Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, July 15, 2025 at 1:00p.m. via videoconference. Upon reaching a quorum, the meeting was called to order by the Chairperson.

Meeting Attendance:

Ron Javier, PhD, Chair
Robert Atmar, MD, Vice Chair
Connor Cordray, MPH, CPH, CHMM, CBSP
Monica Darden, MA
Julia Goldman, DVM
Richard Hamill, MD
Shirley Hutchins, MSN
James Kelaher, MD
Paul Nakata, PhD
Kevin Pope
Lisa Rollins, MS

Shalaka Kotkar, PhD, MPH, CPH, CBSP, Alternate
Brooke Mitchell, Alternate
Vance Hobbs, MBA, Alternate
Holly Robinson, Alternate
Shubhashish Sarkar, PhD, Alternate
Rebecca, Schwiebert, PhD., DVM, Alternate

CONFLICTS OF INTEREST

The Chairperson reminded the committee members about the conflict of interest (COI) policy and process. Any conflicts of interest recognized or declared during the meeting will be documented below. The affected member(s) will be excused from the meeting during the relevant discussion and vote and will not participate in either.

MEETING CONDUCT

The Chairperson reminded the committee members that all protocols that are discussed at the meeting are to be considered confidential due to potential privacy or proprietary concerns and are not to be discussed outside of the meeting room with non-IBC members. For this reason, this meeting is considered closed.

REVIEW OF June 2025 MINUTES

The minutes for June 17, 2025, IBC meeting were reviewed and a motion was made to approve the minutes as written. With the majority of the members present voting for the motion, the vote count for approval of the minutes was as follows:

For:	12
Abstain:	0
Against:	0

RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES RESEARCH APPLICATIONS REVIEW

During the review the committee assessed the appropriate biocontainment levels as well as the facilities, procedures, practices, and training of the PI and laboratory personnel involved in the research including appropriate and relevant training, safe conduct of the research, and knowledge of recombinant or synthetic nucleic acids molecules research. The committee also reviewed agent characteristics, types of manipulations planned, sources of the inserted nucleic acid sequences, nature of the inserted nucleic acid sequences, and whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced. Furthermore, the committee determined the applicable section(s) of the NIH Guidelines.

It was determined that the chair or IBC member assigned by the chair must review the modifications to assure that all required changes have been made and all required training is complete before an approval letter may be sent and the PI may begin the research. Further questions, or changes requiring more than simple concurrence by the PI and the chair/designee will be brought to the next convened meeting for full committee review.

A. <u>Recombinant or synthetic nucleic acid molecules research -- Full Board New/Renewals</u>

Protocol number: D960
PI: Wang, Zhao
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Protocol for Recombinant DNA used in Expression Cell lines for cryoEM/ET

This research uses recombinant DNA techniques to study gene function in bacterial and mammalian systems by engineering wild-type or mutant gene constructs for expression, purification, and functional analysis. Techniques include plasmid transfection and viral delivery for gene manipulation, with downstream assays such as protein-protein interaction studies, antibiotic resistance testing, and electrophysiological recordings to explore diverse cellular processes.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the

approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D961
PI: Meng, Xiangling
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Using Human induced Pluripotent Stem Cell-Derived Brain Organoids to Study Human Brain Development and Neurological Disorders

This project uses human induced pluripotent stem cells to study the molecular and cellular mechanisms of human brain development and neurological disorders such as autism, epilepsy, and neurodegeneration. Techniques include CRISPR-Cas9 genome editing, viral gene delivery, calcium imaging and pooled genetic screens to investigate gene function, neural circuit formation, and potential therapeutic strategies in a human-relevant model system.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D963
PI: Pollet, Jeroen
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: A VapA mRNA Vaccine for R. equi

This project aims to enhance the effectiveness of an mRNA vaccine by engineering an effective vaccine antigen. Researchers will validate this approach in vitro using equine cells and fluorescence microscopy.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D964
PI: Shin, Daniel
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Assess the role of Alpha-Thalassemia Mental Retardation Syndrome X-linked (ATRX) in Immunotherapy Response using Genetically Engineered Mouse Model

This research protocol investigates how loss of the chromatin remodeler ATRX affects tumor response to immune checkpoint blockade therapies in lung cancer and melanoma. The study combines lung tumor models to assess tumor progression and immune response under various treatment regimens.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section A: Please expand the abbreviation "ATRX" within the protocol 2) Section C: Please delete the following from the protocol summary: the procedure for AdenoCre administration is carefully standardized to minimize variability and ensure effective infection of the lung epithelium.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D21
PI: Botas, Juan
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Drosophila as a Model System to Investigate Normal Development and Disease.

