# Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, August 18, 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
Manu Banadakoppa, PhD
Connor Cordray, MPH, CPH, CHMM, CBSP
Monica Darden, MA
Julia Goldman, DVM
Richard Hamill, MD
Shirley Hutchins, MSN
James Kelaher, MD
Nandan Mondal, PhD
Paul Nakata, PhD
Lisa Rollins, MS
Shannon Ronca, PhD, MPH, BS
Poonam Sarkar, PhD

Vance Hobbs, MBA, Alternate Member
Shalaka Kotkar, PhD, MPH, CPH, CBSP
Leticia McGuffey, Alternate Member
Brooke Mitchell, Alternate Member
Shubhashish Sarkar, PhD, Alternate Member
Rebecca, Schwiebert, PhD, DVM

## 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 July 2026 MINUTES

The minutes for July 21, 2026, IBC meeting were reviewed and a motion was made to approve the minutes as written. With the majority of the members present voting for the motion, the vote count for approval of the minutes was as follows:

| | |
|---|---|
| For: | 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: D1020
PI: Kneubehl, Alexander
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Molecular Reagent Generation for Microbiology Research

The project involves cloning target genes into plasmids, producing DNA and RNA standards in E. coli for quantitative molecular assays, and expressing recombinant proteins in E. coli or mammalian cells for antibody detection, antigen-binding studies, and protein interaction analyses. All materials will be handled using established laboratory procedures and commercially available reagents.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please add the genetic material to be used for all bacterium

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: D1025
PI: Escobar, Mario
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Synthetic Biology and Genome Engineering Tools for the Treatment of Human Disease

This research program develops synthetic biology and genome engineering technologies, including CRISPR/Cas platforms, recombinant DNA methods and viral vectors, to study and develop potential treatments for human diseases. The work involves constructing and delivering recombinant genetic materials into human and animal cells using viral and non-viral approaches and evaluating biological outcomes .

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 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: D1028
PI: Serra, Carlo
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Defining The Molecular Mechanism of Inclusion Body Myositis and Facio-Scapulo-Humeral Muscular Dystrophy

This study aims to identify the cellular and molecular mechanisms that drive facioscapulohumeral muscular dystrophy (FSHD) with a focus on disease-associated proteins, inflammation, and progressive loss of muscle function. Researchers use specialized genetic tools

including RNA interference, mammalian expression vectors, plasmids and other vectors to manipulate gene expression and protein function, then evaluate cellular responses .

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 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: D184
PI: Dasgupta, Atreyi
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Evaluation Of Sarcoma Development in Immunodeficient MICE

This research seeks to understand the molecular mechanisms that drive the development, progression, and aggressiveness of pediatric sarcomas which are associated with tumor growth, metastasis, and poor patient outcomes. The laboratory uses genetic overexpression and gene knockdown approaches in sarcoma cell models, followed by in vitro and in vivo studies to evaluate tumor behavior, therapeutic responses, and metastatic potential.

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: D660
PI: Bajic, Aleksandar
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Human Disease Modeling with Patient-Specific Induced Pluripotent Stem Cells

This core laboratory supports research on neurological and neurodegenerative disorders by generating stem cells and enabling investigators to study disease mechanisms, stem cell biology, and neuronal development in vitro. The laboratory employs recombinant DNA, viral vectors, gene overexpression and knockdown systems, and stem cell differentiation methods to evaluate through molecular outcomes, biochemical responses, and genetic results.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 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: D863
PI: Gao, Yudong
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Labeling And Manipulating Proteins and Protein Interactions in Brain Cells.

This research seeks to identify protein interactions and signaling pathways involved in brain disorders and to determine how these interactions influence neuronal function, plasticity, and disease-related phenotypes in experimental models. The laboratory uses recombinant DNA technologies and AAV and lentiviral vectors to manipulate and study proteins of interest, with resulting molecular, cellular, electrophysiological, imaging, proteomic, and behavioral outcomes analyzed to better understand disease mechanisms and identify potential therapeutic targets.

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: D1026
PI: Omer, Bilal
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Calm-70: Chimeric Antigen Receptor Therapy for Relapsed/Refractory Cd70+ Lymphoma and Myeloma

This Phase I clinical trial evaluates the safety and preliminary effectiveness of T-cell therapy for patients with relapsed or refractory lymphomas and multiple myeloma. The study involves manufacturing CAR T cells to test infusion across escalating dose levels, and monitoring patients for treatment response, toxicity, cytokine release syndrome, and long-term outcomes through clinical assessments.

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: D502
PI: Steffin, David
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Gd2 Specific Chimeric Antigen Receptor and Interleukin-15 Expressing Autologous Natural Killer T-Cells to Treat Children with Neuroblastoma (Ginakit2)

The study builds on prior studies with demonstrated safety and evidence of antitumor activity, and seeks to continue enrollment to determine the maximum tolerated dose, improve NKT-cell persistence and tumor control, and reduce treatment-related toxicity. Patients receive engineered NKT cells, with antitumor responses assessed through imaging and bone marrow evaluations.

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: D70
PI: Ling, Paul
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Evasion of Intrinsic Antiviral Host Cell Responses by Herpesviruses, and Investigation of Elephant Herpesvirus Genetics and Transmission

This research aims to combat elephant endotheliotropic herpesvirus (EEHV), a major cause of fatal hemorrhagic disease in young Asian elephants, by developing and evaluating a novel vaccine. The study uses recombinant DNA technology to produce vaccine candidates, with immune responses assessed through protein expression analyses and antibody detection assays following vaccination.

