NIH Institutional Biosafety Committee Minutes
National Institute of Environmental Health Sciences

Thursday, Sept 9, 2025
3:30 PM – 4:30 PM
Virtual via Teams

Members Present:
Quorum Met: Yes

☒	Francesco Demayo	Chair
☒	Christopher McGee	Biosafety Officer
☐	David Kurtz	Animal Expert
☒	Robert Petrovich	Protein Expression Expert
☐	Justin Kosak	Lab Representative
☒	Shih-Heng Chen	Virology Expert
☒	Andrew Newell	Toxicology Expert
☒	Huanchen Wang	Cell & Molecular Expert
☒	Lawrence Kirschner	Clinical Expert
☒	Stephen Novak	Ex Officio
☒	John McLamb	Radiological Expert
☒	Jacqueline Hamilton	Community Representative
☐	Troy Weaver	Community Representative

Guests Present:

Althea Treacy, BMB Branch Chief, NIH

Announcements & Call to Order

I. Meeting called to order by Francesco Demayo at 3:32pm.
II. The IBC Chair reminded all present members to identify any conflicts of interest as each registration is reviewed.

Review of Past IBC Meeting Minutes

I. Aug 14, 2025 Minutes
    a. The Aug 2025 minutes were unanimously approved as written

New Committee Business

I. BSO or IBC lead reviewer preliminary registration approvals since the previous meeting.
    a. None

II. Registrations for Committee review

    a. Registrations for committee review:

    Registration Number, PI: B-1941, Negin Martin
        i. Reviewers: Robert Petrovich
        ii. Review Summary: The investigator seeks to amend a HIV protocol substituting the approved NL4-3 HIV strain with the thymus tropic R3A HIV strain. They will infect differentiated mutant/wt THP-1 cells to determine if targeted genetic variations affect HIV replication. They will conduct p24 and TZM assays to investigate propagation and infectivity. Previously approved, plasmid prep is being

completed using lab adapted e coli strains. Lenti-GFP with immune response regulators will be used for THP-1 transduction.

iii. Committee Discussion: The committee discussed minimum PPE requirements including double glove, closed front splash resistant gown, safety glasses and use of dedicated class II biosafety cabinet for all procedures, incubator, and centrifuge with safety cups. It was noted that all decontamination and hazardous waste disposal procedure documents were available and no changes were needed for the updated strain.

iv. Training: All personnel listed on the biopermit are required to maintain annual biosafety and blood borne pathogens refresher, and biannual laboratory safety training.

v. Animal studies proposed: No

vi. The committee discussed the dual-use and ePPP potential of these experiments. The committee agreed that there were no dual-use or ePPP concerns with the proposal.

vii. Public comment: IBC community member expressed no safety concerns with the experiment or risk mitigation outlined in the permit review. No additional public comment has been made on the permit.

viii. Work is approved at: BSL-2/3.

ix. Relevant sections of the NIH Guidelines: III-D-3-a eukaryotic work, III-D-2-a prokaryotic work.

x. A motion was made and seconded to approve the permit unanimously.

xi. The committee unanimously approved with the stipulation outlined above.

1. Conflicts of interest: Shih-Heng Chen recused himself from deliberations.
2. Votes for:__9__Votes against:__0__Abstained:__0__

Registration Number, PI: B-1989, Negin Martin

i. Reviewers: Francesco Demayo

ii. Review Summary: The viral vector core seeks to construct non-propagating HIV-enveloped viral vector from integrase deficient lentivirus using native CD4-tropic envelope and inducible expression system to offer potential therapeutic delivery and/or immune modulation test system to institute collaborators. Initial testing will deliver Nef-PEST to Jurkat, THP-1 and HeLa-CD4+ cells. All initial testing will be conducted for validating the vector system. Downstream testing using isolated human cell lines will be conducted after initial testing pending IRB approval.

iii. Committee Discussion: The committee discussed approval of project as it pertains to creating the initial plasmids and integrase-deficient viral vector system. Viral vector core collaborators who wish to use the system for therapeutic agent delivery testing within their labs will be required to submit their own biopermit requests, and IRB approvals, depending on study. Minimum PPE requirements discussed included use of double gloves, closed front splash resistant gown, safety glasses, class II biosafety cabinet for all procedures, incubator, and centrifuge with safety caps. All decontamination, disinfection and disposal procedure documents for work with HIV were available and satisfactory for the pathogen.

iv. Training: All personnel listed on the biopermit are required to maintain annual biosafety and blood borne pathogens refresher, and biannual laboratory safety training.

v. Animal studies proposed: No
vi. The committee discussed the dual-use and ePPP potential of these experiments. The dominant negative function and dox-inducible system lead to a safe non-propagating vector. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. Public comment: IBC community member expressed no safety concerns with the experiment and risk mitigation outlined in the permit review. No additional public comment has been made on the permit.
viii. Work is approved at: BSL-2/3 (eukaryotic). BSL-1 (prokaryotic)
ix. Relevant sections of the NIH Guidelines: III-D-3-a, III-D-2-a
x. A motion was made and seconded to approve the permit unanimously.
xi. The committee unanimously approved with the stipulation outlined above.
    1. Conflicts of interest: Martin lab member Shih-Heng Chen recused himself from deliberations.
    2. Votes for:__9__Votes against:__0__Abstained:__0__

Registration Number, PI: B-1988, Jerry Yakel

i. Reviewers: Lawrence Kirschner
ii. Review Summary: The PI seeks to use a commercial iPSC cell line to grow human spinal organoids to determine feasibility for potential in vitro toxicology and disease mechanism studies.
iii. Committee Discussion: The committee discussed minimum PPE requirements following universal precautions handling all human materials.
iv. Training: All personnel listed on the biopermit are required to maintain annual biosafety refresher, blood borne pathogens, and biannual laboratory safety training.
v. Animal studies proposed: No
vi. The committee discussed the dual-use and ePPP potential of these experiments. The committee agreed that there were no dual-use or ePPP concerns with the proposal.
vii. Public comment: IBC community member expressed no safety concerns with the experiment and risk mitigation outlined in the permit review. No additional public comment has been made on the permit.
viii. Work is approved at: BSL-2
ix. Relevant sections of the NIH Guidelines: n/a
x. A motion was made and seconded to approve the permit unanimously.
xi. The committee unanimously approved with the stipulation outlined above.
    1. Conflicts of interest: None
    2. Votes for:__10__Votes against:__0__Abstained:__0__

I. Committee Review of Inactivation Procedures
    a. None

II. Standard Operating Procedures/Plans
    a. None

III. Serious Adverse Events in Clinical Trials reviewed by the Committee
    a. None

Reports

I. Biosafety Officer Report –
   a. Reported mouse bite incident during handling. No biohazardous agents were in use during the incident.
   b. Discussed biosafety modernization initiative aims and next steps.

Around the Room/Committee Discussion

I. None

Adjournment

I. Meeting adjourned by Francesco Demayo at 3:52 pm

Next Meeting

I. Oct 9th, 2025, virtual via Teams