Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, May 19, 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
Connor Cordray, MPH, CPH, CHMM, CBSP
Monica Darden, MA
Richard Hurwitz, MD
Shirley Hutchins, MSN
James Kelaher, MD
Nandan Mondal, PhD
Paul Nakata, PhD
Lisa Rollins, MS
Poonam Sarkar, PhD
Rebecca, Schwiebert, PhD, DVM (for Julia Goldman, DVM)

Vance Hobbs, MBA, Alternate Member
Leticia McGuffey, Alternate Member
Brooke Mitchell, 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 April 2026 MINUTES

The minutes for April 21, 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: D1015
PI: Chandrakantan, Arvind
Containment Level: BSL-1
NIH Guidelines Section: III-D
Title: Pediatric Obstructive Sleep Apnea and Surgical Timing - A Hypothesis Translational Model

The study investigates gene targets linked to neurocognitive deficits in pediatric obstructive sleep apnea by introducing specific genes into mouse models to determine whether restoring gene function can reverse these deficits. It uses viral vectors and intrauterine or neonatal brain injections to assess outcomes through behavioral, molecular, and electrophysiological analyses.

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: D1016
PI: Hecker, Louise
Containment Level: BSL-1
NIH Guidelines Section: III-F
Title: Targeted Knock-In of The Tardigrade Damage Suppressor (Dsup) Gene Conveys Protection against Dna Damage.

The project proposes using transgenic mice engineered with a specific gene to investigate whether enhanced DNA protection can reduce damage from radiation, oxidative stress, and aging-related factors. Researchers will validate gene expression, test cellular resistance to environmental insults, and potentially evaluate whole-animal responses to stressors and lifespan effects depending on initial results.

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: D132
PI: Lopez, Job
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Diagnostics and genetic manipulation of ticks and tick-borne pathogens

The project includes five recombinant DNA–based studies focused on improving genetic tools, identifying key genes for tick borne pathogens, and producing recombinant proteins for diagnostics and research. It also develops molecular assays and RNA interference techniques to study tick biology, gene function, and pathogen–host interactions using bacterial, yeast, and insect expression systems.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please Clarify: How the ticks will be obtained and describe if they will be maintained and stored within the lab 2) Please Clarify how the ticks are transported to the animal facility.

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: D133
PI: Sisley, Stephanie
Containment Level: BSL-1
NIH Guidelines Section: III-D
Title: Metabolic Signals in The Control of Energy Balance and Glucose Homeostasis

The study uses targeted viral approaches to modify gene expression in specific brain regions of mice to investigate neural pathways related to food intake, body weight, and glucose metabolism. By combining gene deletion, neural activation/inhibition, and cell-type–specific expression analyses, the research aims to understand genetic and cellular mechanisms underlying metabolic regulation.

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: D136
PI: Xue, Mingshan
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Neural Circuit Function and Development in Health and Disease

The study aims to understand how different types of neurons communicate through synaptic excitation and inhibition, and how disruptions in this balance contribute to conditions like childhood epilepsy and autism. Using genetic, viral, and molecular techniques in mouse models, researchers will manipulate specific cell types to determine how altered excitation–inhibition dynamics affect neural 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: D140
PI: Catic, Andre
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Decay of Proteins and Mrna in Mammalian Systems

This research examines how protein and mRNA degradation are regulated in mammalian cells, focusing on changes that affect cellular function and gene expression. Using genetic and molecular techniques in cell lines and mouse models, the study investigates how disruptions in these processes influence cellular stress responses, hematopoietic function, and aging.

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

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

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

Protocol number: D506
PI: Oka, Kazuhiro
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Gene Vector Core

This protocol describes the safe production of replication-defective viral vectors (e.g., AAV, adenovirus, lentivirus, retrovirus) by the Gene Vector Core to support gene expression, silencing, and editing studies for internal and external researchers. It also outlines quality control, method development, and biosafety practices to ensure efficient, compliant, and low-risk generation and handling of these recombinant viral materials.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please describe any manipulation or expression of oncogenes in viral vectors, if requested by users.

