# Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, September 16, 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, IBC Vice Chair
Monica Darden, MA
Julia Goldman, DVM
Richard Hamill, MD
Richard Hurwitz, MD
Shirley Hutchins, MSN
James Kelaher, MD
Nandan Mondal, PhD
Paul Nakata, PhD
Robin Parihar, MD
Kevin, Pope
Lisa Rollins, MS
Poonam Sarkar, PhD

Vance Hobbs, MBA, Alternate
Shalaka Kotkar, PhD, MPH, CPH, CBSP
Leticia McGuffey, Alternate
Brooke Mitchell, Alternate Member
Holly Robinson, Alternate
Shubhashish Sarkar, PhD, Alternate
Rebecca, Schwiebert, Ph., 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 August 2025 MINUTES**
The minutes for August 19, 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: | 14 |
| 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: D975
PI: Gibbs, Richard
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Study Of Genetic Variants in Cell Lines

This project investigates how genetic variants contribute to rare monogenic diseases by analyzing their effects on cellular function using human cell lines and advanced molecular techniques. It aims to identify therapeutic targets through detailed molecular assays, without viral vectors or oncogenes.

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, 14; 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: D977
PI: Karch, Jessica
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Investigating Metabolism in the Heart

This research investigates how insulin resistance influences heart disease by manipulating gene expression in cells and genetically modified mice using adenoviruses and adeno-associated viruses. Experiments are conducted to study cardiac insulin signaling and circadian regulation through molecular, transcriptional, and mitochondrial analyses.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please ensure all personnel complete 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, 14; 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: D979
PI: He, Yang
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Neural Mechanisms Mediating Systemic Energy Homeostasis

This project investigates how specific neural circuits in the hypothalamus and hindbrain regulate feeding and energy balance using recombinant viral tools and transgenic mice. The findings aim to advance understanding of appetite control and support new treatments for obesity and metabolic disorders.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please ensure all personnel complete 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, 14; 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: D74
PI: Atmar, Robert
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Molecular Assessment of Noroviruses as Causes of Acute Gastroenteritis

This project investigates norovirus proteins and immune responses by expressing viral genes in viral systems and sequencing viral genomes. It also isolates human monoclonal antibodies from infected patients to study immune repertoire and identify broadly neutralizing antibodies for therapeutic development.

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, 13; Against, 0; Abstaining, 0.

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

Protocol number: D241
PI: Lloyd, Richard
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Mechanisms Of Translation Control During Stress And Virus Infection

This project uses in vitro cell culture models to study how human viruses disrupt translation, affect innate immunity, and develop stress responses by manipulating human gene products. It also investigates host-virus interactions during persistent infections and uses recombinant DNA and lentiviral tools for gene expression and knockdown.

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, 14; 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: D299
PI: Tolias, Kimberley
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Molecular Mechanisms of Synapse Development and Remodeling

This project investigates how neurons regulate synapse formation, dendritic growth, and plasticity in the mammalian CNS using genetic and molecular tools in rodent models. It combines in vitro and in vivo approaches to study signaling pathways involved in development, disease, and injury.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please clarify which viruses are being injected into mice

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, 14; 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: D472
PI: Sonnet, Corinne
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Production of Replication Defective Adenoviruses, Retroviruses, and Lentiviruses by The Vector Development Laboratory

This project constructs replication-defective adenovirus, retrovirus, and lentivirus vectors for gene therapy, using plasmid shuttle vectors provided by investigators. Quality control includes

testing for replication-competent adenovirus (using wild-type virus as a control), titering, and verifying transgene expression.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please add a sentence explaining containment of potential aerosol exposure during virus centrifugation in Section C.

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, 14; 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: D480
PI: Frederick, Mitchell
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Recombinant Dna, Lentiviral And Retroviral Work

This project focuses on manipulating gene expression in human and mouse cancer cell lines using recombinant constructs, shRNA, and CRISPR tools to study genes involved in Head and Neck Cancer. Lentiviral and retroviral vectors—used for overexpression, knockdown, and screening—are replication-defective for both in vitro and in vivo experiments.

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, 14; 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: D804
PI: Ghanta, Ravi
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Multiplexed CRISPRa to Promote Mitochondrial Biogenesis

This study aims to enhance mitochondrial biogenesis in cardiomyocytes using CRISPRa to activate key genes in heart disease and heart failure. Viral vectors are used in vitro and in vivo to enhance gene expression in cellular and animal models for key disease states.

