Johns Hopkins Institutional Biosafety Committee
JHU IBC Minutes for September 15, 2025
Zoom Meeting

Members Present:	Alan F. Scott, Ph.D. (Acting Chair, Molecular Biology and Genetics); 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); 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:	Gary S. Hayward, Ph.D. (IBC Chair, Virology and Gene Therapy); Elizabeth A. Laffan, Ph.D. (Non-affiliated Member, Biology); Ms. Claudia MacAuley, L.A.T. (Non-affiliated Member, Biosafety and High Containment); 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), Mr. Thomas Burns, JD, MBA (Associate Vice Provost for Research Compliance)
IBC Coordinator:	Ms. Tylicia McRae

The Meeting was called to order at 3:08 pm.

Announcements:

No conflicts of interest were reported by IBC members.

Review and Approval of Meeting Minutes:

The minutes of the August 18, 2025, meeting were approved as submitted.

NIH News Update: "Modernizing and Strengthening Oversight of Biosafety"

Dr. Dahl presented an update from the NIH. He noted that the NIH did not release a new policy on dangerous gain-of-function research as expected. Instead, the NIH announced a new initiative titled "Modernizing and Strengthening Oversight of Biosafety." He shared the full statement from NIH Director Dr. Jay Bhattacharya, along with the proposed action plan and approach described in the initiative.

The JH IBC Guidance on Dangerous Gain-of-Function (dGOF) Research

The reporting requirements outlined in the NIH funding agency's Notice of Award (NOA) were discussed, along with Executive Order 14292, NIH Notice NOT-OD-25-112, and NIH Notice NOT-OD-25-127. The committee outlined a guideline for reporting any unanticipated research outcomes that could potentially constitute dangerous gain-of-function (dGOF) research, as defined in Executive Order 14292. This guideline is consistent with NIH funding agency requirements and will serve as interim rules until the final government policy on dGOF is released.

Clinical protocols and Amendments:

Atta Protocol, GT2509150101 (NIH CIT.: III-C-1), "A Phase 1/2 Multicenter, Open Label, two Part Study (Single Ascending Dose [Part 1], and Dose Expansion [Part 2]) to Evaluate Safety, Tolerability and Efficacy of PS-002, a Gene Therapy for the Treatment of Adult Participants with Primary IgA Nephropathy"

The primary objective of the study is to evaluate the safety, tolerability and efficacy of PS-002 in adult patients with immunoglobulin A nephropathy. PS-002 is an adeno-associated viral vector serotype LK03 containing a human complement factor I gene. PS-002 treatment is anticipated to lead to the glomerular production of CFI, to degrade and inactivate C3b and C4b by proteolysis, thereby inhibiting complement activation and reducing inflammatory responses.

This first-in-human study consists of 2 parts. Part 1 is an open label, single ascending dose exploration study consisting of up to 3 dose escalation cohorts with at least 3 evaluable participants in each cohort. Part 2 is an open label, single (or maximum 2) - dose expansion cohort(s) at the optimal biologically active dose (OBD). The first participant will receive an infusion of PS-002 via renal artery into each kidney and observed for 28 days. If there are no safety concerns, the second participant would then receive PS-002. The third participant in the cohort would receive the infusion $\geq$14 days after the second participant.

A maximum of 32 male and female participants $\geq$ 18 years of age will be recruited. Approximately 12 participants in Part 1 with up to 20 participants in Part 2. All participants will be hospitalized for 4 days and monitored for up to one year after receiving infusion of PS-002. The total duration of study participation will be approximately 54 to 56 weeks. Participants will be invited to take part in a separate long-term follow-up study for up to 5 years.

The medical and pharmacy staff involved in the study will be trained to follow the pharmacy manual for the proper handling of PS-002, 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: 7
Disapproval: 0
Abstain: 0

Barth Protocol, GT2310160101 (NIH Cit.: III-C-1), "A PHase 1/2 Study of the Safety and Efficacy of LX2020 Gene TheRapy in Patients with ArrhythmOgenIc Cardiomyopathy (ACM) due to a PlaKoPhilin-2 (PKP2) Pathogenic Variant"

The IBC received Protocol Version 4.0 dated July 25, 2025, for the above referenced protocol. Subjects in Cohort 3 will receive a single dose of LX2020 at 6.0 x 10^{13} gc/kg. The prophylactic corticosteroid regimen was modified. An adjustment of sirolimus dose in the event of elevated liver enzymes or other signs of immunotoxicity was added. Minor clarifications were made throughout the protocol.

The IBC voted to approve the amendment.

