

Johns Hopkins Institutional Biosafety Committee
JHU IBC Minutes for April 20, 2026
Zoom Meeting

Members Present: Gary S. Hayward, Ph.D. (IBC Chair, Virology and Gene Therapy); Alan F. Scott, Ph.D. (IBC member, Genetic Medicine and Molecular Biology); 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 Sittther, 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); 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 3:12 pm.

Review and Approval of Meeting Minutes

The minutes of the March 16, 2026 meeting were approved with a minor change to the affiliations of two committee members.

Announcements:

No conflicts of interest were reported by IBC members.

Clinical Protocols and Amendments:

Bang Protocol, GT1902180301 (NIH Cit.: III-C-1), “A Phase1/2, Randomized, Double-Blind, Sham Control, and Open-Label Study to Explore Safety, Tolerability, and Efficacy Signals of Multiple Doses of Striataly-Administered rAAV5-miHTT Total Huntington Gene (HTT) Lowering Therapy (AMT-130) in Early Manifest Huntington Disease”

The IBC received Amendment 15, Version 16.0, dated September 18, 2025, for the above referenced protocol. One year of long-term follow-up care was added for participants in Cohorts 1 and 2. Flexibility in follow-up actions for DLT and stopping rules was introduced. Clarifications and corrections 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

Christenson Protocol, GT2502170201 (NIH Cit.: III-C-1), “A Pilot Study Comparing Neoadjuvant and Adjuvant GVAX vs a Mutated KRAS Peptide Vaccine given with Bastilimab (Anti-PD-1) and AGEN2373 (Anti-CD137) for the Treatment of Surgically Resectable Pancreatic Adenocarcinoma

The IBC received Protocol Version 4.0, dated January 20, 2026, for the above referenced protocol. An option was added to hold GVAX (and Cy) or KRASvax and continue administration of other study drugs if there are issues with vaccine manufacturing or supply. Footnotes were updated to reflect this change, and minor clarifications were made to the study calendar. 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

Gaillard Protocol, GT2405200501 (NIH Cit.: III-C-1), “A Phase II Study Evaluating the effect of IMNN-001 (IL-12 Plasmid Formulated with PEG-PEI-Cholesterol Lipopolymer) on Second Look Laparoscopy (SLL) when Administered in Combination with Bevacizumab (BEV) and Neoadjuvant Chemotherapy (NACT) in Subjects Newly Diagnosed with Advanced Ovarian, Fallopian Tube or Primary Peritoneal Cancer”

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

Karron Protocol, GT2406170101 (NIH Cit.: III-C-1), “Phase III, Randomized, Observer-Blind, Placebo-Controlled, Multi-Center, Multinational Study to Evaluate the Efficacy, Immunogenicity, and Safety of a Respiratory Syncytial Virus Vaccine in Infants and Toddlers (PEARL)”

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

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

8 research registrations 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 4:15 pm.

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

Name	Synopsis	IBC#	BSL	ABSL	NIH Cit.	Agent	Select Agent
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New Registrations

Cummings, Derek	Replication-deficient dengue reporter virus particles (RVPs) obtained from another investigator will be used to infect cultured cells to study long-term humoral and cellular immune responses to dengue virus. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of RVPs 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-deficient dengue reporter virus particles (RVPs); Human tissue registration:B2603020101	DN2603020101	2		III-D-1-a, III- D-2-a		No
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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

Cummings, Derek	Replication-deficient dengue reporter virus particles (RVPs) obtained from another investigator will be used to infect cultured cells to study long-term humoral and cellular immune responses to dengue virus. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of RVPs 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.	P2603020201	2		III-D-1-a, III- D-2-a	Replication-deficient dengue reporter virus particles (RVPs)	No
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Pathogen/Infectious agent registration for Replication-incompetent lentiviral vectors
RegSupport: R-DNA: DN2603020101; Human tissue registration:B2603020101

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

Lubelski, Daniel	Recombinant rat cells that express the luciferase gene will be implanted into rats to monitor tumor growth. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of recombinant cell lines, 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 and animals.	DN2510290101	2	2 III-D-4-a	No
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Discussion/Review

Protocol Narrative Assessment:	The proposal adequately describes the experiments to be performed. A typo in the summary document was identified and corrected after the meeting.
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

Glowatzki, Elisabeth	Replication-incompetent adeno-associated viral vectors from commercial vendors will be used to transduce mice with Ca ²⁺ indicators, a glutamate sensor, a voltage reporter, or Channelrhodopsins (ChRmine or Chrimson SA) fused to reporter genes to study the functional properties of regenerated cochlear ribbon synapses between inner hair cells and afferent nerve fibers. 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. Amendment for DN1807020108 and P1805240109 (AAVs)	DN1807020108	2	2 III-D-1-a; III-D-4-b	No
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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

Pardoll, Drew	Recombinant, attenuated <i>Listeria monocytogenes</i> strains expressing influenza hemagglutinin (HA) or ovalbumin (Ova), obtained from a collaborating investigator, will be used in mice to study acute and memory immune responses. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of recombinant <i>Listeria monocytogenes</i> strains, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents.	DN0606120318	2	2 III-D-1-a, III-D-4-b	No
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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

Exempt Registrations

Chen, Haiwen	Transgenic mice obtained from another investigator will be used to selectively ablate oligodendrocytes and evaluate resulting changes in synaptic function during development. DE---Uses transgenic mice. RegSupport: Diphtheria Toxin:T2602040101	DE2601070101	1	1 Exempt: III-F-8; 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				
Rangan, Kavita	Plasmid vectors obtained from commercial vendors will be used to express ADARs and EGFP in cultured cells to study how cis- and trans-acting factors influence cephalopod ADAR activity. DE--Uses synthetic nucleic acid molecules in cultured cells. RegSupport: Human tissue registration: B2602200101	DE2603060101	2	III-F-8	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
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Exempt Amendments

Mao, Hai-Quan	Recombinant human cell lines obtained from another investigator will be used to quantitatively characterize intracellular trafficking and subcellular localization of lipid nanoparticle (LNP) cargo. Amendment for DN0303140124 and B0707060119	2	III-F-8	No
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Discussion/Review	The amendment falls under the exempt category under the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, so IBC review is not required
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