Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Tuesday, September 15, 2026, at 1:00 p.m. via videoconference. Upon reaching a quorum, the meeting was called to order by the Chairperson.

Meeting Attendance:

Ron Javier, PhD, Chair
Robert Atmar, MD, IBC Vice Chair
Manu Banadakoppa, PhD
Connor Cordray, MPH, CPH, CHMM, CBSP
Monica Darden, MA
Julia Goldman, DVM
Richard Hamill, MD
Shirley Hutchins, MSN
James Kelaher, MD
Paul Nakata, PhD
Robin Parihar, MD
Lisa Rollins, MS
Shannon Ronca, PhD, MPH, BS
Poonam Sarkar, PhD

Vance Hobbs, MBA, Alternate Member
Shalaka Kotkar, PhD, MPH, CPH, CBSP
Holly Robinson, Alternate
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 August 2026 MINUTES

The minutes for August 18, 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: D1029
PI: Vong, Keng
Containment Level: BSL-1
NIH Guidelines Section: III-D
Title: Mechanisms of Nervous System Dysfunction in Developmental Disorders

This project investigates how genetic factors influence nervous system development by introducing neuronal activity regulators into mouse nervous systems using adeno-associated viral vectors. The effects of these genetic manipulations will be evaluated through molecular analyses, sequencing, behavioral studies, and other relevant biological experiments.

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: D46
PI: Rosen, Jeffrey
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Hormonal Regulation of Breast Cancer

This project studies how genes regulate mammary gland development and breast cancer using mouse and human mammary epithelial and tumor cell lines, as well as primary mouse mammary and tumor cells. Researchers introduce genes into these cells to evaluate gene function, cell behavior, tumor development, and disease mechanisms, with some modified cells transplanted into mice for further analysis.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section E: Please remove room VG4.

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: D65
PI: Crawford, Sue
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Hepatitis B Virus Hbx-Mediated Pathogenesis

This research aims to identify and validate novel antiviral compounds that target hepatitis B virus (HBV) proteins. Candidate compounds are identified through screening, then evaluated for their ability to inhibit HBV replication using assay procedures, protein interaction studies, and HBV infection models in human liver cells.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). If anyone uses or could come into contact with HBV, please have them receive the HBV vaccine.

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: D190
PI: Shen, Lanlan
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Epigenetic Engineering to Study The Role of Aberrant Dna Methylation in Cancer

This research investigates how genetic and epigenetic alterations contribute to cancer development and progression by manipulating gene expression, DNA methylation, and oncogenic signaling in cell culture and mouse models. The studies use multiple approaches including viral vectors to evaluate the roles of tumor suppressor genes, oncogenes, and DNA methylation in tumor initiation, growth, and progression.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please include the use of retroviral and AAV viral constructs 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, 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: D198
PI: Sillitoe, Roy
Containment Level: BSL-1
NIH Guidelines Section: III-D and III-F
Title: Neural Circuit Formation in The Developing Brain

This study investigates how genes control brain development, neural circuit formation, and behavior by modifying gene activity in mice using genetic engineering and recombinant DNA

techniques. Researchers analyze the effects of these genetic changes on brain structure, neural connectivity, motor function, learning, and behavior to better understand the causes of neurological disorders such as autism, ataxia, and dystonia and to identify potential therapeutic targets.

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: D677
PI: Van Nostrand, Eric
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Study of Rna Binding Protein Regulatory Networks with Viral Vectors

This research investigates the roles of specific genes and RNA-binding proteins delivered through replication-deficient lentiviral systems. The effects of these genetic manipulations are analyzed using genomic, molecular, and imaging techniques, including RNA sequencing, protein and RNA expression assays, and fluorescence microscopy, to better understand gene regulation and cellular 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.

Protocol number: D688
PI: Rao, Ganesh
Containment Level: BSL-1
NIH Guidelines Section: III-D
Title: Modeling Malignant Progression in Glioma Using Ectopic Gene Expression in Ntv-A Mice.

This research uses a mouse model to study how specific genes contribute to glioma development and malignant progression by delivering genes of interest into targeted neural cells using engineered viral vectors. Researchers introduce the genes into mice, then evaluate gene expression and tumor formation through immunohistochemistry.

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: D699
PI: Mustoe, Anthony
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Development of Genetic Tools to Facilitate Research of The Regulatory Functions of Rna Structure

This research investigates how RNA structure influences gene regulation by combining chemical biology, synthetic biology, computational biology, biochemistry, and genetics to study both natural and engineered RNA molecules. Researchers create synthetic multiple approaches in bacterial and mammalian cells to identify mechanisms controlling RNA function, structure, and expression..

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: D862
PI: Gorelick, Daniel
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Identification of Genes Required for The Differentiation of Human Embryonic Stem Cells into Hemato-Vascular Lineages

This study aims to identify genes that control the differentiation of human embryonic stem cells and determine how signaling pathways influence these processes. Researchers evaluate changes in cell morphology, gene expression, and protein levels during differentiation to assess the function of specific genes in cultured 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, 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: D864
PI: Wang, Chunmei
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Mouse Models for Intersectional Genetic Tools

This project uses viral vectors and genetically engineered mice to manipulate, monitor, and map specific neuronal populations and neural circuits involved in brain function, metabolism, temperature regulation, and behavior. Researchers deliver genes into targeted brain regions and peripheral tissues, then assess the effects using imaging, photometry, physiological and behavioral 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: D1030
PI: Morales Ubico, Erin
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Auto1-Sl2: A Single-Arm, Open-Label, Phase Ii Study to Determine the Safety and Efficacy of Obecabtagene Autoleucel (Obe-Cel) In Participants with Severe, Refractory Systemic Lupus Erythematosus with Active Lupus Nephritis

The study follows participants through screening, treatment, and extended follow-up periods, with close monitoring for T-cell-related adverse effects and assessment of safety, tolerability, and clinical efficacy. The product is manufactured from each participant's own T cells, genetically modified, and administered as a ready-to-use cellular 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.

