

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

**July 9, 2025**

**Convened at: 1:17 pm and Adjourned at 2:00 pm**

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

**Absent:** Drs Gelman, Ionov, Ms Keough, Ms Oliver, Mr. Atwal, Ms. Bennett

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

**Guests:** None.

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

**Minutes** of June 11, 2025 were approved.

**Vote:** Unanimous.

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

June Employee Health Service report; no follow up required.

ORSP - No reports.

### **Old Business**

1. Safety Story; this months story highlighted being aware and having a questioning attitude.
2. Laboratory inspections; December and March checklists completed. April and May pending:  
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. 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. **Update 7/9:** Memo was sent out to all research staff at the institute regarding the need for Biosafety applications prior to work being performed in the laboratory. PIs biosafety submission will be reviewed at todays meeting, and all training has been completed.

### **New Business:**

1. 3 Laboratories were visited June 18th with Dr. Ionov joining the team.
  - a. Seshadri level 2 lab: No follow up required.
  - b. Flow Cytometry Shared Resource level 2+ lab: OES will follow up (see check list for details).
  - c. Hernandez level 2 lab: OES will follow up (see checklist for details).The next inspection date will be Thursday August 7<sup>th</sup> with Dr. Thanavala joining the team. The July inspection date is canceled.

Protocol review:

10 Biosafety applications were reviewed.

## **2 Protocols referenced Virus**

Application for Lab based 1622M: Approved pending.

Reviewed by Dr. Ding

The Initial application for Lab based/Benchwork/1622M, 24-08-1615 entitled: “Mechanisms Underlying Ncl-driven Breast Cancer Progression and Metastasis” PI: Liu, Xuhang was approved pending designated member review of a revised application.

The purpose of this protocol is to investigate mechanisms underlying breast cancer progression and metastasis.

Biosafety agents include: lentivirus

Application for protocol P4161025: Approved pending.

Reviewed by Dr. McGray

The Initial application for protocol P4161025, 25-06-1674 entitled: “P4161025-A phase 1b/2 Study of GC012F (AZD0120), a Chimeric Antigen Receptor T-Cell (CAR-T) Therapy Targeting CD19 and B-Cell Maturation Antigen (BCMA) in Subjects with Relapsed/Refractory Multiple Myeloma” PI: Hassan, Hamza was approved pending designated member review of a revised application.

The purpose of this protocol is to evaluate in a Phase 1b and Phase 2 clinical trials the safety, tolerability dose and the efficacy of the CAR-T cells in patients with relapsed multiple myeloma.

Biosafety agents used include: lentivirus

## **3 Protocols referenced Continuing review:**

Application for Lab/1545M: Approved.

Reviewed by Dr. Gelman

The Continuing review for Lab/1545M protocol 24-04-1587 entitled: “Biosafety Protocol for Betts Lab” PI: Betts, Brian was approved 7/02/2025 with only personnel changes.

Application for Lab: Approved.

Reviewed by Dr. Thanavala

The Continuing review for Lab protocol 24-05-1600 entitled: “Gelman Lab Biosafety Application” PI: Gelman, Irwin was approved 6/30/2025 with only personnel changes.

Application for 1473F: Approved.

Reviewed by Dr. Gelman

The Continuing review for 1473F protocol 24-07-1604 entitled: “Assisted Reproductive Technologies (ART) in the Cat Model” PI: Sexton, Sandra was approved 6/30/2025 with only personnel changes.

## **Exempt from full committee review:**

Application for protocol 1477M/Bench: Approved.

Reviewed by Dr. Ionov

The renewal application for 1477M/bench protocol 25-05-1670 entitled: “Activating Anti-MDS Immunity through Restoration of the Immune Microenvironment” PI: Nemeth, Michael was approved as Exempt from full committee review 6/12/2025.

Biosafety agents used include: Human specimens in vitro and Teratogen/mutagen; Decitabine.

**Amendments:**

Application for Lab based: Approved.

Reviewed by Dr. Gelman

The amendment for Lab based protocol 24-03-1572 entitled: "Enhancement of PDT Using Biological Response Modifiers" PI: Shafirstein, Gal was approved 6/13/2025.

Biosafety agents used include: OVCAR2 cell line.

Application for protocol Lab based 1404M: Approved.

Reviewed by Dr. Gelman

The amendment for Lab based 1404M protocol 24-08-1621 entitled: "Leveraging Metabolic Vulnerabilities in Cancer" PI: Bianchi-Smiraglia, Anna was approved 6/17/2025.

Biosafety agents used include: E0771 cell line modified to be Dox resistant.

Application for Lab based/1102R: Approved.

Reviewed by Dr. Gelman

The amendment for Lab based/1102R protocol 23-12-1557 entitled: "Toxicologic Evaluation of Test Articles in Rats" PI: Sexton, Sandra was approved 6/23/2025.

Biosafety agents used include: new compound per OES.

Application for Lab based/1143M: Approved.

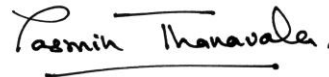
Reviewed by Dr. Gelman

The amendment for Lab based/1143M protocol 24-05-1599 entitled: "Studying the Biology of Interactions Between Tumor Cells and Immune Cells with the Tumor Microenvironment" PI: Mohammadpour, Hemn was approved 6/30/2025.

Biosafety agents used include: YUMM1.7 cell line and compounds; Resiniferatoxin and Rimegepant.

See attached for complete list.

Respectfully Submitted,

A handwritten signature in black ink that reads "Yasmin Thanavala." The signature is written in a cursive style with a horizontal line underneath the name.

Yasmin Thanavala, PhD  
Institute Biosafety Committee Co-Chair  
Professor of Oncology, Immunology