The research project uses Drosophila melanogaster (fruit flies) to study genes involved in human diseases like Alzheimer's, Parkinson's, and Huntington's, and validates findings in mammalian systems, including mice and human cell lines. The goal is to identify and understand genes that can modify disease outcomes, using genetic and biochemical approaches.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D52
PI: O'Malley, Bert
Containment Level: BSL-1
NIH Guidelines Section: III-D, III-E and III-F
Title: Cloning and Characterization of Human Genes

This research investigates nuclear hormone receptors and their coactivators, which are crucial for development, reproduction, and cancer. Using recombinant DNA methods, the lab will study their mechanisms in vitro and validate their functions in vivo, focusing on their role in regulating protein expression and interactions.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D53
PI: O'Malley, Bert
Containment Level: BSL-2

NIH Guidelines Section: III-D
Title: Sex Hormone Receptor Component and then Cell Genome

The research project uses estrogen receptors (ER), progesterone receptors (PR), and steroid receptor coactivators (SRCs) due to their critical role in reproductive biology and disease. By overexpressing these factors in human cells, we aim to understand their impact on reproductive diseases like endometriosis and cancer progression, with potential implications for diagnosis and treatment.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D104
PI: Mejia, Rojelio
Containment Level: BSL-1
NIH Guidelines Section: III-D
Title: Molecular Cloning of Parasite Sequences for Use in Diagnostics as Standard Controls.

The research project aims to produce antigens for Real-Time PCR diagnostic assays by cloning genes of various parasites into E. coli expression systems. The project involves amplifying cDNA regions, cloning them into expression vectors, and upscaling production, with strict safety protocols and training for personnel.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D144
PI: Ballabio, Andre
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Dissecting the Role of Lysosomal Signaling in Kidney Tumorigenesis / Modulating Cellular Clearance to Treat Neurodegenerative Disease / Modulating Lysosomal Function to Treat Lysosomal Storage Diseases

This research uses lysosomes and lysosome-related diseases, focusing on their roles in cellular metabolism, homeostasis, and adaptive responses. The molecular mechanisms of lysosomal and autophagic pathways in diseases like renal cancer, Parkinson's Disease, and Batten disease, using genetic and pharmacological tools are explored.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D271
PI: Li, Yi
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Breast Cancer Initiation ADN Progression

This research involves various viral vectors to introduce oncogenes into mammary cells of rodents and avians to study breast cancer formation, progression, and therapy response. By using specific mouse lines mammary cells are targeted, allowing testing of the efficacy of chemoprevention and chemotherapeutic agents.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D453
PI: Sahin, Ergun
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Role of Telomeres in Aging and Cancer (Previously Protocol D108)

This research aims to understand how short telomeres induce aging by studying their impact on enzymes. By overexpressing proteins in cultured cells and mice, and inhibiting miRNAs that suppress enzymes, the lab will investigate the mechanisms and relevance of telomere shortening in stem cell aging.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D456
PI: St-Pierre, Francois
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Development of Molecular Sensors and Actuators

This research involves developing and testing sensors and actuators to study and manipulate brain function, such as voltage indicators and other reagents. This involves creating several viruses to deliver genes into mammalian cell lines and neurons.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please provide a more detailed and descriptive protocol title.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the

motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D604
PI: Ferreon, Josephine
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Engineering Optogenetic Lentiviral Constructs

This research investigates how protein aggregation is influenced by blue light. By transfecting cells and mice with viral particles containing specific constructs and exposing them to blue light, the lab aims to develop a mouse model for future therapeutic research.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D615
PI: Elsea, Sarah
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Transduction of Viral Recombinant cdna and shrna Constructs in Human and Mouse Cell Lines to Investigate Genetic and Metabolic Contributors to Neuro Development and Cancer

This research aims to identify cancer genes and pathways for targeted therapies and explore genetic approaches to treat neurodevelopmental and neurodegenerative syndromes. Viral vectors and CRISPR-dCas9 systems in various cell lines and mouse models are used to validate these approaches.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D625
PI: Tang, Jianrong
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Neural Circuit Analysis of Neurological Disease Models

The study investigates how the balance between synaptic excitation and inhibition in neural circuits is established during development and how its disruption contributes to neurological disorders. Researchers use molecular tools and viral vectors in mouse models to manipulate specific neuron types and analyze their roles in brain function and disease.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D631
PI: Zhu, Yi
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Intercellular Communications in Metabolism and Inflammation

The project aims to investigate how animal models overexpressing various proteins and cell-based assays are used to evaluate cellular gap junction activity. It also explores how metabolism

and inflammation impacts transgenic mice using a combination of molecular, cellular, and in vivo techniques.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D962
PI: Godoy, Guilherme
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 3, Randomized Study of cg0070 Versus Observation for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer (ir-nmibc) following Transurethral Resection of Bladder Tumor (turbt)”

