Johns Hopkins Institutional Biosafety Committee
JHU IBC Minutes for August 18, 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); Djikolngar Maouyo, Ph.D. (Non-affiliated Member, Biology); Viji Sitther, Ph.D. (Non-affiliated Member, Plant Biology); Prashant Desai, Ph.D. (IBC member, Virology)

Members Absent: Ms. Claudia MacAuley, L.A.T. (Non-affiliated Member, Biosafety and High Containment); 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); Joseph B. Margolick, MD, Ph.D. (IBC member, Medicine, Microbiology and Immunology)

The meeting was called to order at 3:03 pm.

Announcements:

No conflicts of interest were reported by IBC members.

Review and Approval of Meeting Minutes

The minutes of the July 21, 2025, meeting were approved as submitted.

Clinical Protocols and Amendments:

Bang Protocol, GT1902180301 (NIH Cit.: III-C-1), "A Phase I/II, Randomized, Double-Blind, Sham Control Study to Explore Safety, Tolerability, and Efficacy Signals of Multiple Ascending Doses of Striatally-Administered rAAV5-miHTT Total Huntington Gene (HTT) Lowering Therapy (AMT-130) in Early Manifest Huntington Disease"

The IBC received Amendment 14, Version 15.0, dated June 27, 2025, for the above referenced protocol. The amendment adds an open-label, single-arm cohort (Cohort 4) to evaluate the safety and efficacy of high-dose AMT-130 in participants with early manifest Huntington's Disease. The amendment also updates and clarifies clinical laboratory testing in Cohorts 1, 2, 3 and 4. None of the changes were expected to affect the biosafety of the study.

The IBC voted to approve the amendment.

For Approval: 9
Disapproval: 0
Abstain: 0

Bettegowda Protocol, GT2302200201 (NIH Cit.: III-C-1), "A Phase I Study of the Treatment of Recurrent Malignant Glioma with rQNestin34.5v.2, a Genetically Engineered HSV-1 Virus, and Immunomodulation with Cyclophosphamide"

The IBC received the amendment dated March 24, 2025, for the above-referenced protocol. The amendment adds the Koch Institute for Integrative Cancer Research at MIT as a participating site. The incorrect Ommaya sampling schedule was removed from the protocol and the Informed Consent Form (ICF). The laboratory manual was updated, and additional administrative modifications were made throughout the protocol and ICF. None of these changes were expected to affect the biosafety of the study.

The IBC voted to approve the amendment.

For Approval: 9
Disapproval: 0
Abstain: 0

Konig Protocol, GT2508180101 (NIH Cit.: III-C-1), "A Phase 1 Study Evaluating the Safety and Preliminary Efficacy of ALLO-329, A Dual Anti-CD19 / Anti-CD70 Allogeneic CAR T Cell Product in Autoimmune Disease (RESOLUTION)"

The primary objectives of the protocol are to assess the safety of ALLO-329 in participants with autoimmune disease and to establish a recommended phase 2 regimen. ALLO-329 is an allogeneic T cell therapy engineered to express two distinct CARs targeting the human CD19 and CD70 proteins.

Up to 66 adult participants $\geq$18 to <70 years of age will receive a single IV infusion of ALLO-329. Four dosing levels (20 $x10^6$ cells, 40 $x10^6$ cells, 80 $x10^6$ cells, and 160 $x10^6$ cells) are planned for evaluation. The dose escalation portion of the study will follow a modified 3+3 design with escalating doses of ALLO-329 paired with lymphodepletion (LD) or ALLO-329 alone to establish a recommended Phase 2 regimen. Participants assigned to a dosing regimen that includes LD will receive either Cyclophosphamide on Day -3 or fludarabine on days -5, -4 and -3 combined with a single dose of cyclophosphamide on day -3. The first participant in dose level 1 will receive the starting dose of ALLO-329 following Cyclophosphamide and will be followed for 28 days. After the 28-day observation period, the second participant will receive the study intervention and be followed for at least 14 days before the third participant receives treatment.

All participants will be hospitalized for a minimum of 4 days following ALLO-329 administration and must stay within 2 hours driving distance of a study site for at least 35 days post-treatment. Participants are followed for 60 months and will be asked to enroll in a long-term follow-up study for an additional monitoring period of up to 15 years.

