Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, February 17, 2026 at 1:02 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
Leticia McGuffey, Alternate
Brooke Mitchell, Alternate Member
Shubhashish Sarkar, PhD
Rebecca, Schwiebert, Ph.D., D.V.M

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 January 2026 MINUTES

The minutes for January 20, 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: D992
PI: Verma, Nipun
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Novel Antibodies Targeting Immunosuppressive Ligands for Combination Treatments with Radiation

The study examines how certain cancer cells regulate protein expression after radiation and tests a specially engineered antibody designed to trigger protein internalization and degradation. It then evaluates whether this targeted reduction enhances CAR-T-cell cytotoxicity in vitro and 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, 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: 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 study investigates how altering gene expression via lentiviral, adenoviral, and AAV vectors affects metabolic function in adipocytes, liver cells, and mouse tissues, with follow-up analyses including glucose homeostasis tests, gene/protein expression assays, and metabolic respiration measurements.

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: D179
PI: Bottazzi, Maria
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Molecular Cloning of Antigens to Study Pathogenesis and Vaccine Development

The protocol uses multiple expression systems including yeast, E. coli, mammalian, and baculovirus to clone and express recombinant proteins for studying disease mechanisms, developing diagnostics, and creating vaccine candidates. DNA constructs for these antigens are commercially sourced or engineered through molecular cloning and mutagenesis, expressed across several host systems as needed, and used for mechanistic studies, binding assays, or downstream vaccine evaluation in animals.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please include that vaccine studies are done in animals in the project description.

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, 1.

Ronca, Shannon, PhD recused and absented herself during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D294
PI: Palzkill, Timothy
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-F
Title: Novel Diagnostics and Therapeutics for Calciviruses

Virus libraries combined with deep sequencing, will be used to identify the exact amino acid regions recognized by human antibodies, without using whole virus or full viral genomes. These mapped epitopes reveal key features of the humoral immune response and provide insights useful for improving norovirus diagnostics and vaccine design.

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, 1.

Robert Atmar, MD, recused and absented himself during the discussion and vote on this protocol due to a potential conflict of interest.

Protocol number: D353
PI: Yang, Feng
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Regulatory Mechanisms of Cancer Biology and Treatment Resistance

These projects use gain and loss-of-function strategies in engineered cells and multiple transgenic mouse models to define how specific genes regulate tumor initiation, progression, metastasis, treatment response, and resistance in breast and prostate cancer. Across these models,

gene alterations are introduced through multiple systems, with resulting effects on tumor biology analyzed through in vitro assays, xenografts, orthotopic injections, and standard molecular techniques.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section A: Please condense the 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, 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: D652
PI: Dinardo, Andrew
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Regulatory Mechanisms of Cancer Biology and Treatment Resistance

This project uses DNA methylation and chromatin closure to identify causal regulatory marks. By inducing locus-specific changes in T cells and measuring effects on gene expression and immune function, this approach aims to directly link specific epigenetic changes to altered mycobacterial immunity.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section B- B2 Please, attach current affiliate IBC protocol 2) Section C: Please, clarify the work being done at the affiliate and the work being done at BCM 3) .Section C: Please give brief description for the use of lentiviral vector mediated gene delivery 4) Section C: Please, add a few sentences describing your work with the lentiviral vector 5) Section D: D8- Please, explain why a N95 respirator is needed. 6) Please ensure all personnel complete the required 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, 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: D659
PI: Echeverria, Gloria

Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Investigation of The Molecular and Metabolic Evolution of Breast Cancer Therapy Resistance and Metastasis

The lab investigates why certain breast cancers become aggressive or therapy-resistant by studying molecular drivers using cell lines, patient-derived xenografts, and advanced molecular analyses. The lab also use DNA tracking to understand how tumor cell populations evolve during treatment and metastasis.

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: D655
PI: Glinton, Kevin
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Global, Phase 1/2, Open-Label, Dose Optimization Study to Evaluate the Safety, Pharmacodynamics, and Pharmacokinetics of Mrna-3927 In Participants with Propionic Acidemia

This study uses mRNA therapy developed to restore enzyme function in patients with propionic acidemia. It has undergone a global Phase 1/2 trial evaluating safety, pharmacodynamics, and optimal dosing to determine the further use of the therapy.

