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:

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
Nandan Mondal, PhD
Paul Nakata, PhD
Robin Parihar, MD
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
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 March 2026 MINUTES

The minutes for March 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: D999
PI: Bhattacharya, Rajat
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Novel Therapeutic Strategies for Kras and Braf Mutated Colorectal Cancer

This lab uses cancer cell lines that are stably transduced with luminescent genes using lentiviral particles and implanted into mouse livers, enabling monitoring of tumor growth by IVIS 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, 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: D1010
PI: Bouchier-Hayes, Lisa
Containment Level: BSL-1
NIH Guidelines Section: III-D, III-E and III-F
Title: Regulation Of Caspases in Apoptosis, Cell Cycle and Inflammation

The project uses lentiviral and retroviral gene transfer systems to study apoptosis using various proteins for visualization and monitoring. They aim to study cell death, division, and molecular dynamics using microscopy, flow cytometry, and biochemical assays.

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: D170
PI: Dierick, Herman
Containment Level: BSL-1
NIH Guidelines Section: III-D
Title: Molecular and Neurobiological Analysis of Aggression in Drosophila Melanogaster

This project investigates the molecular and neurobiological mechanisms underlying aggressive behavior in the common fruit fly, Drosophila melanogaster, using standard transgenic approaches to study gene function and manipulate neural circuits.

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

The proposed studies investigate neuronal circuitry by using experimental approaches to examine cellular and circuit function in mice to precisely control and monitor the activity of specific neuron populations through viral delivery or transgenic expression of proteins and fluorescent reporters.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section C: Please elaborate on how and where the lab obtains the samples 2) Section E: Please justify human cell lines or cells for viral transfection.

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-1
NIH Guidelines Section: III-D, III-E and III-F
Title: Bmp Signaling in Crainiofacial Development, Pitx2/Hippo/Wnt/Yap Function in Cardiac Development

These studies aim to define how certain signaling pathways regulate craniofacial and cardiac development, cardiomyocyte cell cycle control, and regeneration using gene delivery and transgenic mouse models. .

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: D507
PI: Pollet, Jeroen
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Multiplexed Mrna Vaccine Against Trypanosomatid Parasites

This project aims to develop and evaluate mRNA-based vaccine candidates by generating in vitro–transcribed mRNAs and validating translation, stability, and immunogenicity through extensive in vitro assays. The vaccine candidates will be evaluated through in vitro expression and safety testing, followed by immune response studies in mouse models.

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: D650
PI: Vogel, Tiphanie
Containment Level: BSL-2
NIH Guidelines Section: III-D III-E and III-F
Title: Stat3 and Mechanisms of Inflammation

The laboratory investigates the mechanisms of inflammation in human disease by studying cytokine signaling pathways in patients with immune disorders. By recreating patient-derived mutations in human cell lines, the lab uses standard cloning and functional assays to determine how these genetic changes alter inflammatory responses.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please add safety precautions to be adopted during PEG gradient and centrifugation to concentrate viral preparation.

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: D669
PI: Palzkill, Timothy
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Identifying Novel Sars-Cov-2 Inhibitors to Prevent Covid-19 using Dna-Encoded Chemical Libraries

This study seeks to address the urgent need for COVID-19 therapeutics by using DNA-encoded library technology to identify inhibitors of the SARS-CoV-2 main protease. Purified recombinant protein will be used in binding and inhibition assays to discover and validate candidate inhibitors without using live virus.

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: D847
PI: Pollet, Jeroen
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: mRNA Vaccines for Hookworm

This project addresses limitations in hookworm vaccine development by using mRNA-based expression to generate stable antigens, overcoming technical challenges associated with parasite protein production.

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: D993
PI: Berth, Sarah
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 1, Multicenter, Open-label, Dose-Finding Study to Investigate the Safety and Pharmacodynamics of a Single Intrathecal Injection of INS1202 in Patients with Amyotrophic Lateral Sclerosis

The study targets adult ALS patients meeting defined clinical criteria and includes controlled drug preparation and comprehensive pre- and post-dose laboratory monitoring following injection of the study drug.

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: D994
PI: Parihar, Robin
Containment Level: BSL-2
NIH Guidelines Section: III-C

Title: Phase I study i15.NKG2D.zeta-NK cell conditioning in the tumor micro-environment in combination with C7R/iC9.GD2.CAR-T for the treatment of patients with relapsed or refractory osteosarcoma or neuroblastoma (INCITE-ON)

This study evaluates the safety of escalating doses of a specific combination treatment in children with relapsed or refractory neuroblastoma or osteosarcoma, aiming to improve tumor control while reducing toxicity and cytokine release syndrome without commonly associated symptoms.

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.

