Johns Hopkins Institutional Biosafety Committee
JHU IBC Minutes for January 22, 2026
Zoom Meeting

Members Present: Alan F. Scott, Ph.D. (Acting Chair, Molecular Biology and Genetics); Weiying Pan, Ph.D., RBP (BSO, Molecular Aspect of Drug Design and Biology); Nadia Desir, Ph.D., RBP (Research Lab Safety and 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)

Members Absent: Gary S. Hayward, Ph.D. (IBC Chair, Virology and Gene Therapy); 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); Jason Villano, D.V.M. (IBC member, Animal Science); Stephen C. Dahl, Ph.D., RBP (IBC member, Biology)

IBC Coordinator: Ms. Tylicia McRae

The Meeting was called to order at 3:04 pm.

Review and Approval of Meeting Minutes

The minutes of the December 9, 2025, meeting were approved as submitted.

Announcements:

No conflicts of interest were reported by IBC members.

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 Protocol Version 11 dated October 14, 2025, for the above referenced protocol. Study secondary endpoints were updated and reclassified. Rationale for study design regarding NAb status was added for clarity. Minor 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: 8

Disapproval: 0
Abstain: 0

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 Investigator's Brochure Version 13.0 dated August 25, 2025 for the above referenced protocol. Eligibility criteria and screening procedures have been revised to reinforce compliance with the inclusion/exclusion criteria, additional assessment steps for potential study participants have been incorporated. The table of observed adverse reactions was updated to include a potential risk of exacerbation of pre-existing cardiopulmonary conditions. These changes resulted from a related fatal SAE. Data and status from ongoing and completed studies were added. Minor editorial changes were made throughout the brochure. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the changes.

For Approval: 8
Disapproval: 0
Abstain: 0

Talaat Protocol, GT2504210101, (NIH Cit.: III-C-1), "A Phase 3 Randomized, Modified, Doube-Blind, Active-Controlled Study to Assess the Safety of vYF, Yellow Fever Vaccine in Adults Aged 18 Years up to 60 Years"

The IBC received Investigator's Brochure Version 8.0 dated November 21, 2025 for the above referenced protocol. The name of the study sponsor was updated to Sanofi and Sanofi Winthrop Industrie. The cut-off date was updated to August 28, 2025. Reformatting, minor editorial updates and clarifications were made throughout the brochure. None of the changes are expected to affect the biosafety of the study.

The IBC voted to approve the changes.

For Approval: 8
Disapproval: 0
Abstain: 0

Recombinant DNA/Pathogen Research Registrations and Amendments:

9 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 4:07 pm.

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

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

New Registrations

Conrad, Melissa	A plasmid-based CRISPR/Cas9 system obtained from other investigators will be used to introduce naturally occurring mutations in Plasmodium falciparum to evaluate the impact of these mutations on susceptibility to anti-malaria drugs. Edited parasites will be studied in vitro only and will not be used to infect humans or mosquitoes. 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. DN--Uses recombinant DNA in cultured cells. RegSupport: Plasmodium falciparum:P2512190101; Human tissue registration: B2512190101	DN2512190101	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: 8 Opposed: 0 Abstentions: 0**

Conrad, Melissa	A plasmid-based CRISPR/Cas9 system obtained from other investigators will be used to introduce naturally occurring mutations in Plasmodium falciparum to evaluate the impact of these mutations on susceptibility to anti-malaria drugs. Edited parasites will be studied in vitro only and will not be used to infect humans or mosquitoes. 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: Human tissue registration:B2512190101; R-DNA: DN2512190101	P2512190101	2	III-D-1-a	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: 8 Opposed: 0 Abstentions: 0**

Johnson, Burles	Replication-incompetent lentiviral vectors obtained from commercial sources will be used to deliver siRNAs targeting collagen family genes, including Serpinh1 (SERPINH1), Plk2 (PLK2), Pthlh (PTHLH), and Tmem45a (TMEM45A), into cultured cells to study their roles in urothelial carcinoma. The transduced cells will be implanted into NSG mice to monitor tumor growth kinetics. 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: updated from DE2303070103 to DN2303070103 ; Human tissue registration: B2512290101	P2511060101	2	2	III-D-3-a; III-D-4-b	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: 8 Opposed: 0 Abstentions: 0**

Leung, Anthony	Replication-incompetent pBAC-MERS-REP, which contains only ORF1a, ORF1b, and the N protein from MERS-CoV, will be obtained from another investigator and used to generate macrodomain mutations and to screen for macrodomain inhibitors in vitro. The cloning work will be conducted using Biosafety Level 2 (BSL-2) practices. Infection experiments with pBAC-MERS-REP will be performed in a Biosafety Level 3 (BSL-3) facility in accordance with established BSL-3 standard operating procedures (SOPs). All personnel have been trained to work in a BSL-3 facility. Pathogen/Infectious agent registration for Replication-incompetent pBAC-MERS-REP RegSupport: DN1103180115; Human tissue registration: B1103230115	P2601050101	3	III-D-1-a	Replication-incompetent pBAC-MERS-REP	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: 8 Opposed: 0 Abstentions: 0**

Li, Pan	Replication-incompetent Sindbis viral vectors obtained from a core facility will be used to deliver reporter or barcode sequences into mouse brains to examine the projection patterns of cortical neurons. 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 Sindbis viral vectors RegSupport: R-DNA:DN2108250105	P2512110101	2	2 III-D-1-a, III-D-4-b	Replication-incompetent Sindbis 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: 8 Opposed: 0 Abstentions: 0**

Quinodoz, Sofia	Replication-incompetent lentiviral vectors and plasmid vectors obtained from commercial sources will be used to express nuclear or cytoplasmic human genes (e.g., Histone, Nucleolin, Nucleophosmin, Coilin, Nopp140), as well as hTERT, GFP, miRFP, mCherry, YFP, CFP, BFP, mStayGold, Halo-Tag, and SNAP-Tag in cultured cells. A lentiviral vector-based CRISPR/Cas9 system will be used to conduct gene editing on genes demarcating various condensates/nuclear bodies and structures such as NPM1, SON, SRSF2, COILIN, and H2B for studying RNA processing and gene expression. 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: Lentiviral vectors:P2511190101; Human tissue registration:B2511190101	DN2511190101	2	III-D-3-a, III-E-1, 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: 8 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: 8 Opposed: 0 Abstentions: 0**

Exempt Amendments

Goley, Erin	Recombinant cell line HMEC-1 obtained from ATCC will be cultured in vitro and infected with Rickettsia parkeri to identify host and bacterial factors required for intracellular replication of R. parkeri. All experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of recombinant cells and Rickettsia parkeri, and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents. Amendment for DN1109140115 RegSupport: Human tissue registration: B2103040105	DN1109140115	2	Exempt: III- F-8	No
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				
Smith, Wanli	Plasmid-based CRISPR/Cas9 system obtained from commercial sources will be used to perform gene editing in human cells to generate PD-linked mutations 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 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 DN1802010208 RegSupport: Human tissue registration: B1801310208	DN1802010208	2	Exempt: III- F-8	No
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				