Johns Hopkins Institutional Biosafety Committee
JHU IBC Minutes for February 16, 2026
Zoom Meeting

Members Present: Gary S. Hayward, Ph.D. (IBC Chair, Virology and Gene Therapy); Alan F. Scott, Ph.D. (IBC member, Molecular Biology and Genetics); Weiying Pan, Ph.D., RBP (BSO, Molecular Aspect of Drug Design and Biology); Nadia Desir, Ph.D., RBP (IBC member, Research Lab Safety and High Containment); Viji Sitther, Ph.D. (Non-affiliated Member, Plant Biology); Prashant Desai, Ph.D. (IBC member, Virology); Ms. Claudia MacAuley, L.A.T. (Non-affiliated Member, Biosafety and High Containment); Djikolngar Maouyo, Ph.D. (Non-affiliated Member, Biology); Jason Villano, D.V.M. (IBC member, Animal Science)

Members Absent: Elizabeth A. Laffan, Ph.D. (Non-affiliated Member, Biology); Brigitte Gaume, Ph.D. (Non-affiliated Member, Biology); Douglas Norris, Ph.D. (IBC member, Vector Biology and Entomology); Joseph B. Margolick, MD, Ph.D. (IBC member, Medicine, Microbiology and Immunology); Stephen C. Dahl, Ph.D., RBP (IBC member, Biology)

IBC Coordinator: Ms. Tylicia McRae

The Meeting was called to order at 3:49 pm.

Review and Approval of Meeting Minutes

The minutes of the January 22, 2026, meeting were approved as submitted.

Announcements:

No conflicts of interest were reported by IBC members.

Clinical Protocols and Amendments:

Barth Protocol, GT2312180101 (NIH Cit.: III-C-1), "First-in-Human, Open-Label, Safety, Tolerability, Dose Finding, Pharmacodynamic and Cardiac Transgene Expression Study of TN-401, a Recombinant Adeno-Associated Virus Serotype 9 (AAV9) Containing Plakophilin-2 (PKP2) Transgene, in Adults with PKP2 Mutation-Associated Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)"

The IBC received Protocol Version 5.0 dated December 16, 2025, for the above referenced protocol. Language throughout the protocol was updated to reflect changes in the Statistical Analysis Plan. Hospitalization may be extended to allow for close monitoring and treatment. Exclusion criteria were added for patients with a genetic predisposition to deep vein thrombosis (DVT) and for patients with a personal or family history of DVT. Two 7-day ambulatory cardiac

monitoring assessments were added at all timepoints. Clarifications and revisions were made throughout the protocol. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the amendment.

For Approval: 9
Disapproval: 0
Abstain: 0

Carey Protocol, GT2501140201 (NIH Cit.: III-C-1), "A Phase 1/2 Trial of AAVAnc80-AntiVEGF Gene Therapy in Individuals with Unilateral Vestibular Schwannoma"

The IBC received Protocol Amendment 2 dated December 12, 2023, for the above referenced protocol. Language was amended to clarify that a tumor in contact with brainstem would result in exclusion from the trial. New exclusion criteria were added to further mitigate potential risks of AAV ANC80-antiVEGF. The schedule of assessments was modified to include collection of clinical labs at Screening. Minor updates were made to tables and the list of abbreviations. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the amendment.

For Approval: 9
Disapproval: 0
Abstain: 0

Carey Protocol, GT2501140201 (NIH Cit.: III-C-1), "A Phase 1/2 Trial of AAVAnc80-AntiVEGF Gene Therapy in Individuals with Unilateral Vestibular Schwannoma"

The IBC received Protocol Amendment 3 dated October 3, 2025, for the above referenced protocol. The inclusion criteria and the schedule of assessments were updated. A minimum interval of three days was introduced between assessments. Language clarifications, formatting edits, updated citations and abbreviations, and grammatical changes were made throughout the protocol. None of these changes are expected to affect the biosafety of the study.

The IBC voted to approve the amendment.

For Approval: 9
Disapproval: 0
Abstain: 0

Scott Protocol, GT2502170301 (NIH Cit.: III-C-1), "A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-1)"

The IBC received Protocol Amendment 2 dated December 10, 2025 and Pharmacy Manual Version 5 dated December 5, 2025, for the above referenced protocol. An independent

Supplemental Injection Review Committee was implemented to verify whether a participant has met disease activity criteria. The trial sample size was increased from 400 to 480. Clarifying text was added for guidance, post-administration procedures, and definitions. The Pharmacy Manual was updated to include the changes to the protocol. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the amendment.

