Institutional Biosafety Committee Minutes

The Institutional Biosafety Committee (IBC) met on Monday, November 17, 2025 at 1:01 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
Julia Goldman, DVM
Richard Hamill, 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, Alternate
Shalaka Kotkar, PhD, MPH, CPH, CBSP, 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 October 2025 MINUTES

The minutes for October 21, 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:	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: D283
PI: Schiff, Rachel
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Development Of Fkhr Conditional Mammary Gland Ko And Transgenic Mouse Models For Estrogen Receptor Dependent Breast Cancer

The lab studies how gene ablation or overexpression of oncogenes or tumor suppressors like FKHR impacts estrogen receptor-dependent breast cancer using mouse models. They employ applicable vectors to manipulate genes in mammary glands, aiming to improve understanding and develop better therapies.

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 lab investigates the role of specific genes in heart function using PCR, CRISPR, and viral vector technologies for both in vitro and in vivo studies. These approaches aim to assess gene effects on cellular and cardiac structure, function, and explore gene therapy strategies to prevent or treat heart disease 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, 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: D488
PI: Heaney, Jason
Containment Level: BSL-1
NIH Guidelines Section: III-D, III-E and III-F
Title: Genetically Engineered Rodent Models Core - Rdna for Mouse Transgenics and Gene Targeting

The Genetically Engineered Rodent Models Core creates transgenic and knockout/knock-in mice by using DNA constructs in zygotes and related stem cells. Animals are provided to investigators for breeding and study and further research.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section D: Please change clidox to peroxigard.

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: D824
PI: Hudson, William
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Determinants Of T Cell Function In Viral Disease And Cancer

The research focuses on improving cell function by identifying inhibitory pathways through gene knockout, lentiviral overexpression, and sequencing-based analysis of gene expression and receptor profiles. These studies aim to enhance T cell cytotoxicity against infections and cancer using in vitro assays and in vivo 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, 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: D218
PI: Lagor, William
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Novel Regulators of Lipid Metabolism in Cardiovascular and Metabolic Disease

This project aims to uncover the genetic basis of lipid metabolism and develop novel gene therapy strategies using viral vectors and lipid nanoparticles in mice as preclinical models.

Approaches include manipulating genes with AAV, adenovirus, or LNP delivery systems to study cholesterol synthesis, rare disease correction, and therapeutic efficacy in relevant 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, 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: D656
PI: Patras, Katy
Containment Level: BSL-2
NIH Guidelines Section: III-D and III-F
Title: Contribution of Host Metabolism, Immunity, and Microbiota to Bacterial Colonization and Infection of The Female Urogenital Tract.

This research focuses on understanding interactions between the female urogenital tract and bacteria to identify pathways that maintain health. Molecular cloning is used to generate bacterial mutants and study their role in host interactions through in vitro human cell assays and in vivo mouse models of urinary tract infection and vaginal colonization.

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: D776
PI: Eagen, Kyle
Containment Level: BSL-2
NIH Guidelines Section: III-D, III-E and III-F
Title: Eagen Lab Recombinant and Synthetic Nucleic Acids Molecules Research

This project investigates how certain proteins drive cancer initiation and progression, with the goal of developing targeted therapies that minimize side effects. We use mammalian cell lines and mouse models manipulated through genome editing, loss-of-function studies, and transgene expression to analyze gene regulation and chromatin architecture.

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: D804
PI: Ghanta, Ravi
Containment Level: BSL-2
NIH Guidelines Section: III-D
Title: Multiplexed CRISPRa to Promote Mitochondrial Biogenesis

This project aims to enhance quantity and function in cardiomyocytes using activation of biogenesis factors delivered via viral vectors in vitro and in vivo. Following optimization in cell culture, the top-performing system will be tested in animal infarction models to assess mitochondrial biogenesis and cardiac function.

After the presentation by the assigned reviewer and discussion, the committee requested the following modification: 1). Section C: Please give a brief description of the location of instruments and decontamination process after use of the instruments. 2) Section F: Please elaborate on heart function studies.