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

Protocol number: D1007
PI: Suter, Bernhard
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: An Open-Label First-in-Human Phase 1/2 Study to Evaluate the Safety, Tolerability, and Efficacy of FRF-001, an AAV9 Gene Therapy Administered by Intracerebroventricular Injection in Participants with FOXG1 Syndrome

This study will evaluate the safety, tolerability, and preliminary efficacy of a single dose, within the brain's ventricular system, of an AAV9-based gene replacement therapy using age-based cohorts, intensive safety monitoring, and long-term follow-up consistent with established gene therapy guidelines.

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: D1009
PI: Rouce, Rayne
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Novel Unedited Allo Cell Therapy for High Risk T-Cell Malignancies Using Cd7-Specific Car Expressed on T Cells (Neo-Crimson)

This dose-escalation study evaluates the safety and maximum tolerated dose of allogeneic T cells in patients receiving lymphodepleting chemotherapy. Subjects receiving therapy are closely monitored for adverse events, infections, and treatment response.

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: D1013
PI: Yassine, Khaled
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Single Patient Ind Treatment Plan for Patient Rb to Receive Autologous Cd34+ Cell Enriched Population that Contains Hematopoietic Stem Cells Transduced with Bb305 Lentiviral Vector Encoding The Betaa-T87q-Globin Gene

This study supports compassionate use of a personalized gene-therapy treatment for a subject who lacks alternative curative options. The plan details stem cell mobilization, conditioning chemotherapy, infusion, intensive supportive care, and long-term monitoring to ensure safety, engraftment, and durable therapeutic benefit.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1) Section H2: Please describe what ACE2-expressing cell lines will be used for pseudoviral entry assays. 2) Section D6: Please provide the detailed SOPs

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.

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

Protocol number: D564
PI: Hill, Laquisa
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Chimeric Antigen Receptor T-Cells for The Treatment of Acute Myeloid Leukemia Expressing Cll-1 Antigen – Carmen

This study evaluates a AML protein specific cell therapy in relapsed or refractory AML with the goal of inducing remission by selectively eliminating abnormal cancer cells while allowing for transplant-based rescue if needed.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1) Section C: Please describe what has been accomplished in the last three years and what they hope to achieve in the next three years.
2) Please clarify how many subjects have participated in this research have gone into remission during the course of this research.

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

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

Protocol number: D150
PI: Dong, Bingning
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Function of Nuclear Receptors

This project investigates the biological roles of nuclear hormone receptors involved in metabolism and liver disease by using recombinant DNA, cell-based assays, and genetically modified mouse models. Through targeted gene overexpression, knockdown, and in vivo delivery systems, the study aims to define gene networks and mechanisms relevant to liver cancer and metabolic regulation.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Please list the animal protocol 2) Section C: Please mention how the knockdown will be achieved and give details in section D9 if viral or other vectors are 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: D626
PI: Li, Yong
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Epigenomic Noncoding Rnas and Key Signaling Pathways in Carcinogenesis

This project investigates how noncoding RNAs and their interacting proteins regulate cellular processes and contribute to cancer, using molecular, cellular, and mouse models to manipulate gene expression and assess effects on proliferation, survival, and tumor development.

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: D716
PI: Frankfort, Benjamin
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: An In Vitro/In Vivo System for Targeted Retinal Ganglion Cell Subtype Manipulation

This project develops a mouse model using cell culture and genetic manipulation of retinal ganglion cells to allow investigation of why different final output cells of the retina vary in susceptibility to injury and degeneration.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please ensure all personnel complete Bloodborne pathogen 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: D756
PI: Ronca, Shannon
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Use of Recombinant Viruses for Therapeutic Testing

This protocol evaluates vaccines and post-exposure therapeutics against alphaviruses and flaviviruses using chimeric and cloning systems to establish safe in-vitro neutralization assays and in-vivo efficacy testing.

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.

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

Protocol number: 754
PI: Armaghany, Tannaz
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Interleukin-15 Armored Glypican-3-Specific Chimeric Antigen Receptorexpressing Autologous T Cells as Immunotherapy for Patients with Solid Tumors (Catch)

This trial evaluates the safety and persistence of enhanced T cells in patients with liver cancer in which the tumor cells express glypican-3 (GPC3). Building on encouraging preclinical and early clinical data, the study uses dose escalation and extensive correlative analyses to assess CAR T-cell persistence, tumor effects, and immune responses over long-term follow-up.

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: D925
PI: Hill, Laquisa
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Mb-105-201: A Phase 2, Open-Label, Multicenter Study Of Mb-105 in Patients with Cd5 Positive (Cd5+) Relapsed/Refractory T-Cell Lymphoma (R/R Tcl)

This study evaluates the efficacy and safety of an CAR T-cell therapy in adults with CD5-positive relapsed or refractory T-cell lymphoma who have limited treatment options.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 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 no rDNA IBC protocol closed for the month of April.

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

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 April.

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

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

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

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 1:45 pm

UPCOMING EVENTS:
The next IBC meeting is scheduled for Tuesday, May 19, 2026.