This clinical trial evaluates the safety and efficacy of an oncolytic adenovirus, in adults with intermediate-risk non-muscle invasive bladder cancer (IR-NMIBC) following treatment. Key objectives include assessing recurrence-free survival (RFS), progression-free survival, immune response, molecular markers, and quality of life.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section C: Please update the protocol summary to include a brief description of the trial, IND (cretostimogene), collection of specimen for research etc.2) Section C: Please write project description in abstract style.3) Section D: Please describe liquid waste decontamination and disposal. 4) Section D9: Please move "intravesical (IVE) instillation into the bladder of research participants" from "Point of use" to "Point of use (specify species of cell)".5) Section E: Please describe biohazardous waste sterilization procedure including use of disinfectant 6) Section J: Please provide lab user list & ICF.7) Please ensure all personnel complete Bloodborne Pathogens Training.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D609
PI: George, Anil
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 3 Study Evaluating Gene Therapy by Transplantation of Autologous cd34+ Stem Cells Transduced Ex Vivo with the bb305 Lentiviral Vector in Subjects with Sickle Cell Disease (Bluebird 210)

This study evaluates the safety and efficacy of viral vectors in individuals with sickle cell disease.. The therapy has shown promising results, with 90% of evaluable patients achieving transfusion independence and complete response with ongoing trials expanding to younger children.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D616
PI: Omer, Bilal
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Gail-b: Phase I Study of Autologous T Lymphocytes Expressing GD2-Specific Chimeric Antigen and Constitutively Active il-7 Receptors for the Treatment of Patients with GD2-Expressing Brain Tumors

This Phase I trial explores the use of CAR T cells for treating diffuse midline glioma (DMG), a highly fatal pediatric brain cancer with limited treatment options. Building on promising preclinical and neuroblastoma trial results, the study uses a dose-escalation design to evaluate safety and efficacy of locoregional and intravenous CAR T cell delivery, aiming to enhance anti-tumor activity.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section C: Please provide a summary describing what has been completed so far in the last three years with this study

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

B. Recombinant or synthetic nucleic acid molecules research -- Full Board Amendments

Protocol number: D179
PI: Bottazzi, Maria
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Molecular Cloning of Antigens to Study Pathogenesis and Vaccine Development

This research uses various expression systems to clone and express recombinant proteins for studying disease mechanisms, developing diagnostics, and advancing vaccine research. A virus-like particle platform is used to enhance immunogenicity in vaccine candidates targeting a wide range of infectious and non-infectious diseases.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section D: Please the potential complete risk to humans for gene BM86

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D340
PI: Maletic-Savatic, Mirjana
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Mechanisms of Neurogenesis - from Cells to Animal Models

This research protocol focuses on understanding and regulating neurogenesis in the hippocampus to develop regenerative therapies for neurological disorders such as stroke, epilepsy, dementia, and depression. Using a combination of transgenic mouse models, human stem cells, gene editing, and advanced imaging techniques, the lab investigates the proliferation, differentiation, and death of neural progenitor cells, the role of microglia, and the molecular function of nuclear receptors.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section D: Please name the human cell lines. If cell lines are obtained from collaborator, please mention the source. 2) Section D9: Please update "Risk to human" to reflect AAV.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D560
PI: Burrage, Lindsay
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Impaired Glycogen Metabolism and Chronic Liver Disease in Urea Cycle Disorders and Understanding the Biological Basis of Rare Human Diseases

This research investigates the causes and complications of rare genetic disorders, particularly metabolic diseases like urea cycle disorders, using recombinant synthetic nucleic acid techniques. The projects include studying metabolism, mutations in rare diseases, testing prime editing for gene correction in mouse models, and evaluating inflammation to develop therapies.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please change five projects to six projects in the sentence

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D721
PI: Mills, Jason
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Stem Cells, Paligenosis, and Metaplasia

This research project investigates adult stem cell biology in the gastrointestinal (GI) tract, focusing on how normal differentiation processes become disrupted during injury, metaplasia, and cancer. The research studies pancreatic cells using mouse models, organ models, and tissue microarrays to study key signaling pathways in tissue repair and tumorigenesis.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D818
PI: Preidis, Geoffrey
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: The Metabolic Basis of Impaired Bile Acid Synthesis in Malnutrition

This study investigates how amino acids and heme biosynthesis regulate bile acid production, particularly in the context of malnutrition. The research aims to confirm pathways and gene activity using gene knockdown and overexpression strategies both in vitro and in vivo.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D924
PI: Zhao, Qiancheng
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Adeno-associated Virus (AAV) Application in Neural Tracing and Neuromodulation