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, 14; 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: D813
PI: Li, Hongjie
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-F
Title: Transgenic Fly Work Safety Protocol

This project uses molecular cloning to study Drosophila genes related to brain aging, Alzheimer's disease, and colorectal cancer by generating transgenic flies with gene overexpression or knockdown. Experiments involve phenotype characterization, behavioral assays, and tissue analysis.

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, 14; 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: D816
PI: Kommagani, Ramakrishnan
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F

Title: Transcription Factors and Steroid Hormones In Endometrial Function and Dysfunction

This project investigates the molecular mechanisms regulating reproductive tract function and disease, focusing on nuclear receptor signaling in conditions like endometriosis and endometrial cancer. Using lentiviral tools for gene knockdown or overexpression in cell lines and primary cellsthis study explores gene function, tumor progression, fertility, and the role of gut microbiota in disease development.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please complete Section A4 2) Please ensure all personnel complete 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, 14; 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 explores how certain amino acids regulate bile acid production, particularly in the context of malnutrition. Using in vitro hepatocyte models and in vivo mouse experiments with AAV/adenovirus-mediated gene overexpression, the research aims to restore bile acid synthesis by targeting key enzymes..

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, 14; 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: D821

PI: Lemon, Katherine
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Genetic Determinants Of Microbe-Microbe and Microbe-Host Interactions in Human Nasal Microbiota

This project investigates bacterial genetic factors that mediate interspecies interactions within the human nasal microbiota using recombinant genetics in BSL-1 and BSL-2 bacterial species. By combining genetic manipulation and multi-omics approaches, the study aims to uncover how specific bacterial genes influence microbial behavior and host responses in nasal epithelial models.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please describe spill containment protocol in Section C.

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, 14; 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: D822
PI: Aiba, Isamu
Containment Level: BSL-1
NIH Guidelines Section: III-D
Title: Genetic Modification of Susceptibility to Spreading Depolarization

This project explores the genetic regulation of spreading depolarization (SD) in the brain by using recombinant AAVs to knock down related genes systemically in mice. Following viral delivery, brain tissue is analyzed through imaging, electrophysiology, and molecular assays to assess gene knockdown efficiency and SD-related neuronal activity.

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, 14; 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: D968
PI: Bacino, Carlos
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: H-57160 / Phase 3 Study of The Efficacy and Safety Of Ion582 In Children and Adults with Angelman Syndrome Ion582-Cs2

This project will use a synthetic antisense oligonucleotide designed to treat Angelman Syndrome by degrading the associated RNA, thereby restoring protein expression in neurons. This Phase 3 clinical trial is underway to evaluate its efficacy, safety, and pharmacokinetics in children and adults with genetically confirmed Angelman Syndrome.

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, 14; 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: D976
PI: Nayak, Anuranjita
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Emperor: A Multicenter, Randomized, Double-Blind, Sham-Controlled, Parallel Group, Phase 3 Study Evaluating The Efficacy, Safety, And Tolerability of Zorevunersen (Stk-001) In Patients With Dravet Syndrome

This study evaluates the efficacy, safety, and tolerability of zorevunersen (STK-001), a novel antisense oligonucleotide therapy designed to increase certain protein expression in patients with Dravet syndrome. Approximately 150 patients will be randomized to receive either zorevunersen or a sham procedure over a 60-week period, with the goal of addressing the genetic root cause of DS and improving both seizures and associated comorbidities.
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, 14; 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: D234
PI: Rooney, Cliona
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Studies of Tumor and Virus-Specific Immunity for Immunotherapy Studies

This project develops immune cell-based therapies for virus-associated diseases and cancers by engineering T cells, NK cells, and NKT cells with native or recombinant receptors using viral and non-viral gene modification methods. These modified immune effector cells are tested in vitro and in murine models for specificity, function, and persistence.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please clarify if Macaque T cells are being used. 2). Please clarify which viruses are being used. 3). Please ensure all personnel complete 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.

Parihar, Robin, M.D. and Rollins, Lisa, M.S. 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 and Progression

In this project, several viral vectors are used to deliver oncogenes into mammary cells of rodents, enabling precise modeling of breast cancer initiation and progression. Tumor

development and treatment response are monitored through imaging and clinical observation, with chemoprevention and chemotherapy agents tested for efficacy.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please explain potential aerosol containment during concentrating the virus cultured media by ultracentrifugation in Section E.

