Johns Hopkins Institutional Biosafety Committee
JHU IBC Minutes for December 9, 2025
Zoom Meeting

Members Present: Gary S. Hayward, Ph.D. (IBC Chair, Virology and Gene Therapy); Weiying Pan, Ph.D., RBP (Associate BSO, Molecular Aspect of Drug Design and Biology); Stephen C. Dahl, Ph.D., RBP (BSO, Biology); Nadia Desir, Ph.D., RBP (Associate BSO, High Containment); Viji Sitther, Ph.D. (Non-affiliated Member, Plant Biology); Prashant Desai, Ph.D. (IBC member, Virology); Elizabeth A. Laffan, Ph.D. (Non-affiliated Member, Biology); 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: Brigitte Gaume, Ph.D. (Non-affiliated Member, Biology); Douglas Norris, Ph.D. (IBC member, Vector Biology and Entomology); Alan F. Scott, Ph.D. (IBC member, Molecular Biology and Genetics); Joseph B. Margolick, MD, Ph.D. (IBC member, Medicine, Microbiology and Immunology)

Guests: Ms. Anita Stone (Executive Director, Occupational and Environmental Safety)

IBC Coordinator: Ms. Tylicia McRae

The Meeting was called to order at 11:06 am.

Review and Approval of Meeting Minutes

The minutes of the November 17, 2025, meeting were approved as submitted.

Announcements:

No conflicts of interest were reported by IBC members.

Clinical Protocols and Amendments:

Christenson Protocol, GT2502170201 (NIH Cit.: III-C-1), "A Pilot Study Comparing Neoadjuvant and Adjuvant GVAX vs a Mutated RAS 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 3 dated October 29, 2025, for the above referenced protocol. The study design and text throughout the protocol were updated to describe the study as Phase Ia/Ib (rather than Phase I/II). Phase Ia is a dose-finding phase and Phase Ib is a dose expansion

phase. Minor updates and clarifications were made throughout the protocol. None of the changes were expected to affect the biosafety of the study.

The IBC voted to approve the amendment.

For Approval: 10
Disapproval: 0
Abstain: 0

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

The IBC received an SAE report for the above referenced protocol. A study participant experienced a low-grade fever, chills, leakage and pain at the inoculation site. The patient was hospitalized for further evaluation to rule out infection. Blood cultures resulted positive for Serratia Marcescens. Patient was treated with IV antibiotics. The event is considered unrelated to study drugs and related to underlying disease.

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 purpose of the study is to assess the safety and immunogenicity of sequential intranasal immunization with the respiratory syncytial virus (RSV) vaccine candidate RSV LID/ΔM2-2/1030s ('prime') followed 8 weeks later by the bivalent live-attenuated pediatric parainfluenza virus type 3 (HPIV3)/RSV vaccine candidate B/HPIV3/RSV/PreF/TM in HPIV3-seronegative infants and children, ≥6 months to <25 months of age. The study will have an open-label phase followed by a double-blinded, randomized, placebo-controlled phase. In the open-label phase, HPIV3-seronegative participants will receive a single intranasal dose of RSV LID/ΔM2-2/1030s. In the double-blinded, randomized, placebo-controlled phase, participants confirmed to be RSV-experienced will be randomized in a 2:1 ratio to receive a dose of B/HPIV3/RSV/PreF/TM or placebo, delivered 8 weeks after immunization with RSV LID/ΔM2-2/1030s. Approximately 48-55 infants and children 6 Months to <25 months of age will be accrued for participation in the study. Participants will receive study product outside of the RSV season and will remain on the study until they complete the post–RSV season visits.

The medical and pharmacy staff involved in the study will be trained to follow the pharmacy manual for the proper handling of RSV LID/ΔM2-2/1030s and B/HPIV3/RSV/PreF/TM, 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: 10
Disapproval: 0
Abstain: 0

Lechtzin Protocol. GT2302200101, (NIH Cit.: III-C-1), A Phase 1 Single Dose Escalation Study Evaluating the Safety and Tolerability of VX-522 in Subjects 18 Years of Age and Older with Cystic Fibrosis and a CFTR Genotype Not Responsive to CFTR Modulator Therapy"

The IBC received Protocol Version 9.2 dated June 18, 2025, for the above referenced protocol. An additional treatment arm was added to the multiple ascending dose portion of the protocol. Minor updates, clarifications and revisions were made throughout the protocol. None of the changes were expected to affect the biosafety of the study.

