital Oakland Research Institute. Small molecule RNAs for RNAi-mediated gene silencing will be purchased from commercial vendors. Plasmids and RNA molecules will be introduced to cultured cells by transfection using standard, commercially obtained transfection reagents (e.g., lipofectamine) or by electroporation. Standard replication-deficient, non-pathogenic adenovirus and MMLV-based lentivirus and retrovirus will be used to express wildtype or mutant proteins or to knock down production of endogenous proteins. Adenoviruses expressing Cre recombinase, lacZ or empty vector version will be purchased from the Viral Vector Core at the University of Iowa. Lentivirus and retroviruses will be generated using the standard packaging cell lines like BOSC23 and/ or 293T and used to infect cell lines/primary cells. Human cell line integrity/identity will be periodically tested by STR (short tandem repeat) profiling, which we have performed on a fee-for-service basis by the Genetic Resources Core Facility at the Johns Hopkins School of Medicine.

IBC Discussion and Vote

Discussion: The reviewer discussed that this is a five-year renewal. The reviewer highlighted that when comparing the previous review and documents with the renewal, there are some minor changes, but overall, it's similar. The goal of the lab is to examine factors and pathways that regulate chromatin structure and gene expression in development, cell differentiation, and transformation. The protocol lists several general approaches using tissue culture with human cell lines and mouse cell lines. The reviewer discussed that the flow core will be used with human cell lines that may be modified to express fluorescent tags that are introduced by viral vectors.

Meeting Decision: Vote to approve upon completion of action items.

BSL/ABSL: **BSL-2; BSL-2 Enhanced Flow Sorting**

NIH Guidelines: III-D, III-E, III-F

- 5) Investigator: Kim, D
 Title: **Disruption of Metabolic Enzymes in Human Cancer Cell Lines**
 IBC Registration: **I-655-26, Renewal**
 Training Verification: **Acceptable pending completion of PI training**
 Brief Summary: To examine the effects of various metabolic enzymes on the function, growth, and survival of cancer cells, using cancer cell lines.

Overview and Objectives: The goal of the research is to examine the effects of various metabolic enzymes on the function, growth, and survival of cancer cells.

Experimental Approach: Replication-deficient virus vectors (lentivirus pLENTICRISPR V2), which are designed to deliver CRISPR-Cas9 components to cause gene disruption, or retrovirus (retrovirus pMXS-IRES-blasticidin) or lentivirus vectors (pLV-EF1a-IRES-Puro) overexpress select genes will be used to transduced to human and mouse cell lines. Transduced cells will be selected using puromycin or blasticidin, allowed to grow, and then subjected to viability assays (cell counting, trypan blue, and luminescent cell viability assays) or metabolic assays (oxygen consumption assay and metabolite profiling). Stably selected cells will also be injected into immunocompromised mice to examine the role of these genes in xenograft tumor formation and growth models. Flow sorting is planned.

IBC Discussion and Vote

- Discussion:** The reviewer discussed this is a 5-year renewal with similar goals and experimental methods as previously approved registration. The reviewer highlighted that the goal is to examine the effects of various metabolic enzymes on function, growth, and survival of cancer cells. The reviewer noted that plasmids should be designated as BSL-1. The reviewer mentioned to the committee that this is in response to an ongoing efforts to separate plasmids that are used to make the virus vectors from the vectors themselves.
- Meeting Decision:** Vote to approve upon completion of action items.
- BSL/ABSL:** **BSL-2; BSL-2 Enhanced Flow Sorting; ABSL-1 + BBP with Special Precautions; Administration to Animals using BSL-2 Precautions/ Sharps Safety**
- NIH Guidelines:** III-D, III-F

