Johns Hopkins Institutional Biosafety Committee
JHU IBC Minutes for June 16, 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); Alan F. Scott, Ph.D. (IBC member, Molecular Biology and Genetics); Nadia Desir, Ph.D., RBP (Associate BSO, High Containment); 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); Viji Sitther, Ph.D. (Non-affiliated Member, Plant Biology)

Members Absent: Prashant Desai, Ph.D. (IBC member, Virology); Joseph B. Margolick, MD, Ph.D. (IBC member, Medicine, Microbiology and Immunology); Douglas Norris, Ph.D. (IBC member, Vector Biology and Entomology); Jason Villano, D.V.M. (IBC member, Animal Science); Brigitte Gaume, Ph.D. (Non-affiliated Member, Biology)

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

IBC Coordinator: Ms. Tylicia McRae

The meeting was called to order at 3:56 pm.

Announcements:

No conflicts of interest were reported by IBC members.

Review and Approval of Meeting Minutes

The minutes from the May 19, 2025 meeting were approved as submitted.

Clinical Protocols and Amendments:

Nourbakhsh Protocol, GT2506160101 (NIH Cit.: III-C-1), "A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Dose-Ranging Study of mRNA -1195 Intramuscular Injection in Participants 18 to <55 Years of Age with Multiple Sclerosis"

The primary objective of this protocol is to evaluate the safety and reactogenicity of mRNA-1195 in preventing relapse in individuals with multiple sclerosis. mRNA-1195 is a lipid nanoparticle–encapsulated, mRNA-based vaccine composed of six mRNA sequences encoding Epstein-Barr virus (EBV) antigens.

The study will include an intervention period followed by a safety follow-up period. Approximately 180 EBV-seropositive adult participants will be randomized in a 1:1:1 ratio to receive 25 µg, 50 µg, or placebo of the mRNA-1195 vaccine. The vaccine will be administered intramuscularly at Months 0, 2, and 6.

A study pause for safety review will occur after the last participant completes the Day 85 visit. The total study duration is approximately 30 months.

The medical and pharmacy staff involved in the study have been trained to follow the pharmacy manual for the proper handling of mRNA-1195, 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

Singh Protocol, GT210621101 (NIH Cit.: III-C-1), Updated Pharmacy Manual, "A Phase 2/3, Randomized, Controlled, Masked, Multi-Center Study to Evaluate the Efficacy, Safety and Tolerability of Two Doses of AGTC-501, a Recombinant Adeno-Associated Virus Vector Expressing RPGR (rAAV2tYF-GRK1-RPGR), Compared to an Untreated Control Group in Male Subjects with X-Linked Retinitis Pigmentosa Confirmed by a Pathogenic Variant in the RPGR Gene"

The IBC received Pharmacy Manual Version 8.0, dated February 11, 2025, for the above-referenced protocol. The quantity of drug product supplied was updated. Two vials of drug product will be prepared for each participant instead of one. In addition, editorial and formatting revisions were made throughout the manual. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the changes.

For Approval: 9
Disapproval: 0
Abstain: 0

Recombinant DNA/Pathogen Research Registrations

12 research registrations and 4 amendments were presented for IBC consideration.

Review of Incidents:

No incidents were reported at this meeting.

IBC Training

The new NIH guidance document on IBC meeting minutes was reviewed and discussed.

Public Comments:

There were no public comments.

The meeting was adjourned at 5:06 pm.

June, 2025 R-DNA Research Registrations and Amendments

Name	Synopsis	IBC#	BSL	ABSL	NIH Cit.	Agent	Select Agent
New Registrations:							
Lee, Hungoo	A replication-incompetent lentiviral vector-based CRISPR/Cas9 system will be obtained from commercial vendors and used to transduce EGFP and FMR1 genes into cultured cells. It will also be used to perform gene editing to form R-loops or alter the epigenetic status in order to study the molecular mechanisms of repeat expansion diseases. All experiments involving viral vectors and human cells will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle viral vectors and human cells in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. DN--Uses recombinant DNA in cultured cells RegSupport: Lentiviral vectors:P2505160101; Human tissue registration: B2505160101	DN2505160101		2		III-D-1-a, III-D-3-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**						
Lee, Hungoo	A replication-incompetent lentiviral vector-based CRISPR/Cas9 system will be obtained from commercial vendors and used to transduce EGFP and FMR1 genes into cultured cells. It will also be used to perform gene editing to form R-loops or alter the epigenetic status in order to study the molecular mechanisms of repeat expansion diseases. All experiments involving viral vectors and human cells will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle viral vectors and human cells in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. Pathogen/Infectious agent registration for Replication-incompetent lentiviral vectors RegSupport: R-DNA:DN2505160101; Human tissue registration: B2505160101	P2505160101		2		III-D-1-a, 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: 9 Opposed: 0 Abstentions: 0**