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: D828
PI: Suter, Bernhard
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 1/2/3 Open-Label, Single Arm, Dose-Finding Study to Investigate Long-Term Safety, Tolerability and Efficacy Of GS-100, An Adeno-Associated Virus Serotype 9 (AAV9) Vector-Mediated Gene Transfer Of Human NGLY1, In Patients with NGLY1 Deficiency

This study uses a AAV9 gene-replacement therapy being evaluated in a Phase 1/2/3 open-label study for NGLY1 Deficiency, an ultra-rare autosomal recessive neurodevelopmental disorder with no approved treatments. Early phases focused on dose-finding and safety in children ages 2–18 and Phase 3 assessing clinical benefit over 52 weeks.

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: D328
PI: Lacorazza, Daniel
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Genetic Regulation of Normal and Malignant Hematopoiesis

The study investigates how genes regulate blood-cell development in both healthy and leukemic conditions, identifying specific targets that may contribute to leukemia initiation, maintenance, and treatment resistance. Using genetically modified leukemia cell lines, mouse models, and patient-derived xenografts, the lab seeks to further explore genetic regulation and future 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, 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: D490
PI: Jiang, Xiaolong
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Targeted Neuronal Circuit Control Using Optogenetics

This project investigates how neuronal circuits function by selectively activating or silencing specific neuron populations in mice using genetically targeted expression of certain proteins delivered through viral vectors or transgenic crosses. By combining these genetically defined tools with imaging and electrophysiological approaches, they assess neuronal activity, connectivity, and circuit function across both in vivo and in vitro preparations.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please clarify what type of viral vectors will be injected into the fetus before birth.

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: D504
PI: Martin, James
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Bmp Signaling in Crainiofacial Development, Pitx2/Hippo/Wnt/Yap Function in Cardiac Development

This research investigates how certain signaling pathways regulate craniofacial and cardiac development, cardiomyocyte cell-cycle control, and tissue regeneration, using gene-editing screens, transgenic mouse models, viral reporters, and multi-omic 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, 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: D626
PI: Li, Yong
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Noncoding RNAs and Key Signaling Pathways In Carcinogenesis

The research investigates how noncoding RNAs and their protein partners influence gene regulation, cellular behavior, and tumor development by manipulating their expression in human and mouse cells and evaluating downstream effects such as transcriptional changes, proliferation, cell death, and migration.

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: D682
PI: Steffin, David
Containment Level: BSL-2
NIH Guidelines Section: III-C

Title: Interleukin-15 Armored Glypican-3-Specific Chimeric Antigen Receptor Expressing Autologous T Cells as Immunotherapy for Children with Solid Tumors (Agar)

The research focuses on evaluating specific CAR T-cell therapy engineered to co-express IL-15, designed to enhance T-cell persistence and antitumor activity in patients with relapsed or refractory solid tumors such as hepatoblastoma, hepatocellular carcinoma, Wilms tumor, and other GPC3-positive cancers.

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: D727
PI: Hegde, Meenakshi
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Phase I Study of Her2 Chimeric Antigen Receptor (Car) T Cells in Combination With Checkpoint Blockade in Patients with Advanced Sarcoma (Heros 3.0)

This phase I study evaluates whether combining HER2-targeted CAR T-cell therapy with specific checkpoint blockades can enhance CAR T-cell persistence, function, and antitumor activity in pediatric patients with refractory or recurrent HER2-positive sarcoma.

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)

The trial is an open-label, baseline-controlled study evaluating the efficacy, safety, and tolerability of a single intracerebroventricular administration of NGN-401 in females with genetically confirmed classic Rett syndrome in the post-regression stage.

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: D935
PI: Lulla, Premal
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Constitutive IL7R (C7R) Modified Banked Allogeneic CD30.CAR-Ebvsts for CD30+ Lymphomas (CABAL2)

This Phase 1 dose-escalation study evaluates an off-the-shelf C7R T-cell therapy designed to improve expansion, persistence, and antitumor activity while minimizing risks of graft-versus-host and host-versus-graft responses in patients with relapsed or refractory CD30-positive lymphomas.

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: D968
PI: Bacino, Carlos
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: H-57160 / Phase 3 Study of The Efficacy and Safety of Ion582 in Children and Adults with Angelman Syndrome Ion582-Cs2

This Phase 3 randomized, placebo-controlled trial evaluates ION582, an antisense oligonucleotide designed to reactivate the silenced genes in Angelman syndrome by degrading specific RNA, with the goal of restoring protein expression and improving neurological 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, 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 four rDNA IBC protocol closed for the month of February.

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 February.

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 February.

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

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

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

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 1:33 pm

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