- 6) Investigator: Li, S
 Title: Retroviral and Lentiviral infection of hematopoietic and leukemic stem cells; AAV infection of mouse liver cells
- IBC Registration:** **I-487-26, Renewal**
 Training Verification: **Acceptable**
 Brief Summary: Human Philadelphia chromosome-positive (Ph⁺) leukemias induced by the BCR-ABL oncogene, including chronic myeloid leukemia (CML) and the B-cell acute lymphoblastic leukemia (B-ALL), and human polycythemia vera (PV) induced by the JAK2V617F oncogene, are among the most common hematologic malignancies. Although the BCR-ABL and JAK2V617F tyrosine kinase inhibitors (TKIs) are effective in treating and controlling chronic phase CML and PV, they are not effective for treating advanced phase CML and Ph⁺ B-ALL, and can only reduce symptoms of PV, because TKIs are incapable of eradicating leukemia stem cells.
- Our major goals are to focus on identifying and characterizing novel genes in leukemia stem cells, and test combinatorial therapies that target leukemia stem cells, aiming to developing new therapeutic strategies for curing CML and PV. To specifically target leukemia stem cells, we need to compare with normal hematopoietic stem cells and progenitor cells for differences in gene expression and in response

to novel therapies to be tested. In addition, some genes will be studied by expressing them in the liver of mice to investigate the effects of these genes on the pathogenesises of the mice.

Overview and Objectives: Human Philadelphia chromosome-positive (Ph+) leukemias induced by the BCR-ABL oncogene, including chronic myeloid leukemia (CML) and the B-cell acute lymphoblastic leukemia (B-ALL), and human polycythemia vera (PV) induced by the JAK2V617F oncogene, are among the most common hematologic malignancies. Although the BCR-ABL and JAK2V617F tyrosine kinase inhibitors (TKIs) are effective in treating and controlling chronic phase CML and PV, they are not effective for treating advanced phase CML and Ph+ B-ALL, and can only reduce symptoms of PV, because TKIs are incapable of eradicating leukemia stem cells.

Major goals are to focus on identifying and characterizing novel genes in leukemia stem cells, and test combinatorial therapies that target leukemia stem cells, aiming to developing new therapeutic strategies for curing CML and PV. To specifically target leukemia stem cells, we need to compare with normal hematopoietic stem cells and progenitor cells for differences in gene expression and in response to novel therapies to be tested. In addition, some genes will be studied by expressing them in the liver of mice to investigate the effects of these genes on the pathogenesises of the mice.

Experimental Approach: The cDNA for BCR-ABL or JAK2V617F in the retroviral vector MSCV-IRES-GFP will be used in all experiments. Helper-free retroviral stocks will be generated by transient transfection of 293T cells. To induce CML or PV, bone marrow cells from donor mice (6-8 weeks old) pretreated with 5-fluorouracil (5-FU; 200mg/kg) through intravenous tail injection will be transduced with the BCR-ABL retrovirus, followed by transplantation into recipient mice (6-12 weeks old). Four days later, bone marrow cells will be harvested, prestimulated with IL-3, IL-6, and stem cell factor (SCF), and subjected to two rounds of cosedimentation with retroviral stock. The transduced marrow cells were transplanted by lateral tail vein injection into recipient mice (0.5x10⁶/mouse) of the same genetic background as the donor mice. To model B-ALL, we will transduce bone marrow from non-5-FU-treated donors without cytokines, followed by transplantation of the transduced cells (1x10⁶/mouse) into recipient mice. Prior to transplantation, all recipient mice (when using C57BL/6 mice) will receive two doses of 550-cGy (centiGray) gamma irradiation separated by three hours. Recipient mice will be evaluated daily for symptoms of CML or PV or B-ALL, including difficulty of breathing and overall signs of morbidity (decreased level of activity). Hematopoietic tissues and peripheral blood samples will be collected from the diseased mice for further pathological and FACS analyses. Normal hematopoietic cells will be transduced with retrovirus and transplanted into recipient mice similarly.

