

# NIH Institutional Biosafety Committee Minutes National Institute of Environmental Health Sciences

Thursday, Dec 11, 2025

3:30 PM – 4:30 PM

Virtual via Teams

## Members Present:

Quorum Met: Yes

|                                     |                   |                           |                                     |                     |                          |
|-------------------------------------|-------------------|---------------------------|-------------------------------------|---------------------|--------------------------|
| <input checked="" type="checkbox"/> | Francesco Demayo  | Chair                     | <input checked="" type="checkbox"/> | Huanchen Wang       | Cell & Molecular Expert  |
| <input checked="" type="checkbox"/> | Christopher McGee | Biosafety Officer         | <input checked="" type="checkbox"/> | Lawrence Kirschner  | Clinical Expert          |
| <input checked="" type="checkbox"/> | David Kurtz       | Animal Expert             | <input checked="" type="checkbox"/> | Stephen Novak       | Ex Officio               |
| <input checked="" type="checkbox"/> | Robert Petrovich  | Protein Expression Expert | <input checked="" type="checkbox"/> | John McLamb         | Radiological Expert      |
| <input checked="" type="checkbox"/> | Justin Kosak      | Lab Representative        | <input checked="" type="checkbox"/> | Jacqueline Hamilton | Community Representative |
| <input checked="" type="checkbox"/> | Shih-Heng Chen    | Virology Expert           | <input checked="" type="checkbox"/> | Troy Weaver         | Community Representative |
| <input checked="" type="checkbox"/> | Andrew Newell     | Toxicology Expert         |                                     |                     |                          |

## Guests Present:

Althea Treacy, BMB Branch Chief, NIH

## Announcements & Call to Order

- I. Meeting called to order by Francesco Demayo at 3:30pm.
- II. The IBC Chair noted no committee conflicts of interest on protocol for review.

## Review of Past IBC Meeting Minutes

- I. Sept 11, 2025 Minutes
  - a. The Sept 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-1990, Mario Borgia

- i. Reviewers: Sheh-Heng Chen
    - ii. Review Summary: The investigator seeks to add alpha-synuclein pre-formed fibrils ( $\alpha$ -pff) to their cryo-em imaging protocol for structural characterization. They propose to receive aliquots of alpha-synuclein samples expressed from E. coli and amplified in human cerebral spinal fluid (csf) from dementia patients which are then purified into PBS solution by their external collaborator prior to being brought to the institute. Aliquots are less than 30uL, typically 10uL, at 1-2

mg/mL concentration. Once at the institute 10uL samples at 1-2 mg/mL will be applied to cryo-grids and plunge-frozen using a cryogen at 83K. Grids are then transferred to liquid nitrogen storage for future analysis. For screening and data collection grids are loaded onto cryogenic electron microscope. After imaging, grids are stored in liquid nitrogen or decontaminated in 10% SDS for 30 minutes before disposal and subsequent onsite incineration.

- iii. Committee Discussion: The committee discussed the risk associated with the proposed benchwork during the cryogen grid loading process as opening the sample tube at the bench may generate aerosols due to potential pressure differential and the room does not have a class II biosafety cabinet. The committee expressed concern with allowing this work to be done on an open bench top. Also, the potential for bloodborne pathogens from the use of human csf used in the generation of the  $\alpha$ -pff which would be done by the external collaborator was considered potentially hazardous after purification steps to replace csf with pbs. The committee requested the associated IRB# be added to the biopermit request. The committee expressed concern with no statement of transportation of the material to the institute within the review documents. The biosafety specialist stated he had discussed with the PI that per NIH policy personal vehicles must not be used for the transport of biological hazardous materials and government vehicles can be "signed out" for this purpose by contacting the NIEHS transportation specialist. The decontamination step using 10% SDS for 30 minutes was discussed. Current literature supports the use of SDS for decontamination of preformed alpha-synuclein fibrils. Both identified biological hazards,  $\alpha$ -pff and human materials, were agreed to be adequately contained using BSL-2 containment and practices. However the committee recommended the permit be postponed until the following additions can be submitted for further review, 1) description of transportation including the sample containment and state, 2) description of how potential aerosolization is contained when working with the agent, 3) submitting the IRB#, 4) Written protocol for decontamination and waste management steps to be conducted at NIEHS.
- iv. Training: Additional discussion was postponed pending resubmission.
- v. Animal studies proposed: No
- vi. The committee did not discuss the dual-use and ePPP potential of these experiments as additional discussion was postponed pending resubmission.
- vii. Public comment: There was no additional public comment pending resubmission.
- viii. Work was not approved
- ix. Relevant sections of the NIH Guidelines: N/A no recombinant or synthetic nucleic acids were proposed in the NIEHS work.
- x. A motion was made and seconded to postpone approval of the permit pending resubmission addressing the concerns brought forth during discussion.
- xi. The committee unanimously approved with the stipulation outlined above.
  1. Conflicts of interest: Shih-Heng Chen recused himself from deliberations.
  2. Votes for: 0 Votes against: 13 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. Jan 15<sup>th</sup>, 2025, virtual via Teams