The IBC voted to approve the amendment.

For Approval: 10
Disapproval: 0
Abstain: 0

Talaat Protocol, GT2512090101, (NIH Cit.: III-C-1), "A Phase 3 Protocol to Investigate the Safety, Tolerability, and Immunogenicity of a BNT162b2 (LP.8.1)–Adapted Vaccine in Children 5 Through 11 Years of Age Considered at High Risk for Severe COVID-19"

The primary objective of the protocol is to evaluate the safety, tolerability and immunogenicity of an updated vaccine against COVID-19. BNT162b2 (LP.8.1) is an RNA-LNP vaccine utilizing modRNA. BNT162b2 (LP.8.1) targets a circulating variant of severe acute SARS-CoV-2 and is selected for the 2025-2026 respiratory virus season. Approximately 330 participants, 5 through 11 years of age with at least 1 risk factor for severe COVID-19 will be enrolled. Participants will receive a single intramuscular 10-µg dose of BNT162b2 (LP.8.1). Individuals who have received a 2025-2026 season COVID-19 vaccine will be excluded from participation. Individuals who have had a COVID-19 infection or vaccination within 5 months of enrollment will also be excluded.

The medical and pharmacy staff involved in the study have been trained to follow the pharmacy manual for the proper handling of BNT162b2 (LP.8.1), 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: 10
Disapproval: 0
Abstain: 0

Recombinant DNA/Pathogen Research Registrations and Amendments:

10 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 12:32 pm.

December, 2025,JHU IBC R-DNA Research Registrations and Amendments

Name	Synopsis	IBC#	BSL	ABSL	NIH Cit.	Agent	Select Agent
New Registrations							
Brockhurst, Jacqueline	A replication-incompetent adenoviral vector containing nonstructural proteins and the structural protein E from SARS-CoV-2 will be tested as a COVID-19 vaccine candidate in mice, hamsters and Monkeys. Modified Vaccinia Virus Ankara containing nonstructural proteins and structural protein E from SARS-CoV-2 will be tested as a COVID-19 vaccine candidate in mice and hamsters.The vaccine constructs will be handled in vitro using Biosafety Level 2 (BSL-2) practices. Challenge experiments with SARS-CoV-2 in animals will be conducted in a BSL-3 facility in accordance with established ABSL-3 standard operating procedures (SOPs). All personnel have been trained to work in an ABSL-3 facility. DN--Uses recombinant DNA in animals. RegSupport: Replication-incompetent adenovirals (AVs) vectors:P2308280103; Human tissue registration: B2510010101	DN2510310101	2	3	III-D-1-a, III-D-4-b		No

Discussion/Review

Protocol Narrative Assessment:	The IBC requested that the PI specify the elements included in the vaccine construct and clarify the use of animals in the study. Approval was pending receipt of a revised summary containing the required information. The revised summary has been received and is acceptable, as it 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: 1**

Brockhurst, Jacqueline	A replication-incompetent adenoviral vector containing nonstructural proteins and the structural protein E from SARS-CoV-2 will be tested as a COVID-19 vaccine candidate in mice, hamsters and Monkeys. The vaccine constructs will be handled in vitro using Biosafety Level 2 (BSL-2) practices. Challenge experiments with SARS-CoV-2 in animals will be conducted in a BSL-3 facility in accordance with established ABSL-3 standard operating procedures (SOPs). All personnel have been trained to work in an ABSL-3 facility. Pathogen/Infectious agent registration for Replication-incompetent adenoviral vectors RegSupport: Human tissue registration:B2510010101; R-DNA: DN2510310101	P2511250101	2	3	III-D-1-a, III-D-4-b	Replication-incompetent adenoviral vectors	No

Discussion/Review

Protocol Narrative	The IBC requested that the PI specify the elements included in the vaccine construct and clarify the use of animals in the study. Approval was pending receipt of a revised summary containing the required information. The revised summary has been received and is acceptable, as it adequately describes the experiments to be performed.
Assessment:	
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: 1**

