Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, July 21, 2026 at 1:00 p.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
Shirley Hutchins, MSN
James Kelaher, MD
Brooke Mitchell, Alternate Member
Paul Nakata, PhD
Lisa Rollins, MS
Shannon Ronca, PhD, MPH, BS
Poonam Sarkar, PhD

Vance Hobbs, MBA, Alternate Member
Leticia McGuffey, Alternate Member
Shubhashish Sarkar, PhD, Alternate Member

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 2026 MINUTES

The minutes for June 19, 2026, 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: D1021
PI: Hulsurkar, Mohit
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Targeting Inflammation in Cancer Associated Atrial Fibrillation

This project investigates how cancer-associated inflammation contributes to the development of atrial fibrillation (AF) by using commercially produced, replication-deficient AAV vectors to evaluate their effects. The study will use a variety of molecular, histological, and functional analyses to identify disease mechanisms and potential therapeutic targets for preventing inflammation-driven AF.

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: D71
PI: Wensel, Theodore
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E III-F
Title: Retinal Signal Transduction

This research program investigates the molecular mechanisms of sensory signal transduction using recombinant DNA technologies to characterize gene expression, produce and study proteins in bacterial, yeast, mammalian, and insect cell systems, and examine the function of proteins involved in signaling pathways. The laboratory also generates and studies genetically modified mouse models and uses replication-deficient AAV vectors, fluorescence imaging, histology, electron microscopy, and electrophysiological techniques to evaluate protein 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: D270
PI: Versalovic, James
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Epigenomic Regulation of Metabolism by Nuclear Receptor Corepressors

This research examines how metabolites produced by gut microbiota influence intestinal inflammation and inflammation-associated colorectal cancer. The project employs targeted gene inactivation, complementation, and transposon mutagenesis approaches to evaluate bacterial products and host 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: D513
PI: Martin, James
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Use of Plasmid Dna, Viral Vectors, and Tissue Culture of Cells for Investigation of Epigenetic Mechanisms

This research program aims to identify chromatin-based regulatory mechanisms that drive altered gene expression in human diseases. The laboratory employs molecular and cellular techniques including transfection, viral transduction, microscopy, Western blotting, live-cell imaging, and plasmid production in standard E. coli strains.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please remove repetitive sentences

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: D853
PI: Heaney, Jason
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Adeno-Associated Virus-Mediated Modification of Mouse Embryo Genomes

This project evaluates the safety, tissue targeting, and genome-editing efficiency of adeno-associated virus (AAV)-based gene delivery systems in mice. By administering AAV vectors carrying reporter genes, researchers will assess vector tropism, gene-editing effectiveness, and long-term expression across tissues, supporting the development of prenatal gene-editing strategies for the treatment of genetic 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: D856
PI: Sun, Zheng
Containment Level: BSL-2
NIH Guidelines Section: III-E and III-F
Title: The effect of digenic heterozygous loss of ciliary genes on ciliogenesis

This study investigates how combinations of obesity-associated genes affect cilia formation and function using mouse and human cell models. The research will assess the effects of single and combined gene alterations on ciliogenesis, aiming to better understand the molecular mechanisms underlying obesity and identify interactions between ciliary and non-ciliary pathways that contribute to 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: D857
PI: Herman, Christophe
Containment Level: BSL-1
NIH Guidelines Section: III-E and III-F
Title: Targeted Killing of Antibiotic Resistant Bacteria: Using CRISPR Cas9 to Eliminate Antibiotic Resistant Bacteria.

This project aims to develop a novel, non-antibiotic antimicrobial strategy by engineering harmless bacteria to transfer plasmids to target bacteria.. Current work focuses on building and

testing a large library of genetic tools and conjugative plasmid systems in nonpathogenic bacterial strains.

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: D1023
PI: Lotze, Timothy
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 4 Study to Evaluate the Safety and Effectiveness of ELEVIDYS in Patients with Duchenne Muscular Dystrophy Treated in a Post-Marketing Setting (ENHANCE)

This clinical research study evaluates whether sirolimus, used alongside corticosteroids, can improve the safety profile of the AAV-based gene therapy for Duchenne muscular dystrophy (DMD). The study includes treatment and biopsy cohorts to assess safety, immune responses, vector persistence, and transgene expression.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section I: Please, change NIH Classification to BSL2

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: D1024
PI: El Sahly, Hana
Containment Level: BSL-2
NIH Guidelines Section: III-C

Title: A Phase 1, Open-Label, Safety, Reactogenicity, and Immunogenicity Trial of RVX-sCPD9, a Live-Attenuated SARS-CoV-2, as a Booster Vaccine, Via the Intranasal Route in Previously Vaccinated Adults

This Phase 1 clinical trial is evaluating the safety, tolerability, and reactogenicity of RVX-sCPD9, an investigational live-attenuated intranasal COVID-19 vaccine. The study will enroll previously vaccinated healthy adults and use a dose-escalation design with sentinel participants to assess four dose levels delivered via nasal atomizer, while collecting clinical, laboratory, and immunologic data to determine the vaccine's safety profile.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please, attach the pharmacy manual which covers the handling and storage requirement

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, 11; Against, 0; Abstaining, 0.

