Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, October 21, 2025 at 1:00p.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
Connor Cordray, MPH, CPH, CHMM, CBSP
Monica Darden, MA
Julia Goldman, DVM
Richard Hamill, MD
Shirley Hutchins, MSN
James Kelaher, MD
Nandan Mondal, PhD
Robin Parihar, MD
Kevin, Pope
Lisa Rollins, MS
Shannon Ronca, PhD, MPH, BS
Poonam Sarkar, PhD

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

CONFLICTS OF INTEREST

The Chairperson reminded the committee members about the conflict of interest (COI) policy and process. Any conflicts of interest recognized or declared during the meeting will be documented below. The affected member(s) will be excused from the meeting during the relevant discussion and vote and will not participate in either.

MEETING CONDUCT

The Chairperson reminded the committee members that all protocols that are discussed at the meeting are to be considered confidential due to potential privacy or proprietary concerns and are not to be discussed outside of the meeting room with non-IBC members. For this reason, this meeting is considered closed.

REVIEW OF September 2025 MINUTES

The minutes for September 16, 2025, IBC meeting were reviewed and a motion was made to approve the minutes as written. With the majority of the members present voting for the motion, the vote count for approval of the minutes was as follows:

For:	12
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: D980
PI: Pollet, Jeroen
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Mrna-Based Immunotherapy For Targeting Triple-Negative Breast Cancer

This project proposes the transcription and in vitro testing of seven mRNA vaccine candidates. The study will use certain blood cells to evaluate mRNA translation and peptide presentation, with plans for future in-vivo testing based on initial 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, 12; 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 preclinical study aims to develop lipid nanoparticle (LNP)-based therapies using synthetic RNA to target inflammation in chronic diseases like Alzheimer's and cardiovascular conditions. The project includes in-vitro and in-vivo testing to evaluate RNA delivery, gene silencing, and therapeutic efficacy, with the goal of advancing toward clinical applications.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section I: Please add III-D and III-F

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, 12; 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: D49
PI: Zoghbi, Huda
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Molecular Studies Of Various Genetic Diseases And Genome Mapping Analysis

This project investigates neurodegeneration using molecular and genetic tools such as plasmids, viral vectors, and engineered mice to study related proteins. Techniques include RNAi screening, in-vitro transfection and infection, and in-vivo AAV injections to assess gene expression, protein interactions, and behavioral outcomes 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, 12; 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: Ion Channel Remodeling In Epilepsy

This project aims to treat epilepsy in a mouse model by delivering related recombinant plasmids via an AAV vector to newborn mice. Following the application, researchers will monitor seizure activity and collect tissue for molecular analysis to evaluate therapeutic effects.

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, 12; 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: D443
PI: Young, Nicolas
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Young Lab Human Tissue Culture & Protein Epitope Tags

This project investigates chromatin regulation and aging through proteomics, focusing on post-translational modifications and their role in gene expression and disease. By studying related variants, transcription factors, and lysosome-to-nucleus signaling, the research aims to uncover mechanisms of epigenetic control and identify therapeutic targets to improve health span and treat age-related conditions.

After the presentation by the assigned reviewer and discussion, the committee requested the following modifications: 1). Section C: Please describe how shRNA transfection will be done . 2) Section C: Please mention if transfection of original protein will result in any toxic peptides.

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, 12; 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: D623
PI: Wu, Tao
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Identification Of Novel Epigenetic Regulators With Recombination And Synthetic Nucleic Acid

This project explores how DNA and RNA modifications contribute to cancer drug resistance, focusing on cell adaptation mechanisms. Using gene editing, synthetic peptides, and various molecular assays in stem and cancer cell lines, the study aims to identify key regulators and 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, 12; 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 development and testing of CRISPR/Cas genome editing technologies through the newly established Genome Editing Testing Center (GETC). The GETC provides researchers with mouse model-based platforms to evaluate genome editing efficiency, specificity, and therapeutic potential using various delivery systems and molecular tools.

