

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

**October 8, 2025**

**Convened at: 1:02 pm and Adjourned at 1:56 pm**

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

**Absent:** Dr Gerber, Dr. Ding, and Mr. Atwal

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

**Guests:** None.

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

**Minutes** of September 10, 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 and speaking up for safety.
2. Laboratory inspections; June and August have been completed. 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.

### **New Business:**

1. The next inspection date will be Thursday October 9th with Dr. Ionov joining the team.  
The next inspection date will be Thursday November 13<sup>th</sup> with Dr. McGray joining the team.
2. Dr. Gerber reported that Mr Moslow has retired and Ms Chapman will be the Interim Director of OES.

### **Protocol review:**

4 Biosafety applications were reviewed.

### **2 Protocols referenced Cores**

Application for Core: Approved pending.

Reviewed by Dr. Foster

The Initial Key application for Core, 24-09-1630 entitled: "Biosafety Application for the Genomics Shared Resource." PI: Singh, Prashant was approved pending designated member review of a revised application.

The purpose of this protocol is to analyze cell, tumor and clinical samples by DNA or RNA sequencing.  
Biosafety agents include: Human specimens.

Application for Core protocol: Approved pending.

Reviewed by Dr. Thanavala

The Initial Key application for Core protocol 25-09-1690 entitled: "Bioanalytics, Metabolomics, and Pharmacokinetics (BMPK) Shared Resource" PI: Rosario, Spencer was approved pending designated member review of a revised application.

The purpose of this protocol is to support pre-clinical/clinical research and drug development by providing PK/PD data on cell and clinical samples.

Biosafety agents used include: Human specimens.

### **1 Protocol referenced Virus**

Application for Lab/1384M: Approved.

Reviewed by Dr. McGray

The Initial Key application for Lab/1384M, 25-01-1646 entitled: "Mechanisms of Carcinogenesis and Novel Avenues for Therapeutic Intervention" PI: Knudsen, Erik was approved.

The purpose of this protocol is to analyze the role of CDKs, mainly CDK4/6 and CDK2, in maintaining cell replication as a mechanism for lung and pancreatic cancer progression.

Biosafety agents include: lentivirus, carcinogens/teratogens/mutagens.

Exempt from full committee review:

Application for Lab based: Approved.

Reviewed by Dr. McGray

The Initial Key application for Lab based 24-02-1656 entitled: "Foster Laboratory Biosafety Protocol" PI: Foster, Barbara was approved as Exempt from full committee review 9/16/2025.

Biosafety agents used include: Human/mouse cells/tissues and compounds.

**Amendments: None.**

See attached for complete list.

Respectfully Submitted,



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