Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, June 17, 2025 at 1:00p.m. via videoconference. Upon reaching a quorum, the meeting was called to order by the Chairperson.

Meeting Attendance:

Ron Javier, Ph.D., Chair
Robert Atmar, MD, IBC Vice Chair
Connor Cordray, MPH, CPH, CHMM, CBSP
Monica Darden, M.A
Julia Goldman, DVM
Shirley Hutchins, MSN
James Kelaher, MD
Paul Nakata, Ph.D
Robin Parihar, MD
Kevin, Pope
Shannon Ronca, Ph.D., M.P.H., B.S.
Poonam Sarkar, PhD

Vance Hobbs, M.B.A., Alternate
Shalaka Kotkar, PhD, MPH, CPH, CBSP, Alternate
Leticia McGuffey, Alternate
Holly Robinson, Alternate
Shubhashish Sarkar, PhD, 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 May 2025 MINUTES
The minutes for May 20, 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: D958
PI: Jones, Kathryn
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Chimpanzee Adenovirus Vectored Vaccine Constructs (ChAdOx)

This research involves chronic infection with Trypanosoma cruzi causes heart inflammation, and while current drugs eliminate the parasite, they don't reduce inflammation. The lab is evaluating vaccines developed using a chimpanzee adenovirus vector and containing T. cruzi antigens ability to reduce inflammation and improve heart function in infected mice.

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: D20
PI: Rice, Andrew
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Molecular Mechanisms of Viral Gene Expression

This research involves plasmids to express HIV-1 proteins in human cell lines and plan to use co-immunoprecipitation to identify interacting cellular proteins. Additionally, the lab will assess the effects of these viral proteins on reporter plasmids, viral replication via qRT-PCR, and cellular surface proteins using flow cytometry.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section D: Please clarify the cells being used

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: D22
PI: Palzkill, Timothy
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-F
Title: Role of Beta-Lactamase Mutations in Antibiotic Resistance

This study investigates the catalytic mechanisms and substrate specificity of various beta-lactamases from gram-positive and gram-negative bacteria using site-directed mutagenesis, plasmid libraries, and biochemical assays in E. coli. It also explores the inhibitory effects of proteins and screens for small molecule inhibitors, aiming to better understand and combat antibiotic resistance.

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: D27
PI: Chen, Miao-Hsueh
Containment Level: BSL-1
NIH Guidelines Section: III-D, III-E and III-F
Title: Developmental Signaling Pathway and Mesenchymal Cell Fate Determination

This research investigates how developmentally expressed genes regulate the formation and function of brown, beige, and white adipose tissues from mesenchymal cells, using both in vitro cell models and in vivo transgenic mice. A combination of molecular biology, cell biology (including gene overexpression, knockdown, and 3D organoid models), and genetic lineage tracing techniques are employed to dissect the roles of these genes in adipose tissue development and function.

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: D243
PI: Rowley, David
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Role of Mesenchymal Derived Growth Regulatory Factors in Prostatic Cancer

This project investigates the role of carcinoma-associated fibroblasts and myofibroblasts in tumor progression and wound-related diseases by manipulating gene expression in prostate cancer, epidermal, and stromal cells using transfection, retroviral, lentiviral, and CRISPR-Cas9 systems. These engineered cells are studied in 3D organoid models to assess gene function in cancer growth and stromal biology, using a wide array of molecular tools, plasmids, and both mouse and human cell systems.

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: D261
PI: Tsai, Francis
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-F
Title: Decoding Nacht Proteins: 3d Structure and Mechanisms in Phage Defense

This project aims to elucidate the structure-function relationships of molecular machines across a range of organisms, including bacteria, yeast, protozoa, nematodes, and mammals. Using recombinant protein expression in E. coli and S. cerevisiae, followed by biochemical assays and structural analyses such as X-ray crystallography and cryoEM, the study employs site-directed mutagenesis and various cloning techniques to investigate the roles of these molecular machines in 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: D274
PI: Lewis, Michael
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Analysis of Mammary Gland Development and Neoplasia in Mouse and Human

This project explores how gene expression manipulation via recombinant DNA vectors—both viral and non-viral—affects mouse and human mammary epithelial cell behavior, including proliferation, death, and morphogenesis. Using in-vitro culture and in-vivo transplantation or injection methods, the study focuses on genes in key signaling pathways and includes plans for in vivo overexpression screen using a human cDNA library to identify novel developmental regulators and oncogenes.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please ensure all personnel complete Blood Borne Pathogen 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: D276
PI: Xu, Jianming
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: The Generation of Genetically Engineered Mouse, Rat, and Nile Grass Rat Models

This project focuses on generating genetically engineered rodent models to study the roles of genetic and somatic mutations in disease. Knockout and transgenic models are created by integrating rodent or human DNA fragments to produce animals for research.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section C – Project Description: Please further clarify work being done 2) Section D9: Please move mouse, rat, Nile grass rat embryos to "Point of use" under Eukaryotic vectors 3) Section D: Please clarify the use of Human Cells 4). Section F: Please provide the related IACUC protocol number.