Pederick, Daniel	Replication-incompetent adeno-associated viral vectors will be obtained from commercial vendors and used to transduce fluorescent marker genes (GFP, mCherry, or tdTomato) and/or DNA recombination enzymes such as Cre and Flp into cultured cells and mice. Transgenic mice will be used to study the development of brain connections involved in processing different types of sound information, and how these connections differ in animal models of neurodevelopmental disorders. All experiments involving viral vectors will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle viral vectors in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. DN--Uses recombinant DNA in cultured cells and animals RegSupport: Adeno-associated viral vectors: P2506020101	DN2506020101	2	2	III-D-1-a, III-D-4-b, III-D-4-(c)-2	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.
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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**

Sun, Hui	Replication-incompetent adeno-associated viral vectors will be obtained from commercial vendors and used to transduce tdTomato, shRNAs targeting Kcna1, Kcna2, and/or Kcna6, or the Cre recombinase enzyme into mice. The goal is to study the physiological and pathological roles of two subtypes of voltage-gated potassium channels (D-channel and M-channel) as intrinsic inhibitory mechanisms in vagal nociceptors. Transgenic mice will also be used in this study. All experiments involving viral vectors will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle viral vectors in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. DN--Uses recombinant DNA in cultured cells and animals RegSupport: Adeno-associated viral vectors: P2504290301	DN2504290101	2	2	III-D-4-b; III-D-4-(c)-2		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 in the
Precautions:	research program and identifies proper containment procedures and PPE.
Training:	Acceptable. The proposal adequately describes the training required for personnel to perform the experiments.
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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 in the
Precautions:	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**

Taga, Arens	Replication-incompetent adeno-associated viral vectors will be obtained from commercial vendors and used to transduce EGFP, Importin β, or Flp recombinase into cultured cells to study axonal regeneration under control and amyotrophic lateral sclerosis (ALS) conditions. All experiments involving viral vectors and human cells will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle viral vectors and human cells in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. DN--Uses recombinant DNA in cultured cells RegSupport: Adeno-associated viral vectors:P2505230101; Human tissue registration:B2505150101	DN2505150101	2	III-D-3-a, II-D-1-a		No

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**

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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**

Zimmerlin, Ludovic	Human pluripotent stem cell lines will be transduced with replication-incompetent lentiviral vectors to express tdTOMATO, or transfected with a PiggyBac transposable vector expressing murine E-Cadherin with mCherry fusion. The transduced cells or transfected cells will be implanted into mice for fluorescent detection and improved engraftment. All experiments involving viral vectors and human cells will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle viral vectors and human cells in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. DN--Uses recombinant DNA in cultured cells and animals RegSupport: Lentiviral vectors:P2505300101; Human tissue registration: B2505300201	DN2505300101	2	2	III-D-3-a,III-D-1-a;III-D-4-b	No

Discussion/Review

Protocol Narrative Assessment:	Acceptable after revision. The proposal adequately describes the experiments to be performed but initially lacked information on transplanting the transduced cells into animals and on confirming the use of ABSL-2 cage cards. The revised summary has clarified all issues
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**

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Discussion/Review

Protocol Narrative Assessment:	Acceptable after revision. The proposal adequately describes the experiments to be performed but initially lacked information on transplanting the transduced cells into animals and on confirming the use of ABSL-2 cage cards. The revised summary has clarified all issues
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:

Archer, Nathan	Amendment for the registrations for R-DNA and Methicillin-sensitive Staphylococcus aureus The MN8 strain of Staphylococcus aureus is a patient-derived, methicillin-sensitive strain that produces the Toxic Shock Syndrome Toxin-1 (TSST-1) superantigen. Four recombinant MN8 strains, obtained from another investigator and exhibiting reduced virulence compared to the wild-type strain, will be propagated in vitro and used to infect mouse skin as well as various human and mouse cell lines. These experiments aim to study the binding mechanisms of staphylococcal superantigens in the skin and to better understand how S. aureus initiates pathogenic skin colonization: -The R68A mutant disrupts the T cell receptor binding site of TSST-1, rendering the toxin superantigenically inactive and thereby reducing its virulence. -The S72A mutant disrupts the MHC class II binding site of TSST-1, also rendering the toxin superantigenically inactive and reducing its virulence. -The L129A and D130A mutants disrupt the putative CD40 binding site and are expected to show reduced skin colonization compared to the parental MN8 strain. All work with these strains will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle the strains in the laboratory and to follow standard operating procedures (SOPs) for disposing of contaminated materials, managing incidents, and submitting incident reports. DN--Uses recombinant DNA in cultured cells and animals	DN1911200101	2	2	III-D-1-a; III-D-4-b	Four Staphylococcus aureus mutant strains generated on a MN8 Staphylococcus aureus background: R68A mutant, S72A mutant, L129A mutant, and D130A mutant	No

