

Minutes of the Institute Biosafety Committee Meeting

September 10, 2025

Convened at: 1:03 pm and Adjourned at 1:48 pm

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

Absent: Dr Foster, Mr. Atwal, Mr. Korytko, Ms. Bennett

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

Guests: None.

Meeting Place: Virtual meeting/Teams.

Minutes of August 13, 2025 were approved.

Vote: Unanimous.

Adverse Event/Accident/Incident Report

August Employee Health Service report; no incidents.

ORSP - No reports.

Old Business

1. Safety Story; this months story highlighted having a questioning attitude.
2. Laboratory inspections; April checklist has been completed. May, June and August are pending:
 - 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).
 - Laboratories were visited June 18th with Dr. Ionov joining the team.
 - a. Flow Cytometry Shared resource; OES will follow up (see checklist for details).
 - b. Hernandez level 2 lab: OES will follow up (see checklist for details).
 - Laboratories were visited August 7th with Dr. Thanavala joining the team.
 - a. Liu level 2+ lab; OES will follow up (see checklist for details).
 - b. Li, F level 2+ lab; OES will follow up (see checklist for details).
3. Key database update: Change has been requested: The lab location currently listed for every personnel will be changed to reflect if they are personnel only on a biosafety application, or just administrative or if also listed on the IACUC application (this way required training can be accurate). This change is scheduled to be in the next maintenance update which should be at the end of August. Update 9/10: The change in Key has been made and appears to be working well.

New Business:

1. 4 Laboratories were visited September 4th with Dr. McGray joining the team.
 - a. Gelman level 2+ lab: No follow up required.
 - b. Gelman Core level 2+ lab: No follow up required.
 - c. Paragh level 2 lab: OES will follow up (see checklist for details).
 - d. Das level 2 lab; OES will follow up (see checklist for details).

The next inspection date will be Thursday October 9th with Dr. Ionov joining the team.
2. Dr. Gelman distributed information from NIH. NIH is launching an Initiative to modernize and strengthen Biosafety Oversight. This will be a comprehensive effort to modernize and strengthen biosafety biosafety policies, practices, and oversight to keep pace with the evolving risks posed by today's rapidly advancing science and technology. This initiative will be in 4 Phases, starting in the Fall of 2025 with regional listening sessions and stakeholder events while encouraging maximum public feedback. Phase IV is not expected until the Fall of 2026 with publishing a final policy, releasing community driven guidance and launching rigorous outreach and education efforts.
3. Mr Leonard Caruana was introduced to the committee. He is the new Director of ORSP and will be attending meetings to become familiar with the functions of the committees that have ORSP administrative assistance.

Protocol review:

8 Biosafety applications were reviewed. 1 was a continuing review.

2 Protocols referenced Virus

Application for P 4566925: Approved pending.

Reviewed by Dr. McGray

The Initial application for P 4566925, 25-08-1685 entitled: "A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of LYL314, a CD19/CD20 Dual-Targeting Chimeric Antigen Receptor T-Cell Therapy in Participants with Aggressive B-Cell Non-Hodgkin Lymphoma (LYL314-101)." PI: Hernandez, Francisco was approved pending designated member review of a revised application.

The purpose of this protocol is to test the efficacy and safety of LYL314, a dual-targeting chimeric antigen receptor (CAR) targeting cluster of differentiation CD19 and CD20 in participants with aggressive B-cell Non-Hodgkin Lymphoma.

Biosafety agents include: lentivirus

Application for Lab based/1081M protocol: Approved.

Reviewed by Dr. Ding

The renewal application for Lab based/1081M protocol 25-08-1687 entitled: "Effect of Tumor Microenvironment Modulation on the Efficacy of Oncolytic Virotherapy" PI: Kozbor, Danuta was approved pending designated member review of a revised application.

The purpose of this protocol is to test the ability of oncolytic viruses to kill cancer cells.

Biosafety agents used include: oncolytic vaccinia virus, retrovirus, doxorubicin

1 Protocol referenced Plasmid expression vector

Application for IC 4200825: Approved pending.

Reviewed by Dr. Gelman

The Initial application for IC 4200825, 25-08-1688 entitled: "A Phase II Trial of the Immunogenicity of a DNA Plasmid-Based Vaccine (STEMVAC) Encoding Th1 Selective Epitopes from Five Antigens Associated with Breast Cancer Stem Cells (MDM2, YB1, SOX2, CDH3, CD105) in Patients with Metastatic Triple-Negative Breast Cancer" PI: Kabraji, Sheheryar was approved pending designated member review of a revised application.

The purpose of this protocol is to determine the ability of STEMVAC in combination with standard chemotherapy to suppress the progression of PD-L1-negative triple-negative breast cancer.

Biosafety agents include: STEMVAC (DNA vaccine)

Exempt from full committee review: None.

Amendments:

Application for Lab/1395M: Approved.

Reviewed by Dr. Gelman

The amendment for 1395M protocol 24-07-1608 entitled: "Qiang Li Biosafety Application" PI: Li, Qiang was approved 8/19/2025.

Biosafety agents used include: new cell lines.

Application for protocol Lab/1177M: Approved.

Reviewed by Dr. Thanavala

The amendment for 1177M protocol 24-05-1600 entitled: "Gelman Lab Biosafety Application" PI: Gelman, Irwin was approved 8/19/2025.

Biosafety agents used include: adding cell lines and compounds to cover 1177M.

Application for protocol Lab/1642M: Approved.

Reviewed by Dr. Gelman

The amendment for 1642M protocol 25-02-1656 entitled: "Deciphering the Interplay Between Metabolism and Tumor Initiation, Growth and Progression" PI: Wilde, Blake was approved 8/26/2025.

Biosafety agents used include: 2 human cell lines.

Application for 1094M: Approved.

Reviewed by Dr. Gelman

The amendment for 1094M protocol 120501 entitled: "CAR T Cell Production and Myeloma/CD Signal Transduction Pathways" PI: Olejniczak, Scott was approved 9/9/2025.

Biosafety agents used include: modified animal cell line.

See attached for complete list.

Respectfully Submitted,



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