This project uses viruses to trace and manipulate neural circuits in rodents, aiming to understand how specific neural pathways regulate physiological and immune functions. By delivering genes for neuronal activity, with downstream analysis including microscopy, flow cytometry, and behavioral studies we seek to reveal the roles of targeted neurons in healthy and diseased models.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section F: Please clarify the animal protocol.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D931
PI: Zhao, Qiancheng
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Trans-synaptic tracers in neural circuit mapping

This project aims to map and manipulate body-brain neural circuits in rodents using viral tracing techniques. This study integrates molecular biology, electrophysiology, optogenetics, and high-resolution imaging to uncover how peripheral organs communicate with the brain, with implications for understanding and treating metabolic, neurodegenerative, and inflammatory diseases.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D936
PI: Luznik, Leo
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Targeted and Immunological Therapies in Hematological Malignancies

This research focuses on improving outcomes after allogeneic hematopoietic stem cell transplantation, particularly by preventing graft-versus-host disease and enhancing leukemia immunotherapy. The team investigates bone marrow and T cells for potential therapies.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1) Section C: Please update the project description to include the new work being added. 2) Section F1a. Please update the animal experiments to include the new work being added in this amendment 3) Section F6: Please clarify why this mouse strain needs to be housed in ABLS2 housing.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D728

PI: Salem, Bahey
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Tricar: Trivalent Autologous t-Lymphocytes Co-Expressing three Chimeric Antigen Receptors Targeting cd19, cd20 and cd22 in Acute b-Lineage Leukemia

This research uses CAR-T cell therapy to overcome immune evasion in B-cell leukemia, particularly in cases where other treatments fail. This trial evaluates the safety and efficacy of escalating doses of this therapy, with extensive monitoring and potential for multiple infusions to assess long-term outcomes and optimize treatment.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D747
PI: Steffin, David
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Interleukin-15 and -21 Armored Glypican-3- Specific chimeric antigen receptor expressing autologous t cells as an immunotherapy for children with solid tumors (care)

This research involves CAR-T cell therapy that targets proteins found in several aggressive solid tumors. This Phase I trial aims to determine the safety and optimal dose of this therapy in patients with relapsed or refractory GPC3-positive tumors, with extensive monitoring and correlative studies to assess immune response and tumor microenvironment changes.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 12; Against, 0; Abstaining, 0.

There were no members who recused and absented themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D956
PI: Atmar, Robert
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: dmid 24-0024: a Phase 1 Study to Evaluate the Safety and Immunogenicity of Two Doses of a Novel h5 Antigenically Central (ac)-anhui mrna-lnp Vaccine in Healthy Adults

This Phase 1 clinical trial to evaluate the safety and immune response of two mRNA-based vaccines targeting influenza. The study involves dose escalation and comparison of two vaccine candidates in healthy adults, with close monitoring over several months to determine the optimal dose for future trials.

Following the presentation by the assigned reviewer and discussion of the protocol, the committee IBC concluded that all aspects of review and approval criteria (described above) were met.

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 11; Against, 0; Abstaining, 0.

Robert Atmar, MD recused and absented himself during the discussion and vote on this protocol due to a conflict of interest.

C. Recombinant or synthetic nucleic acid molecule Closure Administrative Report
The IBC Laboratory Compliance Assurance Associate reported to the IBC that there were no rDNA IBC protocols closed for the month of July.

D. Recombinant or synthetic nucleic acid molecule Minor Administrative Report
The IBC Laboratory Compliance Assurance Associate reported to the IBC that there were five administrative rDNA IBC protocols for the month of July.

E. Recombinant or synthetic nucleic acid molecules research -- Exempt Protocols
The IBC Laboratory Compliance Assurance Associate reported to the IBC that there were no exempt protocols submitted in the month of July.

F. IBC Inspection Report

The Biosafety Officer (BSO) informed the committee that there were six inspections performed for the month of July.

G. Research Compliance Services (RCS) Update
The IBC Laboratory Compliance Assurance Associate informed the committee that there were three post-approval monitoring sessions completed.

H. Member Discussion
There were no items to report for the month of July.

I. Spills, Incidents, or Exposures
There were no items to report for the month of July.

J. RAC Decisions and Updates
There were no items to report for the month of July.

K. Issues from the Floor and Public Comments
There were no issues raised from the floor or public comments.

L. Adjournment
The meeting was adjourned at 1:50 pm

UPCOMING EVENTS:
The next IBC meeting is scheduled for Tuesday, August 19, 2025.