Atmar, Robert, MD left the meeting prior to discussion of this protocol due to a conflict of interest.

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

Protocol number: D117
PI: Hartig, Sean
Containment Level: BSL-2
NIH Guidelines Section: III-D III-E and III-F
Title: Metabolic Phenotyping of Preclinical Cell and Animal Models

This research investigates the molecular mechanisms that regulate cellular energy balance and metabolism by using recombinant DNA and viral vector technologies. Lentiviral, adenoviral, and adeno-associated viral vectors will be used to manipulate genes of interest in vitro and in vivo, to determine the physiological effects of altered gene 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, 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: D211
PI: Watanabe, Norihiro
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Cancer Gene Therapy with Helper-Dependent Adenoviral Vectors

This research program develops and evaluates viral vector-based therapies for both cancer and genetic diseases. Studies are conducted in cell culture and mouse models to assess transgene expression, tumor suppression, immune responses, and therapeutic efficacy, with the long-term goal of creating safer and more effective gene and cancer therapies for human use.

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

This research program seeks to understand how adult neurogenesis is regulated in the hippocampus by investigating the molecular and cellular mechanisms. The studies also examine interactions between neural progenitor cells and microglia, to identify pathways that could support regenerative therapies for related conditions.

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: D626
PI: Gorlov, Ivan
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: H-43268: Gbm-001: An Open-Label, Multi-Center Trial of Ino-5401 and Ino-9012 Delivered by Electroporation (Ep) In Combination with Regn2810 in Subjects with Newly-Diagnosed Glioblastoma (Gbm)

This study investigates the biological and disease-related roles of noncoding RNAs and their interacting proteins. The research uses molecular biology techniques to identify molecular pathways and potential treatment targets associated with tumorigenesis and cancer progression.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please clarify if all animal work will still be done. 2) Please remove any closed protocols listed.

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: D922
PI: Chen, Wen-Hsiang
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Molecular cloning of antigens for vaccine and diagnostic tool development

The protocol uses commercially synthesized DNA encoding disease-related antigens for vaccine research, diagnostic development, and laboratory assays. The related proteins are purified and characterized using standard molecular and biochemical techniques to evaluate specific protein functions.

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: D980
PI: Patel, Meera
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: mRNA-based immunotherapy for targeting triple-negative breast cancer

This project proposes the design and in vitro evaluation of mRNA vaccine candidates targeting triple-negative breast cancer (TNBC). Candidate vaccines will be tested to assess mRNA translation and other functional characteristics.

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: D695
PI: Omer, Bilal
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Constitutive Il7 (C7r) Modified Ebv Specific T-Lymphocytes for Treatment of Ebv-Positive Lymphoma (Cileste)

This clinical trial evaluates the safety and maximum tolerated dose of T cells to express possible therapies for EBV. The engineered T-cell persistence and anti-tumor activity is evaluated for patients with limited treatment options.

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.

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: D994
PI: Parihar, Robin
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Phase I study i15.NKG2D.zeta-NK cell conditioning in the tumor micro-environment in combination with C7R/iC9.GD2.CAR-T for the treatment of patients with relapsed or refractory osteosarcoma or neuroblastoma (INCITE-ON)

This clinical trial evaluates the safety of combining off-the-shelf NK cells with autologous CAR-T cells in pediatric patients with relapsed, refractory, or progressive neuroblastoma and osteosarcoma. The strategy is designed to enhance anti-tumor efficacy by targeting immunosuppressive myeloid cells within the tumor microenvironment, improving CAR-T cell activity, reducing cytokine release syndrome (CRS), and eliminating the need for lymphodepleting chemotherapy.

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.

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 seven 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 seven 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 was no exempt protocol 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 four post-approval monitoring sessions.

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 1:30 pm

UPCOMING EVENTS:
The next IBC meeting is scheduled for Tuesday, August 18, 2026.