Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, January 20, 2026 at 1:00 p.m. via videoconference. Upon reaching a quorum, the meeting was called to order by the Vice Chairperson.

Meeting Attendance:

Robert Atmar, MD, IBC Vice Chair
Manu Banadakoppa, PhD
Connor Cordray, MPH, CPH, CHMM, CBSP
Monica Darden, MA
Richard Hamill, MD
Shirley Hutchins, MSN
James Kelaher, MD
Nandan Mondal, PhD
Paul Nakata, PhD
Robin Parihar, MD
Kevin, Pope
Lisa Rollins, MS
Shannon Ronca, PhD, MPH, BS

Vance Hobbs, MBA
Leticia McGuffey, Alternate
Brooke Mitchell, Alternate Member
Holly Robinson, 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 December 2025 MINUTES
The minutes for December 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:	13
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: D240
PI: Sheikh-Hamad, David
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Stanniocalcin-1, A Novel Anti-Inflammatory Protein

This research focuses on the use of gene delivery of a novel protein for efficient, targeted transfection of kidney cells by infusing plasmid-loaded vectors in the kidney cells. The procedure is minimally harmful and allows assessment of potential therapy by gene expression.

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.

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: D499
PI: Putluri, Nagireddy
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Metabolomics In Biomarker Discovery

The lab studies cancer progression by analyzing metabolomic and molecular pathways from cell lines, mouse models, and IRB-approved patient specimens, using extracted RNA, proteins, or small molecules processed through platforms such as microarrays, qPCR, and mass spectrometry. Target genes are manipulated via overexpression, knockdown, or CRISPR knockout in vitro and in vivo, and the resulting effects on tumor growth, metastasis, and metabolic pathways are evaluated to identify and validate potential biomarkers in patient samples.

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.

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: D639
PI: Li, Na
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Study of Molecular Mechanisms of Cardiac Arrhythmias

The lab investigates molecular mechanisms of cardiac arrhythmias by expressing mouse versions of arrhythmia-related genes and analyzing their effects on signaling pathways. 24–48 hours after transfection. In parallel, recombinant adeno associated virus vectors are used in transfection of HEK293T cells and delivered to mice by retro-orbital injection to assess gene-specific physiological and cardiac protein expression changes in vivo.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 13; 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: D661
PI: Meyer, Jochen
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Chronic Structural and Functional Imaging and Optogenetic Manipulation Using Genetically-Encoded Fluorescent Proteins

The lab uses AAV and lentivirus-delivered genetically vectors to image, manipulate, and monitor cortical circuit activity and disease progression in mice over time using in vivo imaging.

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.

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: D833
PI: Dudok, Barna
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-F
Title: Modulation Of Brain Circuit Function In Epilepsy And Related Brain Disorders

The research aims to understand how inhibitory neurons regulate brain circuits and contribute to epilepsy by using AAV-delivered genetically encoded tools to measure and manipulate neuronal activity in 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, 13; 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: D988
PI: Cozart, Jennifer
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A 26-Week (with 26 Week Extension) Randomized, Multi-Center, Double-Blind Phase 2 Study to Evaluate the Efficacy and Safety of XC001 Gene Therapy as an Adjunct to Coronary Artery Bypass Graft Surgery for Patients with Symptomatic Coronary Artery Disease with Left Ventricular Dysfunction at Risk for Incomplete Revascularization

This Phase 2, randomized, double-blind, placebo-controlled trial evaluates a novel replication-deficient adenoviral vector CABG surgery to participants at high risk of incomplete revascularization, with the goal of stimulating therapeutic angiogenesis in ischemic myocardial regions.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please provide the Approved Informed Consent Form when completed.

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, 13; 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: D487
PI: Rouce, Rayne
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Phase 1 Therapy with Manufactured Autologous T-Cells Expressing A Second Generation Chimeric Antigen Receptor for Treatment Of T-Cell Malignancies Expressing Cd5 Antigen-Magenta

This Phase 1 study evaluates the safety, dosing, and preliminary antitumor activity of autologous or donor-derived T cells in patients with relapsed or refractory T-cell malignancies. Participants receive a single intravenous infusion of escalating dose levels, followed by intensive monitoring for toxicity and clinical responses, with the goal of establishing a safe therapeutic dose for future Phase 2 evaluation.

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.

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: D52
PI: Han, Sang
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Oncogenic Pathways, Mechanisms of Resistance and New Treatment Strategies in Breast Cancer

The research investigates how nuclear hormone receptors and their coactivators regulate development, reproduction, and cancer by using recombinant DNA approaches in cell culture to identify regulated target genes, protein–protein interactions, and key post-translational modifications.

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.

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

Protocol number: D53
PI: Han, Sang
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Sex Hormone Receptor Component and Then Cell Genome

The research investigates how nuclear hormone receptors and their coactivators regulate development, reproduction, and cancer by using recombinant DNA approaches in cell culture to identify regulated target genes, protein–protein interactions, and key post-translational modifications.

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.

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: D329
PI: Lee, Hyun-Sung
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-E
Title: Ion Channel Remodeling in Epilepsy

The study aims to clarify how altered estrogen receptors, progesterone receptors, and steroid receptor coactivators contribute to reproductive diseases and cancer. Mice are used to evaluate how nuclear receptor and coactivator overexpression influences the growth of breast tumors and endometriotic lesions in vivo, providing insight into mechanisms relevant to diagnosis and treatment.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 13; 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: 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 aims to study specific constructs targeting tumor antigens to boost their ability to eliminate both tumor cells and poor outcomes in neuroblastoma and other cancers. These constructs will undergo functional testing in vitro and in tumor-bearing mouse models, including live-cell and in vivo imaging.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please clarify animal protocol to be 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, 13; 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 single-group, open-label international extension study evaluates the long-term safety and clinical activity of a novel mRNA therapy in participants with propionic acidemia who previously completed the related previous trial, continuing treatment at their prior dose and interval unless modified by the sponsor. Participants receive ongoing outpatient dosing every 2–4 weeks with safety monitored through clinical assessments, labs, cardiac evaluations, adverse event reporting, and additional follow-up for up to two years after treatment discontinuation, allowing continued evaluation of therapeutic benefit and metabolic stability.

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.

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 January.

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

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 January.

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

G. Research Compliance Services (RCS) Update
The IBC Laboratory Compliance Assurance Associate informed the committee that there were no post-approval monitoring sessions.

H. Member Discussion
The Biosafety Officer (BSO) informed the committee that the BSL3 Inspection was conducted.

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

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

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 1:28 pm

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