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

Protocol number: D55
PI: Crawford, Sue
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Molecular Studies of Rotavirus Replication

This research aims to better understand rotavirus biology and develop improved vaccines, diagnostic tools, and antiviral strategies by producing and studying rotavirus proteins. Researchers also generate recombinant rotaviruses and use genetic tools to investigate the roles of viral and cellular genes in virus replication, infectivity, and disease.

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

This research uses molecular cloning and multiple protein expression systems to produce recombinant proteins for studying disease mechanisms, developing vaccines, improving diagnostics, and evaluating immune responses in disease. Researchers engineer and express native, modified, and fusion proteins from numerous pathogens and disease targets, then assess their potential for vaccine development, functional studies, binding assays, and other biomedical applications.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section D: Please add a line for the decontamination of the culture waste vessels and disposal of culter.

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 themselves during the discussion and vote on this protocol due to a conflict of interest.

Protocol number: D397
PI: Fu, Yingbin
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Animal Models For Vision Impairment

This research program uses recombinant AAV vectors, transgenic mice, and genetically modified mouse models to investigate the mechanisms underlying age-related macular degeneration, while evaluating potential therapies. The studies also employ genetically engineered and conditional knockout mouse models targeting specific metabolic pathways to assess disease progression, therapeutic efficacy, and safety through molecular, histological, and ophthalmic analyses.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1) Section C: Please clarify if BPCI is a complete inhibitor or complement inhibitor 2) Section D: Please clarify if BPCI is a complete inhibitor or complement inhibitor 3) Please clarify the project location

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: D603
PI: Westbrook, Thomas
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Molecular Genetic Approaches to Cancer (Previously D33)

This research program uses replication-incompetent lentiviral and retroviral vectors to investigate the roles of specific genes and signaling pathways in cancer cell proliferation, survival, and transformation. Transgenic animal models are employed to evaluate therapeutic targets and evaluate DNA expression through immunohistochemistry and histopathological 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: D639
PI: Li, Na
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Study of Molecular Mechanisms of Cardiac Arrhythmia

This research investigates the molecular mechanisms underlying cardiac arrhythmias by using recombinant DNA technologies to study the functions of arrhythmia-associated genes in mammalian cell lines and mouse models. Gene expression and cardiac function are evaluated with outcomes assessed through molecular, physiological, and protein expression analyses in harvested heart tissues.

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: D1021
PI: Hulsurkar, Mohit
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-E
Title: Targeting Inflammation in Cancer Associated Atrial Fibrillation

This project investigates the role of inflammation in cancer-associated atrial fibrillation (AF) using commercially produced, replication-deficient recombinant AAV vectors to evaluate their effects on cardiac inflammation, fibrosis, and arrhythmia susceptibility. Mice will undergo molecular, histological, imaging, and electrophysiological analyses, while complementary studies in human cardiac fibroblast cell lines will be evaluated for comparison.

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: D570
PI: Makawita, Shalini
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Vista (Virus Specific T Cells and Adenovirus): A First in Human Phase I Trial of Binary Oncolytic Adenovirus in Combination with Her2-Specific Car Vst Cells in Patients with Advanced Her2 Positive Solid Tumors

This Phase I single-center, clinical trial evaluates the safety, feasibility, maximum tolerated dose, and preliminary efficacy of intratumoral cell injection followed by intravenous HER2-specific CAR T-cell therapy in patients with advanced refractory HER2-positive solid tumors. The study will assess antitumor response, progression-free and overall survival, treatment-related adverse events, and immune 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, 14; Against, 0; Abstaining, 0.

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

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

This gene therapy study evaluates the safety, efficacy, and tolerability of a non-replicating recombinant AAV9 vector administered to subjects with genetically confirmed classic Rett syndrome. Participants will undergo intensive short-term and long-term monitoring, including immune response surveillance, clinical assessments, and safety 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, 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: D898
PI: Ku, Cristy
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Randomized, Controlled, Masked, Multi-Center Study Evaluating the Efficacy, Safety, and Tolerability of Two Dose of AGTC-501 Compared to an Untreated Control Group in Male Participants with X-linked Retinitis Pigmentosa (AGTC-VISTA

This clinical trial evaluates the efficacy and safety of a replication-deficient recombinant gene therapy administered to subjects with genetically confirmed X-linked retinitis pigmentosa (XLRP) caused by pathogenic RPGR variants. Participants will be assessed primarily by visual acuity and safety monitored through ophthalmic examinations, adverse event reporting, 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, 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 werethree rDNA IBC protocol closed for the month of September.

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 September.

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 September.

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

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

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

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

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 1:34 pm

UPCOMING EVENTS:
The next IBC meeting is scheduled for Tuesday, October 20, 2026.