The medical and pharmacy staff involved in the study have been trained to follow the pharmacy manual for the proper handling of ALLO-329, 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

Le Protocol, GT1908190101 (NIH Cit.: III-C-1), "A Phase I, First-In-Human, Multicenter, Open-Label Study of Nous-209 Genetic Vaccine for the Treatment of Microsatellite Unstable Solid Tumors"

The IBC received Continuing Review Approval documents and Protocol Amendment 9.1 dated December 5, 2024 for the above referenced protocol. The amendment brings the protocol in-line with EU Clinical Trial Regulations 536/2014. Clarifications were made to the schedule of assessments and study duration for patients who discontinue treatment due to complete response. Minor inconsistencies were corrected 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: 9
Disapproval: 0
Abstain: 0

Talaat Protocol, GT1802190201 (NIH Cit.: III-C-1), "Phase 1 Evaluation of a Live-Attenuated Human Parainfluenza Virus Type 3 Vectored Vaccine Candidate Expressing Ebolavirus Zaire Glycoprotein as the Sole Envelope Glycoprotein"

The IBC acknowledged receipt of the IRB continuing review approval documents for the above referenced protocol. No further action is considered warranted.

Recombinant DNA/Pathogen Research Registrations and Amendments

6 research registrations and 3 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.

August, 2025, R-DNA Research Registrations and Amendments

Name	Synopsis	IBC#	BSL	ABSL	NIH Cit.	Agent	Select Agent
New Registrations							
Bettegowda, Chetan	Replication-incompetent lentiviral vectors obtained from commercial vendor will be used to transduce green or red fluorescent proteins into cultured cells for evaluating the in vitro therapeutic response of patient-derived glioblastoma (GBM) cells to the metabolic inhibitor ME3BP. All experiments involving viral vectors will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors, 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:DN2410030101; Human tissue registration: B1911080206	P2505230201	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: 9 Opposed: 0 Abstentions: 0**

Casadevall, Arturo	Replication-incompetent adeno-associated viral (AAV) vectors will be obtained from another investigator and used to deliver anti-cryptococcal monoclonal antibody genes into mice to evaluate their efficacy against cryptococcal disease. All experiments involving viral vectors will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors, 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: DN1603140110; Cryptococcus neoformans: P1503300111; Human tissue registration: B1609020109		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**

Pekosz, Andrew	Wild-type measles virus (MeV) will be isolated from clinical specimens or obtained from archived virus stocks previously maintained in the laboratory of the late Dr. Diane Griffin. Recombinant MeV strains, engineered to express reporter genes or to carry specific mutations in viral proteins, will be generated using a plasmid-based infectious clone system or obtained from archived virus stocks previously maintained in the laboratory of the late Dr. Diane Griffin. These mutations are expected to either have no impact on viral replication or to reduce replication efficiency. Both wild-type and recombinant MeV will be propagated in vitro and used to infect cultured cells to study MeV replication. All experiments involving measles virus (MeV) will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel have been trained in the safe handling of measles virus (MeV), 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 Measles virus (wild-type and recombinant strains)	P2507220301	2	III-D-1-a	Measles virus (wild-type and recombinant strains)	No

RegSupport: R-DNA:DN1101050213; Human tissue registration: B0801040118

Discussion/Review

Protocol Narrative Assessment: The proposal adequately describes the experiments to be performed. The IBC approved the use of existing measles virus stocks and mutant strains but deferred approval for generating any new mutant or revertant virus until NIH guidance on gain-of-function research and pathogens with enhanced pandemic potential is released.

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: 7 Opposed: 1 Abstentions: 1**

Pekosz, Andrew	Live attenuated measles virus (LAMV) will be obtained from industry or from archived virus stocks previously maintained in the laboratory of the late Dr. Diane Griffin. Recombinant LAMV strains, engineered to express reporter genes or to contain specific mutations in viral proteins, will be generated using a plasmid-based infectious clone system or obtained from archived virus stocks previously maintained in the laboratory of the late Dr. Diane Griffin.These mutations are expected to either have no effect on viral replication or to attenuate replication. Both LAMV and recombinant LAMV strains will be propagated in vitro and used to infect cultured cells to study MeV replication. All experiments involving LAMV will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel have been trained in the safe handling of LAMV, 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 Live Attenuated Measles Virus (LAMV) and recombinant LAMV strains RegSupport: R-DNA:DN1101050213; Human tissue registration: B0801040118	P2507220401	2	III-D-1-a	Live Attenuated Measles Virus (LAMV) and recombinant LAMV strains	No

