

**Minutes of the Institute Biosafety Committee Meeting
February 11, 2026**

Convened at: 1:00 pm and Adjourned at 2:11 pm

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

Absent: Mr Caruana and Mr. Atwal

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

Guests: None

Meeting Place: Virtual meeting/Teams.

Minutes of January 14, 2026 were approved.

Vote: Unanimous.

Adverse Event/Accident/Incident Report

December Employee Health Service report; no incidents.

ORSP - No reports.

Old Business

1. Safety Story; this months story highlighted following safety precautions.
2. Laboratory inspections; May, September, October and November were approved by OES.

New Business:

1. Lab educational visits:

4 Laboratories were visited February 5th with Dr. Thanavala joining the team.

a. Evans BSL 2 lab: OES to follow up (see checklist).

b. Prahlad BSL2+ lab: No follow up required.

c. Repasky BSL2 lab: OES to follow up (see checklist).

d. Webster BSL2+ lab: OES to follow up (see checklist).

The next inspection date will be Thursday March 5th with Dr. Ionov joining the team

2. Committee update: Dr Fang and Mr. Flagler are committee members as of this meeting.
3. Post Approval monitoring: Dr Gerber visited a PI working with MRSA and reviewed handling/safety precautions while PI and staff administered to animals. All precautions were in place and PI and staff following the approved SOP and checklists. Suggestions made; wear double gloves to ease the process of always being gloved when disposing of gloves that may have directly come in contact with MRSA (outer layer), also the PI/staff were going to bleach the syringes after administration prior to disposal. Recommended to place directly into red sharps container to decrease chance of needle stick.
4. IRB related Biosafety sponsor questioned the need for Continuing reviews to be performed when they are working with CAR T cells. Sponsor believed that NIH claimed it was not necessary. All documentation has been forwarded to Dr Gelman for further review and will update at next meeting.

Protocol review:

6 Biosafety applications were reviewed.

1 Protocol referenced CAR T cells modified by Virus

Application for I-4601225: Approved pending.

Reviewed by Dr. McGray

The Initial application for I-4601225, 25-12-1706 entitled: "A Phase 1, Open-Label, Dose-Escalation Study Evaluating the Safety and Tolerability of GB-5267, an IL-18 Armored CAR T Cell Product Targeting MUC16,

in Patients with Platinum-Resistant Ovarian Cancer.” PI: Zsiros, Emese was approved pending designated member review of a revised application.

The purpose of this protocol is to test the toxicity and tolerability of GB-5267, a, IL-18 armored, MUC16-targeting CAR-T in platinum-resistant ovarian cancers.

Biosafety agents include: lentivirus

1 Protocol referenced CAR T Cells with Gene editing

Application for IC-4439025: Approved pending.

Reviewed by Dr. McGray

The Initial application for IC-4439025, 25-12-1714 entitled: “A Phase 1, Open-label Study to Evaluate the Safety and Clinical Activity of Azercabtagene Zapreleucel in Participants with B-cell Mediated Autoimmune Disorders.” PI: Lieberman, Alicia was approved pending designated member review of a revised application.

The purpose of this protocol is to investigate the safety of Azercabtagene Zapreleucel in patients with B cell mediated autoimmune disorders.

Biosafety agents include: AAV

1 Protocol referenced Toxin

Application for 1515M/lab: Approved.

Reviewed by Dr. Ding

The amendment for 1515M/Lab, 24-04-1586 entitled: “Dr Takabe Lab Based Biosafety Application.” PI: Takabe, Kazuaki was approved.

The purpose of this protocol is to investigate the effect of local anesthetics on immune checkpoint inhibition therapy in breast cancer models.

Biosafety agents include: lentivirus, compounds, and Toxin; botox.

Exempt from full committee review:

Application for 1183M/ Lab: Approved.

Reviewed by Dr. McGray

The Initial Key application for 1183M/Lab, 25-08-1689 entitled: “Evaluation of the safety and efficacy of novel combination therapies and preventions of oral and head and neck cancers” PI: Seshadri, Mukund was approved as Exempt from full committee review 1/30/2026.

Biosafety agents used include: Human CAR T Cells.

Amendments:

Application for Lab/1338M: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based/1338M 24-07-1606 entitled: “Extracellular and intracellular molecular signaling mechanisms of mammalian normal and tumor cells” PI: Hait, Nitai was approved on 1/23/2026. Biosafety agents used include: New modified cell lines.

Application for Lab/1094M: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based/1094M 25-09-1691 entitled: “The study of CAR-T cells and multiple myeloma” PI: Olejniczak, Scott was approved 2/9/2026.

Biosafety agents used include: New modified cell lines.

See attached for complete list.

Respectfully Submitted,

A handwritten signature in blue ink that reads "Irwin Gelman". The signature is written in a cursive style with a prominent loop at the end of the last name.

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