

NIH Institutional Biosafety Committee Minutes National Institute of Environmental Health Sciences

Thursday, July 10, 2025

3:30 PM – 4:30 PM

Virtual via Teams

Members Present:

Quorum Met: Yes

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

Guests Present:

Althea Treacy, BMB Branch Chief, NIH

Justin Bunn, SEPB, NIEHS, 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. Jun 12, 2025 Minutes
 - a. The Jun 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-1986, Hung Chang Yao

- i. Reviewers: Justin Kosak
- ii. Review Summary: The investigator seeks to conduct lentiviral transduction of gRNA targeting select chromatin remodeling proteins in Cas9 expressing mouse tissue ex vivo. Tissue will be screened via live and fixed imaging to determine

transduction efficiency and fetal and neonatal reproductive effects due to targeted gene disruption. Identified hazards are, use of replication incompetent 2nd generation lentivirus delivering gRNA. Wash steps post transduction will clear unincorporated viral particles minimizing risk for any tissue trimming or live imaging work which will happen after 72 hours.

1. The committee discussed a lack of clarity within the permit to the origin of the tissue expressing cas9 as well as specific lentiviral vector information and construct map. The BSO provided clarification and will add these components to the permit.
 2. The committee discussed the safety benefits from separating cas9 and gRNA delivery by using cre recombinase-dependent expression of cas9 in tissue to reduce off target effects and decreased potential for insertional mutagenesis.
 3. Minimum PPE required, splash resistant closed front gown, double gloves, and safety glasses. All aerosol generating work performed in Class II BSC. Disinfect all contact surfaces with 1:10 bleach made fresh at least weekly. Use centrifugation safety caps for all centrifugation processes. All solid biohazardous waste disposed in orange biohazard bags and all liquid biohazardous waste should be decontaminated with 1:10 final concentration of bleach and submitted for pick up through EHSA.
- iii. Training: All personnel listed on the biopermit are required to maintain annual biosafety refresher, and biannual laboratory safety training. All personnel working directly with lentiviral vectors must receive hands-on training with the viral vector core before working independently.
 - iv. Animal studies proposed: Yes. All lentiviral experiments conducted ex vivo using commercially available Cre recombinase-dependent cas9 expressing mice.
 - v. 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.
 - vi. 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.
 - vii. Work is approved at: BSL-2/3.
 - viii. Relevant sections of the NIH Guidelines: III-D-3-a
 - ix. A motion was made and seconded to conditionally approve the permit pending the addition of mouse strain information and source, and viral vector map and source for clarity.
 1. BSO Update 7/15/2025. The animal study proposal showing CAG-Cas9-EGFP strain, and viral vector map and commercial source were added to the permit.
 - x. 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.

Around the Room/Committee Discussion

- I. None

Adjournment

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

Next Meeting

- I. Aug 14th, 2025, virtual via Teams