Discussion/Review

Protocol Narrative Assessment:	The proposal adequately describes the experiments to be performed. The IBC approved the use of existing LAMV stocks and mutant strains but deferred approval for generating any new mutant or revertant virus until NIH guidance on gain-of-function research and pathogens with enhanced pandemic potential is released.
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: 7 Opposed: 1 Abstentions: 1**

Rao, Rajini	Replication-incompetent adeno-associated viral (AAV) vectors obtained from a commercial vendor will be used to deliver ATP2C1 and ATP2C2 into cultured cells and mice to evaluate gene-based therapeutic approaches for targeting Amyotrophic Lateral Sclerosis (ALS). All experiments involving viral vectors will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of viral vectors, 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:DN0812100117; Human tissue registration: B1610260109	P2502260101	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**

Slusher, Barbara	Mice that were infected with Bacillus Calmette–Guérin (BCG) or recombinant BCG-STING and maintained for three months post-infection will be obtained from Dr. Bishai's lab. These mice will undergo neurological behavioral testing to study the effects of BCG on the risk of developing Alzheimer's disease. All experiments involving the mice that were infected with BCG or recombinant BCG-STING will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of these mice, 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 Bacillus Calmette–Guérin (BCG) and recombinant BCG-STING RegSupport: R-DNA: DN1505010111	P2507100101	2	2	III-D-1-a, III-D-4-b	Bacillus Calmette–Guérin (BCG) and recombinant BCG-STING	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

Casadevall, Arturo	Cryptococcus neoformans knockout strains will be obtained from the Fungal Genetics Stock Center. These strains are expected to exhibit loss-of-function phenotypes. DNA complementation, knockout, and recombination techniques will be used to assess restoration of function—not to induce overexpression or create dangerous gain-of-function phenotypes—by comparison with standard library strains or wild-type strains derived from clinical or environmental isolates. The expected pathogenicity of the recombinant strains will be comparable to that of the standard or wild-type strains. These recombinant C. neoformans strains will be cultured in vitro and used to infect mice to study host-pathogen interactions, virulence, pathogenicity, and immune responses. All experiments involving Cryptococcus neoformans will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of Cryptococcus neoformans, 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: DN1603140110 and Cryptococcus neoformans registration: P1503300111; RegSupport: R-DNA: DN1603140110; Cryptococcus neoformans: P1503300111;	DN1603140110	2	2	III-D-1-a; III-D-4-b	No

Discussion/Review

Protocol Narrative	The proposal adequately describes the experiments to be performed. The IBC approved the use of existing Cryptococcus neoformans strains and knockout strains but deferred approval for generating any new mutant or revertant strains until NIH guidance on gain-of-function research and pathogens with enhanced pandemic potential is released.
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: 0**

Lee, Richard	Non-replicating, non-protein-coding DNA fragments (~200 bp), encapsulated within extracellular vesicles (EVs), will be injected into the brains of mice to mitigate the impact of a neurodevelopmental disorder (Prader-Willi Syndrome) in a mouse model and to refine methods for delivering DNA fragments for potential use in other neurodevelopmental and psychiatric disorders. The experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of these DNA molecules, 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: DN1806220108	DN1806220108	2	2	III-D-4-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**

Leung, Anthony	Single-round, replication-deficient SARS-CoV-2 will be generated by co-transfecting BHK21 cells with the SARS-CoV-2 ΔSpike BAC (WA1 strain background), a Spike expression plasmid (CoV2-Spike-D614G), and an N protein expression plasmid (CoV2-N-R203M). The resulting virus will be used to infect cultured cells to study the role of the SARS-CoV-2 macrodomain in viral replication and to identify its substrates. All experiments involving replication-deficient SARS-CoV-2 will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of replication-deficient SARS-CoV-2, 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: DN1103180115 RegSupport: SARS-CoV-2:P2207010104; Human tissue registration: B1103230115	DN1103180115	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**