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, 14; 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 project studies advanced strategies to prevent GVHD using post-transplant cyclophosphamide and explored the bone marrow microenvironment's role in leukemia persistence and immune response after transplant. Through viral and transgenic modelswe aim to uncover mechanisms of relapse, optimize adoptive cell therapies, and identify novel immunogenomic biomarkers to improve outcomes in blood cancers.

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, 14; 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: D446
PI: Ramos, Carlos
Containment Level: BSL-2
NIH Guidelines Section: III-C

Title: Rely-30: Phase I Study of Relapsed Cd30 Expressing Lymphoma Treated with Cd30 Car T Cells

This study is a  Phase I clinical trial is evaluating CD30-targeted CAR T cells in relapsed/refractory lymphoma, aiming to improve safety, persistence, and antitumor activity, with lymphodepletion now being explored to enhance therapeutic efficacy.

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, 14; 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: Mahdi, Jasia
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 study is a Phase I trial is evaluating CAR T cells—engineered to deliver three activation signals—for intravenous and intracerebroventricular administration, aiming to improve safety, tumor response, and long-term survival in children with gliomas.

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, 14; 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: D838
PI: Suter, Bernhard
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: RTT-200 A Phase 1/2, Open-Label Clinical Study to Evaluate Safety, Tolerability, and Efficacy of NGN-401 in Subjects with Rett Syndrome

This study involves a gene therapy trial using adeno-associated virus to deliver a targeted genes for Rett syndrome, aiming to address the root genetic cause of the disorder. Short and long term results will be studied and subjects will be followed for outcomes.

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, 14; 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: D855
PI: Omer, Bilal
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Chimeric Antigen Receptor Treatment Targeting Aml and Other Cd70 (Seventy) Positive Leukemias – Casey

Acute Myeloid Leukemia (AML) is a fast-growing cancer of myeloid cells with poor outcomes in relapsed or refractory cases. This Phase I trial evaluates the safety and efficacy of CD70-targeted CAR T cells with the goal of achieving remission and enabling potential hematopoietic stem cell transplant (HSCT).

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, 14; 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: D893
PI: Baxter, Patricia
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Phase 2 Trial of G207 + 5 Gy Radiation for Children with High-Grade Gliomas; PBTC-061

This is a Phase II trial evaluating intratumoral G207 infusion followed by 5 Gy radiation in children with recurrent high-grade glioma, aiming to improve post-progression survival.

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, 14; 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: D914
PI: Sunde, Jan
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Gog-3076: A Randomized Phase 3 Study Assessing the Efficacy and Safety of Olvi-Vec Followed By Platinum- Doublet Chemotherapy And Bevacizumab Compared With Physician's Choice of Chemotherapy and Bevacizumab in Women with Platinum Resistant/Refractory Ovarian Cancer (Onprime/Olvi-Vec-022)

In this study. a modified vaccinia virus is being evaluated in a Phase 3 trial for patients with platinum-resistant/refractory ovarian cancer , including fallopian tube and peritoneal carcinomas. The virus and chemotherapy agents are administered to enhance antitumor immunity and overcome therapy vresistance.

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, 14; 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: D937
PI: Rao, Ganesh
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Gpc-3 Chimeric Antigen Receptor T Cells for Recurrent Gpc-3 Positive Glioblastoma (Go-Cart)

This study explores administration of GPC3-targeted CAR T cells during surgical resection for recurrent Glioblastoma, aiming to bypass the blood-brain barrier and enhance safety and efficacy by delivering patient-derived T cells.

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, 14; 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.

**C. Recombinant or synthetic nucleic acid molecule Closure Administrative Report**
The IBC Laboratory Compliance Assurance Associate reported to the IBC that there was one rDNA IBC protocol closed for the month of September.

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

**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 September.

**F. IBC Inspection Report**
The Executive Director, Environmental and Laboratory Safety informed the committee that there were nine inspections performed for the month of September.

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

**H. Member Discussion**
The Executive Director, Environmental and Laboratory Safety informed the committee about new safety assignments and coverage of Texas Children's Hospital research buildings. Also, an IBC Member had a question regarding access with the new BCM electronic access policies that will require strict security and encryption.

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

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

**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 1:57 pm

**UPCOMING EVENTS:**
The next IBC meeting is scheduled for Tuesday, September 16, 2025.