Johns Hopkins Institutional Biosafety Committee
JHU IBC Minutes for May 18, 2026
Zoom Meeting

Members Present: Gary S. Hayward, Ph.D. (IBC Chair, Virology and Gene Therapy); 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 and Oncology); Ms. Claudia MacAuley, L.A.T. (Non-affiliated Member, Biosafety and High Containment); Elizabeth A. Laffan, Ph.D. (Non-affiliated Member, Biology); Alan F. Scott, Ph.D. (IBC member, Genetic Medicine and Molecular Biology); Joseph B. Margolick, MD, Ph.D. (IBC member, Medicine, Microbiology and Immunology); Jason Villano, D.V.M. (IBC member, Animal Science, left at 4:31pm); Djikolngar Maouyo, Ph.D. (Non-affiliated Member, Biology)

Members Absent: Stephen C. Dahl, Ph.D., RBP (IBC member, Biology); Brigitte Gaume, Ph.D. (Non-affiliated Member, Biology); Douglas Norris, Ph.D. (IBC member, Vector Biology and Entomology)

Guests: Dr. Anthony Leung, Dr. Rachy Abraham, Dr. Andy Pekosz, Ms. Banhi Biswas, who attended only at the beginning of the meeting to present their request.

IBC Coordinator: Ms. Tylicia McRae

The Meeting was called to order at 3:14 pm.

Review and Approval of Meeting Minutes

The minutes of the April 20, 2026 meeting were approved as submitted.

Announcements:

No conflicts of interest were reported by IBC members.

Review of Dr. Leung's Request for Reconsideration of Assigned Biosafety Level for his registration P2601050101 (pBAC MERS-REP)

The IBC approved Dr. Leung's registration P2601050101 (pBAC MERS-REP), which plans to use replication-incompetent pBAC-MERS-REP obtained from another investigator to generate macrodomain mutations and to screen for macrodomain inhibitors in vitro. The IBC approved cloning work to be conducted using Biosafety Level 2 (BSL-2) practices and requested that

transfection with pBAC-MERS-REP, as well as subsequent cell harvesting, be conducted in a BSL-3 facility out of an abundance of caution.

Dr. Leung presented a literature summary regarding the replication-incompetent features of pBAC-MERS-REP and the safety practices used in published studies. Dr. Pekosz explained that the possibility of forming a functional replication-competent virus via recombination events is extremely low. In addition, Dr. Pekosz noted that the BSL-3 facility may not be available for a few months due to upcoming renovations. Dr. Leung said the department may be able to allocate him a dedicated BSL-2 lab to conduct these experiments.

The IBC reviewed and discussed the request and determined that additional information is needed to assess whether the transfection and subsequent cell harvesting may be conducted in a BSL-2 facility. The IBC requested that Dr. Leung submit additional information regarding the dedicated BSL-2 lab assigned by the department for conducting the experiments, along with the specific SOP for carrying out the transfection with pBAC-MERS-REP and subsequent cell harvesting in the BSL-2 lab. Dr. Leung acknowledged receipt of the IBC request and will provide the requested information to the IBC.

Clinical Protocols and Amendments:

Campochiaro Protocol, GT2012210101 (NIH Cit.: III-C-1) - A Randomized, Partially Masked, Controlled, Phase 2b/3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ATMOSPHERE)

The IBC received Investigator's Brochure Version 15, dated March 24, 2026, for the above referenced protocol. The changes include updated study information from ongoing and completed trials, as well as updated nonclinical studies. Minor formatting and grammatical changes were made throughout the document. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the changes.

For Approval: 11
Disapproval: 0
Abstain: 0

Campochiaro Protocol, GT2008110101 (NIH Cit.: III-C-1) - A Phase 2, Randomized, Dose-Escalation, Ranibizumab-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of RGX-314 Gene Therapy Delivered via One or Two Suprachoroidal Space (SCS) Injections in Participants with Neovascular Age-Related Macular Degeneration (nAMD) (AAVIATE)

The IBC received Investigator's Brochure Version 15, dated March 24, 2026, for the above referenced protocol. The changes include updated study information from ongoing and completed trials, as well as updated nonclinical studies. Minor formatting and grammatical

changes were made throughout the document. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the changes.

For Approval: 11
Disapproval: 0
Abstain: 0

Campochiaro Protocol, GT2303200201 (NIH Cit.: III-C-1) - A Long-term Follow-Up Study to Evaluate the Safety and Efficacy of RGX-314 Following Subretinal Administration in Participants with Neovascular Age-related Macular Degeneration and Fellow Eye Treatment Substudy

The IBC received Investigator's Brochure Version 15, dated March 24, 2026, for the above referenced protocol. The changes include updated study information from ongoing and completed trials, as well as updated nonclinical studies. Minor formatting and grammatical changes were made throughout the document. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the changes.