Lentivirus carrying in a gene of interest will be used to infect in vitro the bone marrow cells from mice, human cord blood cells and leukemia cells from patients. The infected cells will be cultured in vitro or transplanted into mice, and the effect of the gene of interest on cell proliferation and survival will be analyzed.

AAV will be used to overexpress a gene of interest in the liver of a mouse by tail-vein injection of the virus. Expression of the gene of interest will be analyzed later by isolating total RNA or proteins from the liver of the mouse.

IBC Discussion and Vote

Discussion:

The reviewer discussed this is a 5-year renewal. The goals of the protocol are to identify and characterize novel genes in leukemia stem cells and test combinatorial therapies that target leukemia stem cells, aiming to develop new therapeutic strategies for curing chronic myeloid leukemia, B-cell acute lymphoblastic leukemia and polycythemia vera to target leukemia stem cells. The lab will also compare normal hematopoietic stem cells and progenitor cells for differences in gene expression and in response to novel therapies to be tested. The reviewer highlighted that the protocol does a great job describing the different experiments. The reviewer noted that the protocol seemed as though it should be ABSL-1+BBP with Special Precaution because they did not see anything

that would require the work to be done at ABSL-2. An updated BSL-2+ Lab SOP was an action item.

Meeting Decision: Vote to approve upon completion of action items.

BSL/ABSL: **BSL-2+; BSL-2 Enhanced Flow Sorting; ABSL-1 + BBP with Special Precautions; Administration to Animals using BSL-2 Precautions/ Sharps Safety**

NIH Guidelines: III-D, III-E, III-F

- 7) Investigator: Lodato, M
 Title: Analysis of human brain somatic mutations
IBC Registration: **I-942-26, New**
 Training Verification: **Acceptable pending completion of PI training**
 Brief Summary: Our goal is to characterize somatic mutations, which are mutations that occur in cells of the body at any time after fertilization, in the human brain. To do so, we generate and analyze DNA and RNA sequencing data from human brain, perform immunostaining on human tissue, and perform modeling experiments on human cell lines in vitro.

Overview and Objectives: The goal of this project is to characterize somatic mutations in the human brain

Experimental Approach: To characterize somatic mutations DNA and RNA sequencing data from human brain will be generated and analyzed. Additionally, human tissues will be immunostained, and human cell lines will be used for in vitro experimental models.

IBC Discussion and Vote

Discussion: The reviewer discussed that this is a new protocol and the project uses postmortem human brain and other tissues, human iPSC lines, iPSC derived neuronal models, as well as dog and mouse brain tissues. The reviewer highlighted that human iPSC-based models will be used for functional studies, including neuronal differentiation, gene experimentation, CRISPR-based genome editing and the downstream analysis will include immunostaining, microscopy of DNA damage assay, and gene expression analysis to assess somatic mutation important, mutational signatures, neuronal phenotypes, and transcriptional effects. The reviewer noted that the protocol is quite straightforward.

Meeting Decision: Vote to approve upon completion of action items.

BSL/ABSL: **BSL-2; BSL-2 Enhanced Flow Sorting**

NIH Guidelines: III-D, III-F

- 8) Investigator: Quinton, L
 Title: Molecular mechanisms of pulmonary inflammation
IBC Registration: **I-815-26, Renewal**
 Training Verification: **Acceptable pending completion of PI training / Acceptable**
 Brief Summary: Acute lower respiratory tract infections cause a terrible public health burden at present, with potential for worse in the coming years. The outcome of these infections is determined by immune responses (such as neutrophil recruitment and activation), necessary for host defense but also contributing to lung injury. The proposed research is discovering how the lungs and immune system respond to the agents that cause lung infections. These discoveries can be used to improve the body's ability to fight off these agents and to decrease the illnesses caused by infections.

Overview and Objectives: Acute lower respiratory tract infections cause a terrible public health burden at present, with potential for worse in the coming years. The outcome of these infections is determined by immune responses (such as neutrophil recruitment and activation), necessary for host defense but also contributing to lung injury. The proposed research is discovering how the lungs and immune system respond to the agents that cause lung infections. These discoveries can be used to improve the body's ability to fight off these agents and to decrease the illnesses caused by infections.