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: D349
PI: Shen, Hu Ying
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Molecular Mechanisms of Vascular Diseases

This research focuses on uncovering the molecular mechanisms underlying vascular diseases, particularly aortic aneurysms and dissections (AAD), with the goal of developing pharmacological interventions. The roles of specific genes in disease progression will be studied with in vivo mouse models and in vitro molecular and cellular assays.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1) Please clarify number of cells and anticipated culture media volumes being used 2) Please clarify volume of medium will the 293T cells in 10 cm dish be used for viral transfection 3) Please mention the physical location of the room to be used for making nanoparticles 4) Please clarify what concentrations -siRNA /mRNA nanoparticles will be used in mice and mention anticipated volume for tail vein infections.

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: D358
PI: Reimer, Jacob
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Targeted Neural and Network Control using Opto-Genetics

This research uses advanced optogenetic, viral, and genetic techniques to manipulate and study neuronal activity and connectivity in the mouse brain. By expressing light-sensitive proteins fluorescent markers, and genetically encoded sensors, the team aims to dissect neural circuit function with high spatial and temporal precision, both in vivo and in vitro.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please clarify appropriate safety protocols 2) Please clarify if an IACUC protocol is being used 3) Please clarify if Human Cells are being used 4) Please clarify if Primate work is being used.

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: D400
PI: Liang, Xie
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: The Roles of Prolyl Hydroxylase Domain Proteins in Cardiac Function

The research explores how protein depletion affects downstream gene delivery in mouse models to assess whether restoring these targets can rescue cardiac phenotypes. The ultimate goal is to uncover the molecular mechanisms by which proteins regulate heart health and to identify potential therapeutic strategies for heart 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: D451
PI: Walker, Cheryl
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Use of Tissue Culture Cells, Plasmid DNA, and Viral Vectors for Investigation of Kidney, Uterine, Prostate, and Hepatic Pathways that Lead to Tumoriogenesis

This research focuses on dissecting cell signaling and protein interactions in human and rodent cell lines, particularly in response to treatments like siRNA, plasmid transfection, and chemotherapy drugs. Lentiviral systems are employed for gene knockdown to investigate mitotic regulation and neuronal function.

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: D469
PI: Elefteriou, Florent
Containment Level: BSL-2
NIH Guidelines Section: III-D III-E and III-F
Title: Research on bone development and diseases

This research focuses on understanding skeletal diseases such as osteoporosis, genetic bone disorders, and bone metastasis using mouse models, particularly those with floxed genes for targeted gene ablation. To investigate gene function and signaling pathways in bone cells, the lab uses adenoviral and lentiviral vectors to manipulate gene expression in vitro in established cell lines, followed by classical assays to study cell proliferation, differentiation, and function.

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

Protocol number: D607
PI: Barbieri, Eveline
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Functional Characterization of Novel Mycn Targets in Neuroblastoma Oncogenesis.

This research investigates how neuroblastoma reprograms its metabolism to support tumor growth, focusing on the roles of the molecular clock, and the tumor microenvironment, using genetic manipulation, viral vectors, and recombinant proteins in both in vitro and in vivo models. These studies aim to determine therapeutic targets and optimize treatment timing

(chronotherapy) by exploring metabolic gene rhythmicity, immune cell interactions, and neural crest transformation mechanisms using human and murine cell lines and xenograft models.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please clarify the names of the human and mouse cell lines that will be used in the protocol. 2) Please add category III-F. 3) Please ensure all personnel complete Blood Borne Pathogen 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: D790
PI: Monsivais, Diana
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: The Biological Control Endometrial Regeneration, Fertility and Cancer

This research investigates the genetic and molecular mechanisms underlying endometrial disorders such as implantation failure, defective decidualization, and endometrial cancer. Using mouse models, human cell lines, primary cells, and organoids, the lab explores the roles of signaling pathways in endometrial regeneration and homeostasis.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section F: Please include all animal work in this section 2) Please clarify what IACUC protocol is being used.

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: D802
PI: Barrozo, Enrico
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F

Title: Ha-CoV-2, a Non-replicative Vector for Pseudotyped SARS-CoV-2 Immunology

This project proposes the use of BSL-2 non-replicative pseudoviruses to study spike-mediated entry into human cells, and to assess their immunogenicity and potential for neutralization by human antibodies. A lentiviral pseudovirus will be tested in various human cell lines and primary trophoblasts for entry efficiency, immune response, and antibody neutralization.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section D9: Please delete cell type & add Rapid Pseudovirus. 2) Section E3: Please indicate what type of vector is being used. Is the backbone a lentivirus or is it an alphavirus 3) Section E3: Please indicate what type of vector is being used. Is the backbone a lentivirus or is it an alphavirus.

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: D803
PI: Foight, Glenna
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Engineering Control of Human Transcription Factors in T Cells

This research focuses on retroviral and lentiviral vectors to introduce native and engineered human transcription factors targeting tumor antigens. These constructs are tested in vitro for their effects on T cell phenotype, tumor killing, and gene expression using flow cytometry and co-culture assays.

