Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, April 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
Manu Banadakoppa, PhD
Connor Cordray, MPH, CPH, CHMM, CBSP
Monica Darden, MA
Julia Goldman, DVM
Richard Hurwitz, MD
Shirley Hutchins, MSN
James Kelaher, MD
Paul Nakata, PhD
Kevin, Pope
Lisa Rollins, MS
Shannon Ronca, PhD, MPH, BS
Poonam Sarkar, PhD

Vance Hobbs, MBA
Shalaka Kotkar, PhD, MPH, CPH, CBSP
Brooke Mitchell, Alternate Member
Holly Robinson, Alternate
Shubhashish Sarkar, PhD

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 February 2026 MINUTES

The minutes for February 17, 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:	14
Abstain:	0
Against:	0

RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES RESEARCH APPLICATIONS REVIEW

During the review the committee assessed the appropriate biocontainment levels as well as the facilities, procedures, practices, and training of the PI and laboratory personnel involved in the research including appropriate and relevant training, safe conduct of the research, and knowledge of recombinant or synthetic nucleic acids molecules research. The committee also reviewed agent characteristics, types of manipulations planned, sources of the inserted nucleic acid sequences, nature of the inserted nucleic acid sequences, and whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced. Furthermore, the committee determined the applicable section(s) of the NIH Guidelines.

It was determined that the chair or IBC member assigned by the chair must review the modifications to assure that all required changes have been made and all required training is complete before an approval letter may be sent and the PI may begin the research. Further questions, or changes requiring more than simple concurrence by the PI and the chair/designee will be brought to the next convened meeting for full committee review.

A. <u>Recombinant or synthetic nucleic acid molecules research -- Full Board New/Renewals</u>

Protocol number: D109
PI: Satter, Lisa,
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Understanding Molecular Mechanisms in Human Immunobiology

This project investigates rare immunologic diseases by recreating patient-specific genetic variants in laboratory cell models using recombinant DNA, viral transduction, and functional assays to understand how these mutations disrupt immune pathways.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please define HSCT 2) Section E: E3. Please describe what is meant by “Lentivirus OR Retrovirus” in the third entry.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D128
PI: Stout, John
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-F
Title: Gene Therapy for Ocular Diseases

This project studies Retinopathy of prematurity (ROP) and laser-induced choroidal neovascularization (CNV) in mice, which are used to model human retinal diseases in which abnormal blood vessel growth, driven largely by dysregulated VEGF,causes vision loss in premature infants and adults with wet AMD.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D265
PI: Van Den Veyver, Ignatia
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Genetic Studies in Developmental Disorders

The lab investigates genes involved in human developmental, reproductive, and imprinting disorders by maintaining previously generated recombinant DNA constructs, diverse species homologs, and genetically modified cell lines—including CRISPR-edited and shRNA-engineered human embryonic stem cells—for future functional studies.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please remove the sentence "Newly discovered disease

genes may in the future be studied by generating transgenic and knock-out mice using recombinant DNA technology. 2) Section C: Please confirm that replication deficient lentiviral particles were employed for the generation of recombinant cell lines in every instance.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D345
PI: Deneen, Benjamin
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Developmental Analysis of Glial Fate Determination in The Central Nervous System

The research aims to uncover how specific transcription factors and signaling pathways regulate glial and astrocyte development by manipulating candidate genes through viral overexpression, shRNA knockdown, CRISPR deletion, and chemogenetic tools, in various embryonic CNS model 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, 14; Against, 0; Abstaining, 0.

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

Protocol number: D508
PI: Jones, Kathryn
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Targeting Leishmania Chaperones To Combat Parasite Infection

The project aims to establish an in-vitro system that reliably induces Leishmania mexicana parasites by enabling controlled testing of lab-generated inhibitory molecules on parasite viability and infectivity. Differentiated parasites will be evaluated alone and in infected cells,

using biosafety-controlled centrifugation, staining, fixation, and flow cytometry to quantify treatment-dependent effects on survival and host-cell infection.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D668
PI: Pollet, Jeroen
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Viral Assays with Pseudotyped Particles to Study Coronaviruses in a Biosafety Level 2 Setting

The project uses replication-deficient lentiviral pseudotyped particles displaying coronavirus spike proteins to safely model viral entry under BSL-2 conditions and quantify infection via luciferase reporter expression in target cells.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please describe what ACE2-expressing cell lines will be used for pseudoviral entry assays.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D837
PI: Bajic, Aleksandar
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Reprogramming of Human Somatic Cells Using Either Episomal Vectors or Sendai Virus

This lab receives frozen patient-derived samples, typically fibroblasts or PBMCs from multiple labs and reprograms them into induced pluripotent stem cells (iPSCs) using primarily non-integrating Sendai viral vectors, with other distinct DNA vectors offered as an alternative.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D841
PI: Rodriguez, Antony
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Delineating The Role of Let-7 Microrna on Lung At2 Cell Homeostasis, Alveolar Regeneration, and Interstitial Lung