Brockhurst, Jacqueline	Modified Vaccinia Virus Ankara containing nonstructural proteins and structural protein E from SARS-CoV-2 will be tested as a COVID-19 vaccine candidate in mice, hamsters and Monkeys. The vaccine constructs will be handled in vitro using Biosafety Level 2 (BSL-2) practices. Challenge experiments with SARS-CoV-2 in animals will be conducted in a BSL-3 facility in accordance with established ABSL-3 standard operating procedures (SOPs). All personnel have been trained to work in an ABSL-3 facility. Pathogen/Infectious agent registration for Modified Vaccinia Virus Ankara RegSupport: R-DNA: DN2206010104	P2510310101	2	3	III-D-1-a, III-D-4-b	Modified Vaccinia Virus Ankara	No

Discussion/Review

Protocol Narrative Assessment:	The IBC requested that the PI specify the elements included in the vaccine construct and clarify the use of animals in the study. Approval was pending receipt of a revised summary containing the required information. The revised summary has been received and is acceptable, as it 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: 1**

Ekiert, Damian	The plasmid-based CRISPR/Cas9 system will be used to deliver homology arms targeting the PF3D7_0214800 gene, along with Cas9 and sgRNA, into red blood cells (RBCs) using the Lonza Nucleofector. Following this, the transfected RBCs will be exposed to late-stage Plasmodium falciparum parasites, which will infect the transfected RBCs and take up the plasmid DNA. This approach aims to investigate the role of the PF3D7_0214800 gene in lipid transport mechanisms in Plasmodium falciparum. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of Plasmodium falciparum 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. Pathogen/Infectious agent registration for Plasmodium falciparum RegSupport: R-DNA:DN2404220102; Human tissue registration:B2404220102	P2511100101	2	Plasmodium falciparum	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**

Gharagozloo, Marjan	Replication-incompetent adeno-associated viral vectors from a commercial vendor will be used to transduce NLRX1 into mice to study the cell-autonomous role of NLRX1 in protecting RGCs from inflammatory neurodegeneration and to assess the beneficial effect of NLRX1-based gene therapy for promoting RGC survival. Transgenic mice will be used in the study as well. The plasmid-based the CRISPR/Cas9 system obtained from a commercial vendor will be used to generate NLRX1-/- hiPSC cell line to evaluate the role of NLRX1 in regulating the immunometabolic pathways that drive reactive astrocytes, and to test whether activating NLRX1 with small molecule agonists could prevent the neurotoxic activity of human astrocytes. 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 and animals. RegSupport: Human tissue registration:B2509030101; Replication-incompetent adeno-associated viral vectors: P2509300101	DN2509110101	2	III-D-4-b, III-D-4c(2), III-F-8	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**

Gharagozloo, Marjan	Replication-incompetent adeno-associated viral vectors from a commercial vendor will be used to transduce NLRX1 into mice to study the cell-autonomous role of NLRX1 in protecting RGCs from inflammatory neurodegeneration and to assess the beneficial effect of NLRX1-based gene therapy for promoting RGC survival. 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: DN2509110101; Human tissue registration:B2509030101	P2509300101		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

Glowatzki, Elisabeth	Red fluorescent human induced pluripotent stem cells (hiPSCs) obtained from a collaborator, along with optogenetically competent hair cells derived from transgenic mice, will be used to test whether neuronal progenitors (NPs) differentiated from hiPSCs can form new synapses with auditory hair cells and whether these newly established synapses are functional in vitro. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of human cells 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 R-DNA registration: DN1807020108 RegSupport: Human tissue registration: B2511140101	DN1807020108	2	III-D-1-a, III-D-3-a, III-D-4-c(2), III-F-8		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**

Kokkoli, Efie	Cells expressing luciferase obtained from a commercial vendor or colleagues will be used to form tumors in mice for monitoring tumor growth, invasion, and metastasis. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of human cells 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 R-DNA registration: DE1811200108, updated to DN1811200208 RegSupport: Human tissue registration: B2003120106	DN1811200208	2	2	III-F-6, III-D-4-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 Registration

Kam, Tae-In	Drp1 knockout cell lines generated using CRISPR/Cas9 system will be used to study the role of Drp1 in glial cells in a model of Parkinson's disease, utilizing human stem cell-derived microglia, astrocytes, and cortical neurons. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of human cells 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. DE---Uses recombinant DNA in cultured cells RegSupport: Human tissue registration: B2507220101	DE2511110101	2	Exempt: 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				
Ravi, Rajani	Transgenic mice obtained from a commercial vendor will be used to investigate the role of specific genes in tumor growth and immune responses in the context of combination studies. Experiments involving transgenic mice will be conducted using Biosafety Level 1 (BSL-1) practices. DE---Uses transgenic mice.	DE2511060101	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				