For Approval: 7
Disapproval: 0
Abstain: 0

Talaat Protocol, GT2209190101 (NIH Cit.: III-C-1), "A Master Phase 1/2/3 Protocol to Investigate the Safety, Tolerability, and Immunogenicity of Bivalent BNT162b2 RNA-Based Vaccine Candidate(s) in Healthy Children"

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

Recombinant DNA/Pathogen Research Registrations and Amendments:

12 research registrations and 2 amendments were presented for IBC consideration.
Dr. Casadevall's amendment to his R-DNA registration and Dr. Pekosz's registrations for Measles virus and Live Attenuated Measles Virus from last month's meeting have been granted full approval. The JH IBC Guidance on Dangerous Gain-of-Function (dGOF) Research has also been emailed to the PIs.

Review of Incidents:

No incidents were reported at this meeting.

Public Comments:

There were no public comments.

The meeting was adjourned at 4:34 pm.

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

Name	Synopsis	IBC#	BSL	ABSL	NIH Cit.	Agent	Select Agent
New Registrations							
Durbin, Anna P.	Plasmid vectors obtained from NIH will be used to generate pseudo-infectious reporter virus particles (RVPs) for West Nile virus (WNV), Dengue virus-1–4, St. Louis Encephalitis Virus (SLEV) , Zika, and yellow fever. These RVPs are replication-incompetent and will be used in neutralization assays to measure flavivirus-neutralizing antibodies in serum collected from clinical trial participants. All experiments involving RVPs will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of RVPs, 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: Human tissue registration: B0512200120; DENV-1–4:P0101110124; Zika Virus:P1601280110; Yellow Fever 17D Vaccine:P1805110108; SLEV Reporter Virus Particles:P2509120301; WNV Reporter Virus Particles:P2509120401;	DN2508280101	2		III-D-1-a, III-D-2-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: 7 Opposed: 0 Abstentions: 0**

Durbin, Anna P.	Plasmid vectors obtained from NIH will be used to generate pseudo-infectious reporter virus particles (RVPs) for St. Louis Encephalitis Virus (SLEV). These RVPs are replication-incompetent and will be used in neutralization assays to measure flavivirus-neutralizing antibodies in serum collected from clinical trial participants. All experiments involving RVPs will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of RVPs, 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 St. Louis Encephalitis Virus (SLEV) Reporter Virus Particles. RegSupport: Human tissue registration:B0512200120; R-DNA: DN2508280101	P2509120301	2	III-D-1-a, III-D-2-a	St. Louis Encephalitis Virus (SLEV) Reporter Virus Particles	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: 7 Opposed: 0 Abstentions: 0**

Durbin, Anna P.	Plasmid vectors obtained from NIH will be used to generate pseudo-infectious reporter virus particles (RVPs) for West Nile virus (WNV). These RVPs are replication-incompetent and will be used in neutralization assays to measure flavivirus-neutralizing antibodies in serum collected from clinical trial participants. All experiments involving RVPs will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of RVPs, 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 West Nile virus (WNV) Reporter Virus Particles. RegSupport: Human tissue registration:B0512200120; R-DNA: DN2508280101	P2509120401	2	III-D-1-a, III-D-2-a	West Nile virus (WNV) Reporter Virus Particles	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: 7 Opposed: 0 Abstentions: 0**

Hart, Thomas	A plasmid-based CRISPR/Cas9 system obtained from another investigator will be used to knock down gene expression and assess candidate adhesins and host-interacting proteins involved in mammalian infection and transmission of Borrelia burgdorferi. Plasmid vectors obtained from a commercial vendor will be used to produce and purify recombinant B. burgdorferi lipoproteins (e.g., OspC, CspA, CspZ) for downstream biochemical and immunological studies in vitro. These experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of these agents 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: Borrelia burgdorferi: P2411150301	DN2507310101	2	III-D-1-a, III-D-2-a; 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: 7 Opposed: 0 Abstentions: 0**

Hwang, Taeyoung	Replication-incompetent lentiviral vectors obtained from a commercial vendor will be used to express the KDM1A gene, to modify or mutate the KDM1A gene, to alter genes that interact with KDM1A, or to modify microRNAs (miRNAs) in cultured cells. 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. DN--Uses recombinant DNA in cultured cells RegSupport: Lentiviral vectors:P2503070101; Human tissue registration: B2508070101	DN2508070101	2	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: 7 Opposed: 0 Abstentions: 0**

Hwang, Taeyoung	Replication-incompetent lentiviral vectors obtained from a commercial vendor will be used to express the KDM1A gene, to modify or mutate the KDM1A gene, to alter genes that interact with KDM1A, or to modify microRNAs (miRNAs) in cultured cells. 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:DN2508070101; Human tissue registration: B2508070101	P2503070101	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: 7 Opposed: 0 Abstentions: 0**