Experimental Approach: Experiments involve bacterial or viral infections in vivo and in vitro. The in vivo infections are with mice, performed with ABSL2 precautions. The in vitro infections are in murine primary cells, murine cell lines, or human cells or cell lines, performed with BSL2 precautions. All experiments that involve primary human tissues and cells will be performed with BSL2 precautions, regardless of whether microbes are added in the experiment itself.

Infections of mice.

Bacteria will be instilled intratracheally or injected intraperitoneally to mice. Bacteria will be *E. coli* (serotype O6:K2:H1), *S. pneumoniae* (serotype 3 from ATCC or serotype 19F, *K. pneumoniae* (serotype 2), *P. aeruginosa* (designation Boston 41501), or *S. aureus* (subsp. *aureus* Rosenbach, designation Seattle 1945; antibiotic-susceptible / not MRSA). Influenza virus PR8 (will be instilled intranasally or intratracheally to mice).

Additional agents: Transgenic/genetically altered mice will be used to interrogate the influence of host immune factors on infection and immunity. Mutant mouse studies will involve traditional knockout mice (with global deletions) and conditional mutant systems for targeted removal of immune genes in select cell types or the expression of the diphtheria toxin (DT) receptor in order to render specific cell types vulnerable to DT. Recombinant viral vectors/plasmids will be used to silence/express host immune factors and for the expression of reporters in select cases. LPS will be used as a sterile stimulus to elicit inflammatory responses in vivo and in vitro, whereas DT will be used, as mentioned above, as a means to selectively deplete cells bearing the diphtheria toxin receptor.

For Flow core, sorting and cytometry with: 1). unfixed human, non-human primate, mouse cells / cell lines labeled with cell surface antibodies for cell population separation, 2). unfixed cells transfected or transduced with gene of our interest, 3). unfixed cells/cell lines infected with BSL-2 infectious agents, 4). fixed infected cells (at least 1-hour 4%PFA fixation). BSL-2 enhanced.

Genes of interest: Innate immune genes (various pattern recognition receptors, adaptor molecules, transcription factors, cytokines, etc). Promoter regions of various characterized and potentially novel candidate innate immune genes.

Viral vectors used: Lentiviral and AAV will be used in vivo and in vitro. pRZ, MSCV

Mice will be transferred in microisolator cages to the laboratory in LRB in a sealed secondary container secured to a cart. In all cases, mice will be in the laboratory for <24h, preceding euthanasia and tissue harvest.

Animals must be removed from the vivarium for several reasons due to the circumstances of our experimental procedures. The intratracheal instillation procedure is a survival surgery typically involving the delivery of microbes into the lungs to elicit a pathological state consistent with human pneumonia. The procedure itself requires mice to undergo general anesthesia, the recovery from which should be monitored carefully by trained laboratory personnel. The animal addednum indicates this will be performed in the LRB space, where all equipment and sufficient space are present.

Mice of different genetic backgrounds will receive intrapulmonary challenges with vehicle or BSL-2 level pathogens, including *S. pneumoniae*, *E. coli*, *S. aureus*, *P. aeruginosa*, *K. pneumoniae*, and Influenza A. In some cases, mice will also receive pharmacologic interventions (such as neutralizing Abs, recombinant cytokines, or other immunomodulatory substances such as clodronate to deplete macrophages). After a period of time spanning 0-14 days post-infection, mice will be euthanized for specimen collections.

IBC Discussion and Vote

Discussion: The reviewer discussed that this is a 5-year renewal and similar to other renewals that were discussed, there is very little that is different from the 2021 version of this registration. The reviewer highlighted that the objectives are to address the observation that acute lower respiratory tract infections are a health burden, and the outcome of these infections are determined by immune responses such as neutrophil recruitment and activation necessary for host defense, but also contributing to the lung injury, and so their research is looking into how lungs and immune systems respond to agents that cause lung infections, hoping to improve on ways of the body's ability to fight off these agents and decrease illnesses that are caused by infections.