For Approval: 9
Disapproval: 0
Abstain: 0

Talaat Protocol, GT2602160201, (NIH Cit.: III-C-1), "A Phase 3, Randomized, Double-Blind, Placebo-Controlled Clinical Study Evaluating the Safety, Tolerability, Immunogenicity and Efficacy of a Variant-Adapted BNT162b2 Vaccine in Healthy Participants 50 through 64 Years of Age"

The primary objective of the protocol is to evaluate the safety, tolerability, immunogenicity and efficacy of BNT162b2 against placebo in the prevention of COVID-19 in adults 50 through 64 years of age. BNT162b2 consists of a nucleoside-modified messenger RNA (modRNA) that encodes the SARS-CoV-2 spike protein. Approximately 25,500 healthy participants will be enrolled and randomized 1:1 to receive a single 30ug intramuscular injection of variant-adapted BNT162b2 or placebo. The duration for participation in the study is approximately 6 months or when COVID-19 surveillance ends, whichever occurs later.

The medical and pharmacy staff involved in the study have been trained to follow the pharmacy manual for the proper handling of BNT162b2, as well as the standard operating procedures (SOPs) for incident management, including spill response.

The submission complies with the requirements of the Johns Hopkins IBC, institutional policies, and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

The IBC voted to approve the protocol.

For Approval: 9
Disapproval: 0
Abstain: 0

IBC review and recommendation of Recombinant DNA Research Registrations and Amendments:

6 research registrations and 1 amendment were presented for IBC consideration.

Review of Incidents:

No incidents were reported at this meeting.

Public Comments:

There were no public comments.

The meeting was adjourned at 4:44 pm.

February, 2026,JHU IBC R-DNA Research Registrations and Amendments

Name	Synopsis	IBC#	BSL	ABSL	NIH Cit.	Agent	Select Agent
New Registrations							
Graham, Thomas	Replication-incompetent adeno-associated viral vectors will be used to transduce episomal reporter gene arrays and fluorescent proteins into cultured cells to study how proteins and protein complexes bind to target genes to regulate their transcription. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors and all other recombinant DNA materials, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. Pathogen/Infectious agent registration for Replication-incompetent adeno-associated viral vectors RegSupport: R-DNA:DN2506240101; Human tissue registration: B2506240101	P2601150201	2		III-D-1-a	Replication-incompetent adeno-associated viral vectors	No

Discussion/Review

Protocol Narrative Assessment:	Acceptable. The proposal adequately describes the experiments to be performed.
Hazard Assessment and Precautions:	Acceptable. The proposal adequately describes the potential biohazards inherent in the research program and identifies proper containment procedures and PPE.
Training:	Acceptable. The proposal adequately describes the training required for personnel to perform the experiments.
Decontamination and Waste Disposal:	Acceptable. The proposal adequately describes proper decontamination and disposal procedures.
Committee Vote:	**For: 9 Opposed: 0 Abstentions: 0**

Green, Jordan	Replication-incompetent adeno-associated viral vectors obtained from collaborators will be used to transduce reporter genes including green fluorescent protein (GFP), and therapeutic genes including anti-VEGF antibody, anti-VEGF/Ang2, or VEGF TRAP, into cultured cells and animals. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors and all other recombinant DNA materials, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. Pathogen/Infectious agent registration for Replication-incompetent adeno-associated viral vectors RegSupport: R-DNA:DN0906080317; Human tissue registration: B0906260117	P2601080101	2	2 III-D-1-a; III-D-4-b	Replication-incompetent adeno-associated viral vectors	No

Discussion/Review

Protocol Narrative Assessment:	Acceptable. The proposal adequately describes the experiments to be performed.
Hazard Assessment and Precautions:	Acceptable. The proposal adequately describes the potential biohazards inherent in the research program and identifies proper containment procedures and PPE.
Training:	Acceptable. The proposal adequately describes the training required for personnel to perform the experiments.
Decontamination and Waste Disposal:	Acceptable. The proposal adequately describes proper decontamination and disposal procedures.
Committee Vote:	**For: 9 Opposed: 0 Abstentions: 0**

Jenkins-Lord, Brittany	Replication-incompetent lentiviral vectors obtained from a commercial vendor will be used to knock down the expression of tumor suppressor genes LRIG1 and WWOX in cultured cells to study their roles in breast cancer. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors and all other recombinant DNA materials, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. Pathogen/Infectious agent registration for Replication-incompetent lentiviral vectors RegSupport: R-DNA: updated from DE2310250103 to DN2310250131; Human tissue registration: B2310040203	P2512290101	2	III-D-3-a	Replication-incompetent lentiviral vectors	No

Discussion/Review

Protocol Narrative Assessment:	Acceptable. The proposal adequately describes the experiments to be performed.