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: D678
PI: Van Nostrand, Eric
Containment Level: BSL-2
NIH Guidelines Section: III-E
Title: Study of Human: Viral Rna Processing Interactions

The project uses overexpression of non-infectious fragments of viral RNA in mammalian cells to study how host RNA-binding proteins interact with viral RNA and regulate RNA processing. The lab aims to identify RNA regulatory mechanisms and assess how specific viral sequences or proteins influence host RNA 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: D839
PI: Marshall, Kara
Containment Level: BSL-2

NIH Guidelines Section: III-D and III-F
Title: Labeling Neuron Populations using Viral Injections

This study investigates how internal mechanical signals regulate responses such as feeding, digestion, and sensory behaviors. Using viral labeling and imaging techniques in mice, researchers will track and analyze neuron activity across organs and nervous system pathways to understand mechanotransduction and its impact on physiology.

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: D806
PI: Glinton, Kevin
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 1/2, Global, Open-Label, Extension Study to Evaluate the Long-Term Safety and Clinical Activity of Mrna-3927 in Participants Previously Enrolled in The Mrna-3927-P101 [Version: 5.0 Dated 25 June 2025]

This study is an open-label extension trial evaluating the long-term safety and effectiveness of mRNA therapy in participants who completed a prior clinical study. Participants will continue treatment with regular monitoring of safety, metabolic events, and clinical outcomes, while the study supports ongoing data collection to guide potential regulatory approval and future clinical 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.

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

Protocol number: D534
PI: Metelitsa, Leonid
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: The Use of Chimeric Antigen Receptors for Nkt Immunotherapy

The study focuses on T cells with CAR constructs to target tumor cells and tumor-associated macrophages, aiming to enhance anti-tumor immune responses in cancers such as neuroblastoma. Using viral transduction and in vitro and in vivo testing, the project evaluates the effectiveness, persistence, and safety of these modified cells in killing tumors and improving survival 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, 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: 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 evaluates T cell therapy as a potential treatment for a highly aggressive pediatric brain tumor with limited treatment options. It uses a dose-escalation clinical trial design with both intravenous and intracerebroventricular administration to assess safety, tolerability, and anti-tumor effectiveness while monitoring patient outcomes and immune 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: D747
PI: Steffin, David
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Interleukin-15 And -21 Armored Glypican-3- Specific Chimeric Antigen Receptor Expressing Autologous T Cells As An Immunotherapy For Children With Solid Tumors (Care)

This study evaluates CAR T-cell therapy targeting certain antigens in patients with relapsed or refractory solid tumors to improve immune-mediated cancer treatment. It assesses safety, optimal dosing, and therapeutic effectiveness while monitoring immune responses and long-term persistence of the engineered 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, 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: D902
PI: Lulla, Premal
Containment Level: BSL-2
NIH Guidelines Section: III-C

Title: Immunotherapy For Adults With Gpc3-Positive Solid Tumors Using Interleukin-15 and -21 Armored Glypican-3-Specific Chimeric Antigen Receptor Expressing Autologous T Cells (Co-Exist)

This study evaluates CAR T-cell therapy as a potential treatment for patients with relapsed or refractory solid tumors, aiming to improve outcomes where traditional therapies have limited success. It uses a dose-escalation Phase 1 trial to assess safety, optimal dosing, and effectiveness, while monitoring immune responses, tumor changes, and long-term persistence of the engineered 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, 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: 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 evaluates CAR T cells as a treatment for glioblastoma, aiming to overcome limitations of current therapies and bypass the blood-brain barrier. It uses a dose-escalation clinical approach to assess safety, feasibility, and therapeutic effect while monitoring patients long-term for immune response, tumor progression, and adverse effects.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please complete Section D5.

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: 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 evaluates an antisense therapy in a severe genetic disorder with no disease-modifying treatments. Using specific dosing and careful monitoring, it assesses safety, optimal dosing, and therapeutic effects while minimizing risks of excessive gene suppression and treatment-related side effects.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please add a concise clarification in regard to ASO mechanism, administration procedural risks, platelet monitoring and target gene knockdown risk 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, 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 two rDNA IBC protocol closed for the month of May.

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

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 May.

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

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

H. Member Discussion
There were no items to report for the month of May.
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I. Spills, Incidents, or Exposures
There were no items to report for the month of May.

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

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 1:27 pm

UPCOMING EVENTS:
The next IBC meeting is scheduled for Tuesday, June 17, 2026.