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: D293
PI: Wehrens, Xander
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Mutagenesis Analysis of Ryanodine Receptor Intracellular Calcium Release Channels and Their Regulatory Proteins

This research aims to identify genes and molecular pathways that regulate heart function and contribute to heart disease by using genetic engineering, gene therapy, and CRISPR-based approaches in cultured cells and mouse models. The laboratory studies how changes in gene expression affect cellular structure, protein interactions, signaling pathways and cardiac performance.

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: D299
PI: Duman, Joseph
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Molecular Mechanisms of Synapse Development and Remodeling

This research investigates the molecular and cellular mechanisms that govern neural circuit development, plasticity, and repair in the mammalian central nervous system. The laboratory also examines how disruptions in signaling pathways contribute to neuropsychiatric disorders and CNS injury, with the goal of identifying strategies that promote recovery and functional restoration.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section D4: Please specify if the cell sonicator is enclosed or contained.

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: D624
PI: Lagor, William
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Genome Editing Testing Center

This project supports the Genome Editing Testing Center (GETC), which evaluates the safety, efficiency, specificity, and therapeutic potential of genome editing technologies in mouse models. The center provides researchers with standardized testing of genome-editing reagents and delivery platforms, assessing factors such as tissue targeting, editing accuracy, biodistribution, toxicity, and the ability to correct disease-causing genetic variants.

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

This research seeks to understand how neurons regulate brain circuit activity in healthy and diseased states, particularly in epilepsy, with the goal of developing targeted therapies that restore normal brain function. By studying specific inhibitory neuron populations in living animal models, the laboratory investigates how neural circuits change during chronic epilepsy and how these changes contribute to seizures and other neurological disorders.

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: D981
PI: Ghaghada, Ketankumar
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Lipid Nanoparticles Containing Synthetic RNA for Immune Modulation and Treatment of Inflammatory Diseases.

This research focuses on developing and evaluating lipid nanoparticle (LNP)-based RNA therapies for chronic inflammatory diseases, including Alzheimer's disease, cardiovascular disease, and inflammatory liver disorders. The project uses synthetic nucleic acids to modulate disease-related genes, assess therapeutic efficacy, and optimize RNA delivery systems that may ultimately support future clinical applications.

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: D616
PI: Mahdi, Jasia
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Gail-B: Phase I Study of Autologous T Lymphocytes Expressing Gd2-Specific Chimeric Antigen and Constitutively Active Il-7 Receptors for The Treatment of Patients with Gd2-Expressing Brain Tumors

This clinical trial is evaluating the safety, feasibility, and antitumor activity of directed T cell therapy for children with diffuse midline glioma (DMG) and other pediatric brain tumors. Building on promising preclinical studies and early clinical experience, the therapy is designed to enhance T-cell activity and target specific antigens on tumor cells.

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

Next, a motion was made and seconded to approve the protocol. The motion passed with a majority of the committee members present voting for the motion. The vote count for the approval of the protocol with all applicable approval criteria was as follows: For, 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: D846
PI: Nicholson, Erin
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 1/2a Trial of the Safety, Tolerability and Immunogenicity of PIV5-vectored RSV Vaccine (BLB-201) in RSV Seronegative and Seropositive Infants and Children

This clinical trial evaluates the safety, tolerability, and immune response of an intranasal live viral vaccine candidate designed to prevent respiratory syncytial virus (RSV) infection in infants and young children. This study assesses vaccination regimens at different dose levels through clinical monitoring, immune response testing, and surveillance for RSV-related illnesses and adverse events.

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: D880
PI: Lulla, Premal
Containment Level: BSL-2
NIH Guidelines Section: III-C

Title: Expanded Access Protocol (EAP) for Subjects receiving Idecabtagene Vicleucel that is nonconfirming for Commercial Release (BB2121)

This study provides eligible patients with multiple myeloma access to novel CAR T-cell therapy, when a commercially manufactured product does not meet all release specifications, remanufacturing is not feasible, and the treating physician determines that the potential benefits outweigh the risks. The study evaluates the safety and clinical outcomes with patients monitored for adverse events, treatment response, and disease status for up to three months after infusion.

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: D881
PI: Nair, Ajith
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 3, Multinational, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Ntla-2001 in Participants with Transthyretin Amyloidosis with Cardiomyopathy (Attr-Cm) ( Protocol (Version 6.0, Dated 24 February 2026))

This clinical trial evaluates the safety, efficacy, and long-term effects of a gene-editing therapy for adults with transthyretin amyloid cardiomyopathy (ATTR-CM), by determining whether it reduces the risk of cardiovascular death, heart failure events, arrhythmias, and stroke compared with placebo. The study will enroll approximately 1,200 participants who will receive either study drug or placebo, with outcomes assessed through clinical evaluations, imaging, laboratory testing, functional assessments, and 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, 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: D936
PI: Luznik, Leo
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Targeted and Immunological Therapies in Hematological Malignancies

This research program aims to understand the mechanisms of leukemia relapse, graft-versus-host disease (GVHD), and graft-versus-leukemia (GVL) responses following stem cell transplantation. Using primary patient samples, leukemia models, advanced genomic and single-cell technologies, the laboratory investigates immune and molecular factors associated with disease remission, relapse and therapeutic response to identify novel biomarkers and improve immunotherapies.

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 August.

**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 August.

**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 August.

**F. IBC Inspection Report**

The Biosafety Officer (BSO) informed the committee that there were five inspections performed for the month of August.

**G. Research Compliance Services (RCS) Update**
The IBC Laboratory Compliance Assurance Associate informed the committee that there was one post-approval monitoring session.

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

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

**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 1:30 pm

**UPCOMING EVENTS:**
The next IBC meeting is scheduled for Tuesday, September 15, 2026.