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: D954

PI: Pehlivan, Davut
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 1-2, Double-Blind, Sham-Controlled Multiple Ascending Dose Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Intrathecally-Administered ION440 in Patients with MECP2 Duplication Syndrome

This study investigates the safety and therapeutic potential of an oligonucleotide designed to reduce overexpression of the MECP2 gene in patients with MECP2 Duplication Syndrome (MDS)—a rare, X-linked neurodevelopmental disorder primarily affecting males.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section C: Please update the protocol summary 2) Please indicate what specimen will be collected 3) Please ensure all personnel complete Blood Borne Pathogen 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: D959
PI: Ramos, Carlos
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Expanded Access Program (eap) for Obecabtagene- Autoleucel (obe-cel) out-of-Specification (oos) in Adult Patients with Acute Lymphoblastic Leukemia

This research involves an expanded access program (EAP) is designed to provide out-of-specification Obecabtagene autoleucel to adult patients with relapsed/refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) who have already been prescribed commercial obe-cel but whose final manufactured product does not meet full commercial release specifications.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please expand the abbreviations: EAP, ALL CRS, ICANS and AEs 2) Please update Section D9 3) Please update Section H4 and H5.

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: D446
PI: Ramos, Carlos
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Rely-30: Phase I Study of Relapsed cd30 Expressing Lymphoma Treated with CD30 Car t Cells

This research involves a Phase I clinical trial is designed to evaluate the safety and potential efficacy of autologous CD30-directed CAR T cells (CD30.CAR-Ts) in patients with relapsed or refractory CD30-positive Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL). The study builds on prior work showing that CD30.CAR-Ts—engineered using a retroviral vector to express a CAR with CD28 and CD30 signaling domains—can be safely administered without preconditioning, but with limited persistence and modest clinical responses.

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: D703
PI: Rouce, Rayne
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Pediatric and Young Adult Leukemia Adoptive Therapy (plat)-07: A Phase i/ii Study of CD22-Specific Car TCells for CD22+ Leukemia orLymphoma

This research involves a Phase 1/2 open-label, non-randomized clinical trial evaluating the safety, feasibility, and efficacy of a novel CD22-targeted CAR T-cell therapy—SCRI-CAR22v2—in pediatric and young adult patients with relapsed or refractory CD22+ leukemia or lymphoma, including those with prior allogeneic hematopoietic cell transplantation (allo-HCT).

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.

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

Protocol number: D168
PI: Arenkiel, Benjamin
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Monitoring Neuronal Circuits in the Mammalian CNS

This research aims to determine how neuronal activity influences the integration and maintenance of neurons using genetic, imaging, and electrophysiological tools to trace synaptic connections, manipulate activity, and identify molecular regulators. Additionally, the study explores how signaling from the forebrain affects circuits involved in feeding behavior.

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: D922
PI: Chen, Wen-Hsiang
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Molecular Cloning of Antigens for Vaccine Development

This research project uses E. coli, Bacillus subtilis, and yeast, for molecular cloning and expression of antigens related to Lyme disease and ticks, with the goal of producing recombinant

proteins for assays and vaccine development. The process includes cloning, protein purification, spore surface display using B. subtilis, and immunogenicity testing in mice to evaluate the potential of an oral vaccine platform.

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 LymphocytesExpressing GD2-Specific Chimeric Antigen and Constitutively Active il-7 Receptors for the Treatment of Patients with GD2-Expressing B Tumors

This study explores an immunotherapy approach for treating diffuse midline glioma (DMG), a highly aggressive and fatal pediatric brain tumor, by using T cells engineered to deliver three activation signals. A Phase I clinical trial is underway to evaluate the safety and efficacy of these cells administered intravenously and intracerebroventricularly, with the goal of improving immune response and survival in children with relapsed or refractory DMG.

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: D655
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 research involves a clinical trial is exploring the use of GD2-specific CAR T cells engineered to deliver three activation signals—including a constitutively active IL-7 receptor—to target GD2-expressing DMG cells, with early preclinical models showing promising tumor eradication and the trial aiming to assess safety and 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, 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: 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)

This research involves a Phase 3 multicenter, randomized, open-label study evaluating the efficacy of Olvi-Vec, in combination with platinum-doublet chemotherapy and bevacizumab in patients with platinum-resistant/refractory ovarian cancer (PRROC), including fallopian tube carcinoma and peritoneal carcinomatosis. Building on promising Phase 2 results, the trial hypothesizes that Olvi-Vec primes the immune system by inducing immunogenic tumor cell death and modulating the tumor microenvironment, thereby enhancing the antitumor effects of subsequent chemotherapy and improving clinical outcomes such as progression-free survival and overall response rate.

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.

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 June.

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

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 June.

F. IBC Inspection Report
The Biosafety Officer (BSO) informed the committee that there were six inspections performed for the month of June.

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 Director, Research Compliance informed the committee of the new NIH Requirements for IBC Minutes and IBC Rosters.

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

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

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 1:55 pm

UPCOMING EVENTS:

The next IBC meeting is scheduled for Tuesday, July 15, 2025.