Monosov, Ilya E.	Replication-incompetent adeno-associated viral (AAV) vectors obtained from a commercial vendor will be used to deliver GFP, HM4DI, HM3DI, CHR2, ARCH, ARCHT, CHRONOS, and JAWS into macaques and mice to study the neural circuits underlying voluntary control of action. Replication-incompetent Sindbis vectors obtained from a commercial vendor will be used to deliver GFP and light- or chemically sensitive ion/proton pumps (or channels) into monkey brains for the same purpose. 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. DN--Uses recombinant DNA in cultured cells and animals. RegSupport: Replication-incompetent adeno-associated viral vectors:P2504100101; Replication-incompetent Sindbis vectors: P2504100201	DN2506110101	2	2	III-D-1-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: 7 Opposed: 0 Abstentions: 0**

Monosov, Ilya E.	Replication-incompetent adeno-associated viral (AAV) vectors obtained from a commercial vendor will be used to deliver GFP, HM4DI, HM3DI, CHR2, ARCH, ARCHT, CHRONOS, and JAWS into macaques and mice to study the neural circuits underlying voluntary control of action. 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:DN2506110101	P2504100101	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: 7 Opposed: 0 Abstentions: 0**

Monosov, Ilya E.	Replication-incompetent Sindbis virus vectors obtained from a commercial vendor will be used to deliver GFP and light- or chemically sensitive ion/proton pumps (or channels) into monkey to study the neural circuits underlying voluntary control of action. 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 Sindbis virus vectors RegSupport: R-DNA:DN2506110101	P2504100201	2	2	III-D-1-a, III-D-4-b	Replication-incompetent Sindbis virus 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: 7 Opposed: 0 Abstentions: 0**

Poy, Matthew	Replication-incompetent adeno-associated viral vectors obtained from a commercial vendor will be used to express mCherry and Cre recombinase in cultured cells and mice. Replication-incompetent lentiviral vectors obtained from a commercial vendor will be used to overexpress or suppress non-coding RNAs and proteins involved in systemic energy metabolism (e.g., Cadm1, Cadm2, Argonaute2, miR-375, and others to be identified) in cultured cells to better understand how these target genes contribute to metabolism. 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. DN--Uses recombinant DNA in cultured cells and animals. RegSupport: Replication-incompetent adeno-associated viral vectors:P2509120201 ; Replication-incompetent lentiviral vectors:P2509120101; Human tissue registration: B2508200101 Note:The lab was relocated from the JHU All Children's Hospital campus to the JHU Bayview campus.	DN2508200101	2	2	III-D-1-a; III-D-4-b; 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: 7 Opposed: 0 Abstentions: 0**

Poy, Matthew	Replication-incompetent lentiviral vectors obtained from a commercial vendor will be used to overexpress or suppress non-coding RNAs and proteins involved in systemic energy metabolism (e.g., Cadm1, Cadm2, Argonaute2, miR-375, and others to be identified) in cultured cells to better understand how these target genes contribute to metabolism. 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:DN2508200101; Human tissue registration: B2508200101	P2509120101	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: 7 Opposed: 0 Abstentions: 0**

Poy, Matthew	Replication-incompetent adeno-associated viral vectors obtained from a commercial vendor will be used to express mCherry and Cre recombinase in cultured cells and mice. 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:DN2508200101; Human tissue registration: B2508200101	P2509120201	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: 7 Opposed: 0 Abstentions: 0**

Amendments

Baumgarth, Nicole	Mammalian expression plasmids obtained from a commercial vendor will be used to generate recombinant biotinylated influenza virus hemagglutinin from mouse-adapted influenza A/Puerto Rico/8/34 in cultured cells. The recombinant protein will be used in downstream studies, including as antigen baits in flow cytometry and to analyze antigen binding using microfluidic devices. These experiments will be conducted using Biosafety Level 2 (BSL-2) practices. Laboratory personnel will be trained in the safe handling of these agents and will follow established standard operating procedures (SOPs) for the disposal of contaminated materials and for responding to laboratory incidents.	DN2208310103	2	III-D-2-a		No

Amendment for R-DNA registration: DE2208310103, and the updated IBC number is DN2208310103
RegSupport: Human tissue registration:B2509120101; Mouse-adapted Influenza A/ Puerto Rico/8/34 (H1N1): P2208190104

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: 7 Opposed: 0 Abstentions: 0**

Weeraratna, Ashani	Replication-incompetent lentiviral vectors obtained from a commercial vendor will be used to generate control cell lines to study the effects of genes on melanoma progression in vitro. 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. Amendment for R-DNA registration: DN2001230105; Lentiviral vector registration:P2002110305 RegSupport: Human tissue registration:B1912230106	DN2001230105	2	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: 7 Opposed: 0 Abstentions: 0**