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

This study investigates the role of noncoding RNAs and their protein partners in cancer development using molecular and cellular techniques in both cell lines and mouse models. Through gene manipulation, viral delivery, and compound screening, the research aims to uncover how these genetic elements influence tumor-related processes such as cell death, proliferation, and migration, potentially identifying new therapeutic targets.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Please ensure all personnel complete 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: D819
PI: Reddy, Pavan
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Genetic Manipulation for GVHD Studies

This research uses mouse models to study bone marrow transplantation and immune responses in Graft-versus-Host Disease (GVHD) and Graft-versus-Leukemia (GVL), employing gene editing

tools like CRISPR and viral delivery systems to investigate antigen presentation and immune regulation. It also includes CRISPR-based genetic screens and the production of related cells to explore therapeutic strategies and disease mechanisms.

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: D820
PI: Benham-Pyle, Blair
Containment Level: BSL-1
NIH Guidelines Section: III-F
Title: Construction And Utilization of Recombinant Host-Vector Systems to Screen Planarian Gene Function and Synthesize In Situ Probes

This study involves generating and using non-hazardous plasmids in E. coli to produce RNA for gene depletion and probe synthesis in the regenerative flatworm Schmidtea mediterranea. The goal is to target around 15,000 planarian gene transcripts to investigate regeneration, aging, and cancer-related processes .

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: D29
PI:, Stevens, Alexandra

Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Genetic Manipulation of Pediatric Leukemia Cells

This project aims to investigate chemotherapy resistance in leukemia by using RNA and related vectors to suppress or edit genes involved in signal transduction, DNA repair, and histone methylation. Fluorescent and luminescent markers are used to track modified cells in-vitro and in-vivo, enabling analysis of drug response and survival in both cell cultures and 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: D781
PI: Sandweiss, Alexander
Containment Level: BSL-2
NIH Guidelines Section: III-F
Title: Transient Transfection for Cell-Based Assay of anti-NMDAR IgG

This project uses a cell-based assay to detect anti-NMDAR antibodies, the hallmark of autoimmune encephalitis, by transiently transfecting associated cells with NMDAR-expressing plasmids and analyzing antibody binding. The transfected cells are fixed and used solely for antibody detection in mouse and human samples, with no live-cell transfection beyond this context.

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: D569
PI: Hill, Laquisa
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Cell Therapy For High Risk T-Cell Malignancies Using Cd7-Specific Car Expressed On Non-Edited T Cells (Crimson-Ne)

This project focuses on a Phase 1 clinical trial evaluating CD7-targeted CAR T cells as a treatment for leukemia and lymphoma, aiming to overcome challenges in targeting T-cell malignancies. The trial will assess safety, anti-tumor efficacy, and potential to enable stem cell transplant in previously ineligible patients, using a dose-escalation approach with chemotherapy and monitoring for toxicity and therapeutic 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: 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 trial will evaluate the safety, pharmacodynamics, and pharmacokinetics of mRNA-3927, an investigational mRNA therapy designed to treat propionic acidemia. The study includes dose optimization and expansion phases using a “3+3” design and sentinel dosing strategy.

The study includes dose optimization and expansion phases to evaluate safety, pharmacodynamics, and efficacy, with the goal of identifying a suitable dose for future trials.

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 study evaluates the safety and effectiveness of C7R.CD30.CAR-EBVST cells, a modified T cell therapy designed to treat relapsed or refractory CD30+ lymphomas using an off-the-shelf approach. It uses a dose-escalation protocol to identify the safest and most effective dose, with long-term follow-up and built-in safety mechanisms to minimize toxicity and improve accessibility to CAR T cell 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.

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 October.

D. Recombinant or synthetic nucleic acid molecule Minor Administrative Report

The IBC Laboratory Compliance Assurance Associate reported to the IBC that there were eight administrative rDNA IBC protocols for the month of October.

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 October.

F. IBC Inspection Report

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

G. Research Compliance Services (RCS) Update

The IBC Laboratory Compliance Assurance Associate informed the committee that there were three post-approval monitoring sessions completed.

H. Member Discussion

The Biosafety Officer (BSO) informed the committee about new safety assignments and coverage of Texas Children's Hospital research buildings.

I. Spills, Incidents, or Exposures

There were no items to report for the month of October.

J. RAC Decisions and Updates

There were no items to report for the month of October.

K. Issues from the Floor and Public Comments

There were no issues raised from the floor or public comments.

L. Adjournment

The meeting was adjourned at 1:28 pm

UPCOMING EVENTS:

The next IBC meeting is scheduled for Monday, November 17, 2025.