

Minutes of the Institute Biosafety Committee Meeting

June 11, 2025

Convened at: 1:04 pm and Adjourned at 1:59 pm

Present: Drs. Gelman (Chair), Ding, Gerber, Ionov, Foster, McGray, Thanavala, Mr. Hartley, Ms. Holtz, Ms Keough, Mr. Korytko

Absent: Mr. Atwal, Ms. Bennett

ORSP Staff: Ms Oliver, Ms. Pusateri, and Ms Herter

Guests: None.

Meeting Place: Virtual meeting/Teams.

Minutes of May 14, 2025 were approved.

Vote: Unanimous.

Adverse Event/Accident/Incident Report

May Employee Health Service report; no follow up required.

ORSP - No reports.

Old Business

1. Safety Story; this months story highlighted taking a step back and reset/verify.
2. Laboratory inspections; February checklist completed. December, March, April and May pending:
3 pending laboratory visits from December with Dr Foster joining the team:
 - a. Nemeth Level 2+ lab: See checklist for details.
 - b. Tang, D Level 2+ lab: See checklist for details.
 - c. Bakin Level 2+ lab: See checklist for details.

Laboratories were visited March 6th with Drs McGray and Ionov joining the team:

- a. Bianchi Smiraglia Level 2+ Lab: See checklist for details.
- b. Smiraglia Level 2 Lab: See checklist for details.
- c. Gurova Level 2+ Lab: See checklist for details.
- d. Dasgupta Level 2+ Lab: See checklist for details.

Laboratories were visited April 10th with Dr Ionov joining the team.

- a. Ohm level 2+ lab: OES will follow up (see check list for details).

Laboratories were visited May 15th with Dr. McGray joining the team.

- a. Chandra level 2 lab: OES will follow up (see check list for details).
- b. Sung level 2+ lab: OES will follow up (see check list for details).

3. NIH notification: Institute Biosafety Committee's received a notification from NIH regarding an Implementation update. To maximally meet the transparency aims of the NIH Guidelines on June 1, 2025 NIH OSP (office of science policy) will publicly post the rosters of all active IBCs registered. The rosters will include all members identified by name and role on the committee. In addition, NIH will be posting the contact information for the IBC Chair, Biological Safety Officer, and IBC contact. Also, NIH expects that approved meeting minutes from all IBC meetings occurring on, or after the June 1st date will be posted publicly on an institutional website. NIH expects that minutes will be posted immediately upon approval and once all appropriate and allowable redactions have been made. An FAQ detailing how IBC minutes should be prepared, what information should be included in them and what information may and may not be redacted was included. All committee members were tasked with reviewing the FAQ and what can be redacted will be discussed at next months meeting. The administrative staff will meet with the Dr. Gelman and determine a location on our external web page where the minutes can be posted. Update 5/14: A meeting is being planned with legal for May 20th to discuss details of minutes. Already discussed removing inspection specifics and to instead state "see checklists for details". **Update 6/11:** All recommendations will be incorporated into this months meeting minutes. Once these minutes are approved at the July meeting, they will be sent to IT for posting on the external website.

New Business:

1. The next inspection date will be Wednesday June 18 with Dr. Thanavala joining the team. The July inspection date will be canceled.
2. When visiting the CGP lab space at the last inspection date; it was noticed that a lab space appeared to be in use. However, the IBC did not have an application on file for the PI. The PI was contacted by Dr Gelman and instructed to complete his training and submit his biosafety application for review (stopping all work until submission is submitted and approved). OES had visited the lab space when it was originally set up. PI reported he was performing work with lentivirus. The PI has now submitted an IACUC and IBC application (both to be reviewed at next months meetings). The PI has completed online courses, wet lab for animal work pending. Discussion revolved around sending a reminder memo to all Research personnel highlighting the need for applications to be in place prior to work beginning. Ms. Bennett will work on preparing a memo to be sent to Research staff. In the future, discussed ways of obtaining new recruit researcher names to ensure they are aware of the application process and all the mandatory training prior to beginning biosafety related work.

Protocol review:

4 Biosafety applications were reviewed.

2 Protocols referenced Virus

Application for Lab based 1442M: Approved pending.

Reviewed by Dr. Ding

The renewal application for Lab based/Benchwork/1442M, 25-04-1668 entitled: "Study of UVA and UVB Irradiation on Cellular Regulatory Pathways and the Preclinical Study of Ultraviolet Light Sensitive Clonal Mutations" PI: Paragh, Gyorgy was approved pending designated member review of a revised application. The purpose of this protocol is to evaluate clonal mutations in irradiated skin tissue.

Biosafety agents include: lentivirus, 5-FU, Brij L23, azathioprine, adapalene.

Application for protocol P3675325: Approved pending.

Reviewed by Dr. McGray

The Initial application for protocol P3675325, 25-05-1672 entitled: "P 3675325-A phase 1a/b study to evaluate the safety and efficacy of OPB-101, an autologous mesothelin (MSLN) CAR T cell therapy with antigen-dependent expression of OUTSMART™ designed IL-2 cytokine in platinum-resistant ovarian cancer." PI: Zsiros, Emese was approved pending designated member review of a revised application.

The purpose of this protocol is to evaluate the safety and efficacy of OPB-101 (multi-transgene CAR-T).

Biosafety agents used include: lentivirus

Exempt from full committee review: None.

Amendments:

Application for 1462M: Approved.

Reviewed by Dr. Gelman

The amendment for 1462M protocol 24-12-1641 entitled: "Molecular Mechanisms of Resistance and Sensitivity to Targeted Therapies" PI: Kandel, Eugene was approved 5/15/2025.

Biosafety agents used include: 2 human cell lines.

Application for protocol 1625M: Approved.

Reviewed by Dr. Gelman

The amendment for 1462M protocol 24-09-1627 entitled: "Combination Small Molecule Inhibitor and T Cell Immunotherapy Approaches in ALL" PI: Niswander, Lisa was approved 5/22/2025.

Biosafety agents used include: Unmodified human T cells.

See attached for complete list.

Respectfully Submitted,

A handwritten signature in blue ink, reading "Irwin Gelman". The signature is fluid and cursive, with the first name "Irwin" and last name "Gelman" clearly distinguishable.

Irwin Gelman, PhD
Institute Biosafety Committee Chair
Director of Research Integration; Professor of
Oncology