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: D727
PI: Hegde, Meenakshi
Containment Level: BSL-2

NIH Guidelines Section: III-C
Title: Phase I Study Of Her2 Chimeric Antigen Receptor (Car) T Cells In Combination With Checkpoint Blockade In Patients With Advanced Sarcoma (Heros 3.0)

This Phase I study evaluates the safety of combining autologous HER2 CAR T cells with PD-1 checkpoint blockade drugs in pediatric patients with refractory or recurrent sarcoma, following lymphodepletion. The combination of therapies and procedures seeks to increase safety, tolerance and therapeutic outcome for these patients.

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: D828
PI: Suter, Bernhard
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 1/2/3 Open-Label, Single Arm, Dose-Finding Study to Investigate Long-Term Safety, Tolerability and Efficacy Of GS-100, An Adeno-Associated Virus Serotype 9 (AA V9) Vector-Mediated Gene Transfer Of Human NGLY1, In Patients with NGLY1 Deficiency

This Phase 1/2/3 study evaluates the long-term safety, tolerability, and efficacy of GS-100, an AAV9-based gene replacement therapy for a rare neurodevelopmental disorder with no approved treatment. Subjects aged 2–18 years will receive treatment, with Phase 1/2 focused on dose-finding and safety, and Phase 3 assessing clinical benefit at 52 weeks, followed by a 5-year monitoring period under regulatory oversight.

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: 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 study is an open-label, baseline-controlled, multicenter trial evaluating the efficacy, safety, and tolerability of an AAV9-based gene therapy, administered via intracerebroventricular infusion in female patients with classic Rett syndrome. Subjects will receive a single dose under general anesthesia, followed by intensive short-term monitoring and long-term follow-up for 12 years to assess safety, immune response, and sustained clinical benefit.

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: D914
PI: Sunde, Jan
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: Gog-3076: A Randomized Phase 3 Study Assessing The Efficacy And Safety Of Olvi-Vec Followed By Platinum- Doublet Chemotherapy And Bevacizumab Compared With Physician's Choice Of Chemotherapy And Bevacizumab In Women With Platinum Resistant/Refractory Ovarian Cancer (Onprime/Olvi-Vec-022)

This multicenter, randomized, open-label Phase 3 trial will compare an oncolytic vaccinia virus administered via intraperitoneal infusion followed by platinum-doublet chemotherapy and bevacizumab, against standard chemotherapy regimens in patients with platinum-resistant/refractory ovarian cancer.

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: 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 single-arm, two-stage Phase 2 study evaluates an autologous T-cell therapy, in patients with relapsed/refractory T-cell lymphoma to confirm efficacy and further assess safety.

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: D927
PI: Patel, Meera
Containment Level: BSL-2
NIH Guidelines Section: III-C
Title: A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INTerpath-009)

This Phase 3 study evaluates the safety and efficacy of adding an individualized mRNA-based neoantigen therapy, to current therapies in patients with resectable Stage II–III NSCLC who did not achieve pathologic complete response after neoadjuvant chemoimmunotherapy and surgery.

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 Director, Research Compliance reported to the IBC that there were no rDNA IBC protocols closed for the month of November.

D. Recombinant or synthetic nucleic acid molecule Minor Administrative Report
The Director, Research Compliance reported to the IBC that there were six administrative rDNA IBC protocols for the month of November.

E. Recombinant or synthetic nucleic acid molecules research -- Exempt Protocols
The Director, Research Compliance reported to the IBC that there were no exempt protocols submitted in the month of November.

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

G. Research Compliance Services (RCS) Update
The Director, Research Compliance informed the committee that there were five post-approval monitoring sessions completed.

H. Member Discussion
There were no items to report for the month of November.

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

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

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 1:24 pm

UPCOMING EVENTS:
The next IBC meeting is scheduled for Monday, December 15, 2025.