Hazard Assessment and	Acceptable. The proposal adequately describes the potential biohazards inherent
Precautions:	in the research program and identifies proper containment procedures and PPE.
Training:	Acceptable. The proposal adequately describes the training required for personnel to perform the experiments.
Decontamination and Waste Disposal:	Acceptable. The proposal adequately describes proper decontamination and disposal procedures.
Committee Vote:	**For: 9 Opposed: 0 Abstentions: 0**

Pederick, Daniel	Replication-incompetent Sindbis viral vectors obtained from a commercial vendor will be used to transduce GFP, RFP, Vamp2, and barcode sequences into cultured cells and mice to study the formation of high-resolution auditory circuits in the mammalian brain. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors and all other recombinant DNA materials, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. Pathogen/Infectious agent registration for Replication-incompetent Sindbis viral vectors RegSupport: DN2506020101;	P2601260201	2	2	III-D-1-a, III-D-4-b	Replication-incompetent Sindbis viral vectors	No

Discussion/Review

Protocol Narrative Assessment:	Acceptable. The proposal adequately describes the experiments to be performed.
Hazard Assessment and	Acceptable. The proposal adequately describes the potential biohazards inherent
Precautions:	in the research program and identifies proper containment procedures and PPE.
Training:	Acceptable. The proposal adequately describes the training required for personnel to perform the experiments.
Decontamination and Waste Disposal:	Acceptable. The proposal adequately describes proper decontamination and disposal procedures.
Committee Vote:	**For: 9 Opposed: 0 Abstentions: 0**

Yang, Xiao	Replication-incompetent adeno-associated viral vectors from a commercial vendor will be used to transduce YFP, mCherry, and hSyn1 into cultured cells for the generation and maintenance of organoids, enabling advanced modeling for developmental biology, disease studies, and drug discovery. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors and all other recombinant DNA materials, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. DN--Uses recombinant DNA in cultured cells RegSupport: Replication-incompetent adeno-associated viral vectors:P2602040101; Human tissue registration: B2601140101	DN2602040101	2	III-D-1-a		No

Discussion/Review

Protocol Narrative Assessment:	Acceptable. The proposal adequately describes the experiments to be performed.
Hazard Assessment and Precautions:	Acceptable. The proposal adequately describes the potential biohazards inherent in the research program and identifies proper containment procedures and PPE.
Training:	Acceptable. The proposal adequately describes the training required for personnel to perform the experiments.
Decontamination and Waste Disposal:	Acceptable. The proposal adequately describes proper decontamination and disposal procedures.
Committee Vote:	**For: 9 Opposed: 0 Abstentions: 0**

Yang, Xiao	Replication-incompetent adeno-associated viral vectors from a commercial vendor will be used to transduce YFP, mCherry, and hSyn1 into cultured cells for the generation and maintenance of organoids, enabling advanced modeling for developmental biology, disease studies, and drug discovery. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors and all other recombinant DNA materials, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. Pathogen/Infectious agent registration for Replication-incompetent adeno-associated viral vectors RegSupport: R-DNA:DN2602040101; Human tissue registration:B2601140101	P2602040101	2	III-D-1-a	Replication-incompetent adeno-associated viral vectors	No

Discussion/Review

Protocol Narrative Assessment:	Acceptable. The proposal adequately describes the experiments to be performed.
Hazard Assessment and Precautions:	Acceptable. The proposal adequately describes the potential biohazards inherent in the research program and identifies proper containment procedures and PPE.
Training:	Acceptable. The proposal adequately describes the training required for personnel to perform the experiments.
Decontamination and Waste Disposal:	Acceptable. The proposal adequately describes proper decontamination and disposal procedures.
Committee Vote:	**For: 9 Opposed: 0 Abstentions: 0**

Amendments

O'Connor, Tamara	A plasmid-based CRISPR/Cas9 system will be used to conduct gene editing on host cell proteins. Endogenous Legionella pneumophila proteins MavP will be overexpressed and purified from Legionella pneumophila using plasmids. In vitro culture experiments will be added to examine how Legionella pneumophila adaptations to the host impact its ability to infect macrophages. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of Legionella pneumophila and all recombinant DNA materials, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. Amendment for DN1308220113 RegSupport: Legionella pneumophila: P1308220113	DN1308220113	2	III-D-1-a	No

Discussion/Review

Protocol Narrative Assessment:	Acceptable. The proposal adequately describes the experiments to be performed.
Hazard Assessment and Precautions:	Acceptable. The proposal adequately describes the potential biohazards inherent in the research program and identifies proper containment procedures and PPE.
Training:	Acceptable. The proposal adequately describes the training required for personnel to perform the experiments.

Decontamination and Waste Disposal:	Acceptable. The proposal adequately describes proper decontamination and disposal procedures.

Committee Vote: **For: 9** **Opposed: 0** **Abstentions: 0**