The project focuses on defining how microRNA regulates key stem cell transcription factors to influence epithelial stem cell renewal, differentiation, and dysfunction in pulmonary fibrosis, using both mouse models and human primary cultures.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section D: Section D7a. Tamoxifen-contaminated tissues, carcasses, and bedding must be disposed of as hazardous chemical waste, specifically treated as cytotoxic or antineoplastic waste, usually requiring incineration. Waste should be double-bagged, clearly labeled, and collected by the Office of Environmental Safety for proper disposal to prevent exposure, using yellow disposal bags.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D842
PI: Li, Wei
Containment Level: BSL-2

NIH Guidelines Section: III-D and III-F
Title: Recombinant Adeno-Associated Virus in Animal Studies

The project aims to develop a safer, long-lasting anti-angiogenic gene therapy for ocular diseases such as choroidal neovascularization and diabetic retinopathy, leveraging its selective action on diseased vessels to avoid the widespread side effects associated with current treatments.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D838
PI: Suter, Bernhard
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: RTT-200: Baseline-Controlled, Open-Label Multicenter, Single-Arm, Pivotal Study to Evaluate the Efficacy, Safety, and Tolerability of NGN-401 in Subjects with Rett Syndrome (EmboldenTM)

This study is an open-label, baseline-controlled, multicenter Phase 1/2 conversion designed to evaluate the safety, tolerability, and efficacy of a single intracerebroventricular infusion of an AAV9-based gene-replacement therapy in female subjects with genetically confirmed classic Rett syndrome.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

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

Protocol number: D134
PI: Sun, Zheng
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Epigenomic Regulation of Metabolism by Nuclear Receptor Corepressors

This study uses genetic mouse models, recombinant viral vectors, and cell-based systems to investigate how nuclear receptor corepressors regulate metabolism, cancer development, circadian control, and organ-specific physiology by selectively knocking out, overexpressing, or monitoring genes in tissues such as liver, brain, muscle, heart, and adipose tissue.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D271
PI: Li, Yi
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Breast Cancer Initiation and Progression

This work employs multiple viral vectors to deliver oncogenes or other genetic elements into mammary cells from human, rodent, and avian systems, enabling controlled induction of breast tumors and evaluation of tumor initiation, progression, and imaging-based monitoring.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please mention the imaging protocol number for CT/PET/SPECT imaging and for PET/SPECT imaging name of the radioisotope 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, 14; Against, 0; Abstaining, 0.

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

Protocol number: D329
PI: Anderson, Anne
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-E
Title: Targeted Neuronal Circuit Control Using Optogenetics

This project uses a knockout mouse model that causes hyperactive signaling and seizures to evaluate whether AAV9-delivered recombinant proteins can rescue the epileptic phenotype. Newborn mice will receive a single AAV9 based gene therapy injection, followed by seizure monitoring and collection of tissue for molecular analyses to determine therapeutic efficacy.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section F: Please specify the KO mouse strain.

Next, a motion was made and seconded to approve the protocol with modifications required to secure approval. The motion passed with a majority of the members present voting for the motion. The vote count for the approval of the protocol with modifications required to secure approval was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: 487
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 aims to evaluate the safety, antitumor activity, and in vivo persistence of CAR T cells in patients with relapsed or refractory T-cell malignancies, addressing the urgent need for effective therapies in a population with limited treatment options and poor prognosis. Using a dose-escalation design and chemotherapy, the trial will determine the maximum tolerated dose across three dosing levels while assessing clinical responses, manufacturing feasibility, and disease clearance to enable previously ineligible patients to proceed to allogeneic stem cell transplant.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D693
PI: Curry, Daniel
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: An Open-Label Trial to Address The Safety of The Smartflow® Mr Compatible Ventricular Cannula for Administering Eladocagene Exuparvovec to Pediatric Subjects

This open-label study enrolls pediatric subjects to receive a single infusion of eladocagene exuparvovec via the SmartFlow® MR-compatible ventricular cannula, followed by intensive short- and long-term safety monitoring—including DSMB review—and pharmacodynamic assessments over approximately five years.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

Protocol number: D899
PI: Chen, Natalie
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: (Trailblaser) Trail-R2 and Her2 Bi-Specific Chimeric Antigen Receptor T Cells for The Treatment of Metastatic Breast Cancer

This Phase 1 clinical study evaluates the safety and preliminary antitumor activity of autologous CAR T cells engineered with a unique receptor, designed to show in preclinical models overcoming immunosuppression, enhanced CAR-T expansion and persistence, and inducing complete responses in HER2-expressing breast cancer.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 14; Against, 0; Abstaining, 0.

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

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

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

E. Recombinant or synthetic nucleic acid molecules research -- Exempt Protocols
The IBC Laboratory Compliance Assurance Associate reported to the IBC that there was one exempt protocol submitted in the month of March.

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

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

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

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

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 1:31 pm

UPCOMING EVENTS:
The next IBC meeting is scheduled for Tuesday, April 21, 2026.