

## **Minutes of the Institute Biosafety Committee Meeting**

**November 12, 2025**

**Convened at: 1:01 pm and Adjourned at 1:25 pm**

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

**Absent:** Dr Ionov, Ms Pusateri and Mr. Atwal

**ORSP Staff:** Ms Oliver, Ms Herter Ms. Bennett and Mr. Caruana

**Guests:** None.

**Meeting Place:** Virtual meeting/Teams.

**Minutes** of October 8, 2025 were approved.

**Vote:** Unanimous.

### **Adverse Event/Accident/Incident Report**

September Employee Health Service report; no follow up required.

ORSP - No reports.

### **Old Business**

1. Safety Story; this months story highlighted speaking up for safety.
2. Laboratory inspections; May and September 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 September 4<sup>th</sup> with Dr. McGray joining the team:
  - a. Paragh level 2 lab: OES will follow up (see checklist for details).
  - b. Das level 2 lab: OES will follow up (see checklist for details).
3. 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. Update 10/8: Dr. Gelman provided a link to a NIH Sponsored listening session that he attended regarding the new Initiative. **Update 11/12:** No new update. Topic will be removed from minutes but the committee will be informed of any new updates as they occur.

### **New Business:**

1. 3 Laboratories were visited October 9th with Dr. Ionov joining the team.
  - a. McGray BSL 2 lab: No follow up required.
  - b. Atanassov BSL2+lab: OES will follow up (see checklist for details).
  - c. Feigin BSL2+ lab: No follow up required.The next inspection dates will be Thursday November 13<sup>th</sup> with Dr. McGray joining the team and Thursday December 11<sup>th</sup> with Dr. Ding joining the team.
2. The administrative staff reviewed an updated Continuing review question with the committee. The update will request further information when an IRB related continuing review is required. Questions were reviewed and approved. The administrative staff will work with Key Solutions personnel to get the questions updated.

### **Protocol review:**

8 Biosafety applications were reviewed. 3 were continuing reviews.

### **1 Protocol referenced Virus**

Application for P 4594825M: Approved pending.

Reviewed by Dr. McGray

The Initial application for P 4594825, 25-10-1692 entitled: "P 4594825 The CAROLYN Trial: Lisocabtagene Maraleucel as First-Line Therapy for Primary Central Nervous System Lymphoma (PCNSL) in Transplant-Ineligible Patients (CA082-1215)" PI: Schofield, Grant was approved pending designated member review of a revised application.

The purpose of this protocol is to evaluate whether liso-cel infusion results in improved efficacy in first line therapy for PCNSL in transplant-ineligible patients.

Biosafety agents include: lentivirus

Exempt from full committee review: None.

#### **Amendments:**

Application for Lab/1612M: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based/1612M 25-02-1652 entitled: "Ohm Lab Biosafety Protocol" PI: Ohm, Joyce was approved as Exempt from full committee review 10/10/2025.

Biosafety agents used include: Cell lines and CAR T cells.

Application for Lab/960M: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based/960M 24-11-1636 entitled: "Preclinical Evaluation of Novel Biological Therapies in Immunodeficient Mice Engrafted with Human and Murine Hematological Malignancies" PI: Wang, Eunice was approved as Exempt from full committee review 10/16/2025.

Biosafety agents used include: Human primary cells.

Application for Lab/1492M: Approved.

Reviewed by Dr. Gelman

The amendment to 1492M (Old form) entitled: "Targeting DNA Damage Repair Pathways in Ovarian Cancer" PI: McLean, Karen was approved as Exempt from full committee review 10/24/2025.

Biosafety agents used include: new compound.

Application for Lab/1545M: Approved.

Reviewed by Dr. Gelman

The amendment to Lab based/1545M 24-04-1587 entitled: "Biosafety Protocol for Betts Lab" PI: Betts, Brian was approved as Exempt from full committee review 11/5/2025.

Biosafety agents used include: New cell line.

See attached for complete list.

Respectfully Submitted,



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