Meeting Decision: Vote to approve upon completion of action items.

BSL/ABSL: **BSL-2; BSL-2 Enhanced Flow Sorting; ABSL-2**

NIH Guidelines: III-D, III-E, III-F

9) **Investigator:** Schafer, D
Title: Visualizing and Assessing Roles for Glia and Immune Signaling in the Brain
IBC Registration: **I-600-24, Amendment**
Training Verification: **Acceptable pending completion of PI training / Acceptable**
Brief Summary: To add: ASOs, and siRNAs

Brief Summary and Review by Primary Reviewer

Overview and Objectives: The goal of this project is to understand how neural-immune and glial cells regulate overall nervous system function in health and disease.

Experimental Approach: 1. Experiments will involve labeling or manipulating cells in vitro and/or in vivo (mouse) with plasmids, AAVs, ASOs/siRNAs and agents to regulate inflammation in mice or tissue culture.
2. Tissue and cells from mice will then be either imaged, fixed and immunostained, prepared for biochemistry, or prepared for flow cytometry (mouse tissue and cells).
3. Fresh frozen or fixed human and non-human tissue (including common marmoset) will be used at times for imaging or biochemistry (no flow cytometry).

IBC Discussion and Vote

Discussion: The reviewer discussed that this is an amendment to a registration approved last year. The reviewer highlighted that the amendment requests approval for utilizing antisense oligos and siRNAs that for to deliver genes for manipulating gene expression in the neuron cells. There are additional serotypes of AAVs that the lab is going to use. Animals will receive these ASOs and siRNAs or RNA protein complexes. New transgenic mice will be generated.

Meeting Decision: Vote to approve upon completion of action items.

BSL/ABSL: **BSL-2; ABSL-1 with Special Precautions; Administration to Animals using BSL-2 Precautions/ Sharps Safety**

NIH Guidelines: III-D, III-E, III-F

V. Report on incidents/accidents/issues involving BSL-3 & ABSL-3 Facilities

1) Chris Sasseti new director of BSL-3 core as of 09/01/2026.

Dates to track:

N/A

VI. Information from the field (Senior Biosafety Officer)

N/A

VII. Other Business

- 1) Medical SOP for Hantavirus (including Andes). To be posted for review/comment and approval.

Acknowledgement Items:

- 1) Caricchio 880-23: CAB-201-001 **“A Phase 1/2, Open-label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells (CABA-201) in Subjects with Active Systemic Lupus Erythematosus”** Updated IB
- 2) Luzuriaga 871-23: **“A Phase I, Randomized, Observer-Blind, Placebo-Controlled, 2-Part, Dose-Ranging Study of an EBV Candidate Vaccine, mRNA-1195, in Healthy Participants 18 through 55 Years of Age”** Updated IB
- 3) Caricchio 889-24: **“A PHASE 1 STUDY OF CC-97540 IN SEVERE, REFRACTORY AUTOIMMUNE DISEASES: SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), IDIOPATHIC INFLAMMATORY MYOPATHY (IIM) OR SYSTEMIC SCLEROSIS (SSc)”** BMS-CA061-1001 Updated IB
- 4) Wang 631 and Hafer 443: Adding a new clinical trial, **“A Phase 4 open-label, single-arm study to evaluate the safety and immunogenicity of an Omicron subvariant-based SARS-CoV-2 recombinant spike (rS) vaccine adjuvanted with Matrix-M in participants ≥ 65 years of age and participants 12 through 64 years of age who are at increased risk for severe COVID illness”** NUVAXOVID; a recombinant glycoprotein adjuvanted with Matrix-M

Adjourned at 1:40pm