For Approval: 11
Disapproval: 0
Abstain: 0

Campochiaro Protocol, GT2011160101 (NIH Cit.: III-C-1) - A Phase 2, Randomized, Controlled, Dose-Escalation Study to Evaluate the Efficacy, Safety, and Tolerability of RGX-314 Gene Therapy Delivered via a Single Suprachoroidal Space (SCS) Injection in Participants with Diabetic Retinopathy (DR) With and Without Center Involved-Diabetic Macular Edema (CI-DME) (ALTITUDE)

The IBC received Investigator's Brochure Version 15, dated March 24, 2026, for the above referenced protocol. The changes include updated study information from ongoing and completed trials, as well as updated nonclinical studies. Minor formatting and grammatical changes were made throughout the document. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the changes.

For Approval: 11
Disapproval: 0
Abstain: 0

Campochiaro Protocol, GT2201110201 (NIH Cit.: III-C-1) - A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD

The IBC received the IRB termination report acknowledgment for the above referenced protocol. No further action is considered warranted.

Karron Protocol, GT2512090201 (NIH Cit.: III-C-1), "Phase 1 Placebo-Controlled Study to Evaluate the Safety and Immunogenicity of Sequential Immunization with RSV LID/ΔM2-2/1030s Followed 8 Weeks Later by B/HPIV3/RSV/PreF/TM, Delivered by Nose Drops to HPIV3-Seronegative Infants and Children 6 Months to <25 Months of Age"

The IBC received Investigator's Brochure Version 1.0, dated March 16, 2026, for the above referenced protocol. Changes were made to the study title, tables, and figures to include preclinical evaluation data in animal models. None of the changes are expected to affect the biosafety of the study

The IBC voted to approve the changes.

For Approval: 11
Disapproval: 0
Abstain: 0

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

7 research registrations and amendments 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 4:46 pm.

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

Name	Synopsis	IBC#	BSL	ABSL	NIH Cit.	Agent	Select Agent
New Registrations							
Das, Samarjit	Replication-incompetent adeno-associated viral vectors obtained from a commercial vendor will be used to transduce miRNAs into cultured cells and animals to study their biological effects. 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: updated from DE1401280111 to DN1401280111; Human tissue registration: B2111030304	P2605040101	2	2	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: 10 Opposed: 0 Abstentions: 0**

Page, Stephanie	Replication-incompetent adeno-associated viral vectors obtained from commercial vendors will be used to transduce EGFP, mCherry, and GCaMP6 into cultured cells to study morphology and calcium activity in cell cultures.Replication-incompetent lentiviral vectors obtained from commercial vendors will be used to reprogram human fibroblasts into human induced pluripotent stem cells (hiPSCs) or directly into NGN2-positive neurons to study the function of genes associated with brain disorders. 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:P2604230101 ; Replication-incompetent lentiviral vectors:P2604230201; Human tissue registration:B2604230101	DN2604230101	2	III-D--3-a, 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: 10 Opposed: 0 Abstentions: 0**

Page, Stephanie	Replication-incompetent adeno-associated viral vectors obtained from commercial vendors will be used to transduce EGFP, mCherry, and GCaMP6 into cultured cells to study morphology and calcium activity in cell cultures.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: DN2604230101; Human tissue registration:B2604230101	P2604230101	2	III-D-1-a, III-D-3-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: 10** **Opposed: 0** **Abstentions: 0**

Page, Stephanie	Replication-incompetent lentiviral vectors obtained from commercial vendors will be used to reprogram human fibroblasts into human induced pluripotent stem cells (hiPSCs) or directly into NGN2-positive neurons to study the function of genes associated with brain disorders. 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: DN2604230101; Human tissue registration:B2604230101	P2604230201	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 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: 10** **Opposed: 0** **Abstentions: 0**

Reddy, Sashank	Replication-incompetent adeno-associated viral vectors obtained from commercial vendors will be used to deliver shRNAs targeting Zfp423 and Tle3 into mice to study their roles in maintaining white adipose tissue. 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 Propagation-incompetent rabies virus vectors RegSupport: R-DNA: updated from DE2108240105 to DN2108240105	P2604060101	2	2	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: 10 Opposed: 0 Abstentions: 0**

Amendments

Roden, Richard	Plasmid vectors will be used both to express and purify Kaposi's sarcoma-associated herpesvirus (KSHV) antigens for a protein-based therapeutic vaccine and to create DNA vaccine constructs; these vaccines will be tested in mice and nonhuman primates. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of the recombinant DNA materials and KSHV, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. Amendment for DN1205290115 RegSupport:KSHV: P2604240101	DN1205290115	2	2	III-D-2-a, III- D-4-b	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: 10 Opposed: 0 Abstentions: 0**

Exempt registrations

Chatterjee, Subroto	Transgenic mice will be used to study the efficacy of mouse and human galactosyltransferase in mitigating hair loss, discoloration, and wound-healing DE---Uses transgenic mice.	DE2604160101	1	1	III-D-4-c(2)	No

Discussion/Review

It falls under the exempt category under the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, so IBC review is not required