

NIH Institutional Biosafety Committee Minutes National Institute of Environmental Health Sciences

Thursday, June 12, 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
☐	Janine Santos	Toxicology Expert			

Guests Present:

Andrew Newell, Neurotoxicologist, NIEHS

Althea Treacy, BMB Branch Chief, NIH

Announcements & Call to Order

- I. Meeting called to order by Francesco Demayo at 3:31pm.
- 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. Apr 10, 2025 Minutes
 - a. The May 2025 meeting was cancelled per the IBC chair and executive secretary due to no permits for review, and no new business to conduct.
 - b. The April 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-1984, John Cidlowski

- i. Reviewers: Robert Petrovich

- ii. Review Summary: The investigator seeks to study protein-protein interactions and regulatory dynamics using cDNA transfection, or transduction via 2nd generation lentiviral vector, of glucocorticoid and endocrine receptors in established human and non-human primate cell lines. Identified risks include the use of replication incompetent 2nd generation lentiviral vector systems, transduction of mitogenic genes, and use of human and non-human primate cells lines.
- iii. Committee Discussion: Required PPE for prokaryotic BSL1 work includes lab coats, gloves, and eye protection. The initial eukaryotic work recommendation of BSL-2 was determined to be inadequate and BSL-2/3 was recommended for approval based on the potential consequence of using a 2nd generation lentiviral system delivering mitogenic genes into human cell lines. Eukaryotic work for vector propagation and cellular transduction is to be conducted in a class II biosafety cabinet using a splash resistant closed front gown, double gloves, and eye protection. A 1-2-3 Injury or Exposure Response poster should be posted in lab. Biohazard sign should be used to identify lab space where agent is used and/or stored. Universal precautions sign should be posted in lab where human and/or non-human primate cells will be used or stored. A [1:10] dilution of sodium hypochlorite should be used for disinfection. Biohazardous waste should be orange bagged and submitted in EHSA for pickup.
- iv. Training: All personnel listed on the biopermit are required to maintain annual blood borne pathogen, annual biosafety 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: No public comment was offered.
- viii. Work is approved at: Prokaryotic work should be conducted at BSL-1. Eukaryotic work should be conducted at BSL-2/3.
- ix. Relevant sections of the NIH Guidelines: III-D-2-a, III-D-1-a
- x. A motion was made to approve the registration with the modification of eukaryotic work being adjusted from BSL-2 to BSL-2/3.
- xi. The committee unanimously approved with the stipulation of adjustment to the biosafety level previously mentioned.
 - 1. Conflicts of interest: None
 - 2. Votes for: 11 Votes against: 0 Abstained: 0

Registration Number, PI: B-1985, Rajula Alleva

- i. Reviewers: Lawrence Kirschner
- ii. Review Summary: The investigator seeks to study how problems in certain Fanconi anemia genes working together can lead to shutdown of vital cell processes and cell death using commercially available Adenovirus-CMV-iCre and mouse embryonic stem cells previously prepared for conditional knockdown of specific cancer genes. The identified risks include use of replication deficient type 5 adenoviral vector.
- iii. Committee Discussion: Required PPE includes lab coats, gloves, and eye protection. Work is to be conducted in a class II biosafety cabinet. 1-2-3 Injury or

Exposure Response poster should be posted in lab. Biohazard symbol should be used to identify lab space where agent is used and/or stored. A [1:10] dilution of sodium hypochlorite should be used for disinfection. Biohazardous waste should be orange bagged and submitted in EHSA for pickup.

- iv. Training: All personnel listed on the biopermit are required to maintain annual biosafety refresher training 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: No public comment was offered.
- viii. Work is approved at: BSL-2.
- ix. Relevant sections of the NIH Guidelines:
- x. A motion was made to approve the registration as is.
- xi. The committee unanimously approved as written.
 - 1. Conflicts of interest: None
 - 2. Votes for: 11 Votes against: 0 Abstained: 0

b. Registration amendments for committee review:

Registration Number, PI: B-1938, Carlos Guardia

- i. Reviewers: Shih-Heng Chen
- ii. Review Summary: The investigator seeks to amend a current permit that will introduce transient expression of anti-angiogenic factor genes using adenoviral vector delivered via tail-vein route in mice to induce preclampsia-like phenotypes to study placental formation. The identified risks include use of replication deficient type 5 adenoviral vector for gene transfer, and the use of syringes to complete tail-vein injection of the viral vector.
- iii. Committee Discussion: Required PPE includes lab coats, gloves, and eye protection. Eukaryotic work is to be conducted in a class II biosafety cabinet. 1-2-3 Injury or Exposure Response poster should be posted in lab. Biohazard sign should be used to identify lab space where agent is used and/or stored. A [1:10] dilution of sodium hypochlorite should be used for disinfection. Biohazardous waste should be orange bagged and submitted in EHSA for pickup.
- iv. Training: All personnel listed on the biopermit are required to maintain annual biosafety refresher training and biannual laboratory safety training. Personnel who conduct mouse tail-vein injections are required to work with the Comparative Medicine Branch to maintain animal handling and tail-vein injection proficiency.
- v. Animal studies proposed: Yes, mice.
- 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: No public comment was offered.
- viii. Work is approved at: Prokaryotic work should be conducted at BSL-1. Eukaryotic work should be conducted at BSL-2. Work with animals should be conducted at ABSL-2 for a minimum of 96 hours followed by ABSL-1 after initial cage change.
- ix. Relevant sections of the NIH Guidelines: III-D-2-a, III-D-3-a, III-D-4-a

- x. A motion was made to approve the registration as is.
- xi. The committee unanimously approved as written.
 - 1. Conflicts of interest: None
 - 2. Votes for: 11 Votes against: 0 Abstained: 0

II. Committee Review of Inactivation Procedures

- a. None

III. Standard Operating Procedures/Plans

- a. None

IV. Serious Adverse Events in Clinical Trials reviewed by the Committee

- a. None

Reports

- I. Biosafety Officer Report –
 - a. Reviewed meeting minutes template changes to further alignment with other NIH IBCs.
 - b. Reviewed EO definition of gain of function and notified committee that 137 current active NIEHS biopermits have been reviewed and no studies meet the definition as outlined by the EO.

Around the Room/Committee Discussion

- I. None

Adjournment

- I. Meeting adjourned by Francesco Demayo at 4:15 pm

Next Meeting

- I. July 10th, 2025, virtual via Teams