RegSupport: Methicillin-sensitive Staphylococcus aureus: P1911200206; Human tissue registration: B1907160307

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**

Archer, Nathan	Amendment for the registrations for R-DNA and Streptococcus pyogenes	DN1911200101	2	2 III-D-1-a; III-D-4-b	Streptococcus pyogenes: MGAS5005/ ΔSpeJ MGAS5005; GA19681/ΔSpeC GA19681; 5448AP/ ΔSpeA2 5448AP	No

Recombinant Streptococcus pyogenes strains with knockouts of streptococcal pyrogenic exotoxins (Spe) will be obtained from another investigator. These mutant strains exhibit reduced virulence compared to wild-type strains. Both wild-type and mutant strains will be propagated in vitro and used to infect mouse skin and various human and mouse cell lines. The goal is to study the binding mechanisms of streptococcal superantigens in the skin, understand how S. pyogenes initiates pathogenic skin colonization, and determine whether this is a conserved pathogenic mechanism among Gram-positive skin pathogens.
All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle these strains in the laboratory and to follow standard operating procedures (SOPs) for disposing of contaminated materials, responding to incidents, and submitting incident reports.
DN--Uses recombinant DNA in cultured cells and animals
RegSupport: Streptococcus pyogenes: P1911200206; Human tissue registration: B1907160307

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 in the
Precautions:	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**

Bishai, William	Amendment for the registrations for R-DNA and BCG Recombinant BCG strains will be created using the wild-type BCG Pasteur strain as the parental strain and will be administered to animals via intravesical instillation to evaluate their efficacy as immunotherapies for bladder cancer. These recombinant BCG strains are live-attenuated. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle both the BCG Pasteur strain and the recombinant BCG strains in the laboratory, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents DN--Uses recombinant DNA in cultured cells and animals RegSupport: BCG:P9501270229	DN1803090108	2	2	III-D-1-a; III-D-4-b	Recombinant BCG strains	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 in the
Precautions:	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 :

Kim, Michelle	The mRNA molecules carry a GFP reporter gene will be transfected into HeLa cells to study the effects of modulating the 5'UTR, 3'UTR, and polyA regions on GFP expression . All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle recombinant DNA and human cells in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. DE--Uses synthetic nucleic acid molecules in cultured cells. RegSupport: Human tissue registration: B2504290101	DE2504290101	2		Exempt: III- F-1, III-F-8	No
Discussion/Review	It qualifies as exempt under the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, so IBC review is not required.					
Miao, Yuchuan	A plasmid-based CRISPR/Cas9 system will be obtained from commercial vendors and used to create stable human iPS cell lines, including the expression of fluorescent marker genes and gene editing of the PITX1 gene, which plays a key role in hindlimb development. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle recombinant DNA and human cells in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. DE--Uses synthetic nucleic acid molecules in cultured cells. RegSupport: Human tissue registration: B2505280101	DE2505280101	2		Exempt: III- F-8	No
Discussion/Review	It qualifies as exempt under the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, so IBC review is not required.					

Exempt Amendment

Lemberg, Kathryn	Plasmid vectors will be obtained from commercial vendors and used to transfect shRNAs targeting phosphoribosylformylglycinamidine synthase (PFAS) to knock down PFAS expression in cultured cells for studying its role in cancer. Transgenic mice will be obtained from an academic collaborator and used to investigate the interactions between metabolism and hyperactive RAS signaling in animal models. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Personnel will be trained to properly handle recombinant DNA and human cells in the lab, and to follow standard operating procedures (SOPs) for disposing of contaminated materials and responding to incidents. DE--Uses synthetic nucleic acid molecules in cultured cells, and Uses transgenic mice (Amendment). RegSupport: Human tissue registration: B2211300403	DE2211300103	2	1	Exempt: III- D-4-(c)-2; III-F-8	No

Discussion/Review	It qualifies as exempt under the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, so IBC review is not required.