MINUTES FOR THE BIOSAFETY COMMITTEE

Thursday November 13, 2025 Meeting 2:30pm

PRESENT: Christopher Schmoutz, Ph.D., Vice–Chairman

Stephanie Ander, Ph.D.
Jessica Esparza, Ph.D.
Sarah Harold, B.S., Ex-Officio
Demonzo Mcginnis,B.S.(BSO)
Hugh Price, DVM
Krista Rodgers, Ph.D.
Hong Sun, Ph.D.
Vesna Tesic, Ph.D.
Ana Maria Dragoi, Ph.D.
Hongyan Guo, Ph.D.
Seong Kim, Ph.D
Rebecca Murphy, Ph.D.
Krista Queen, Ph.D. Ex-Officio
Xinggui Shen, Ph.D.
Tousif Sultan, Ph.D

ABSENT:

Arrigo "Ricky" De Benedetti, Ph.D., Chairman.
Omar Franco, M.D., Ph.D
Ashley Krukowsky, (OSP) Ex-Officio
Michael Stroud, B.S., (BOS)

I. **MEETING CALLED TO ORDER:** The meeting called to order at 2:30pm with a quorum of 14 voting members.

II. **Approval of Minutes from the previous meeting.** Minutes October 30, 2025

III. **NEW PROTOCOLS TO BE CONSIDERED:** The sponsors of both clinical trials are requesting Biosafety Protocols.

IV. The sponsors of both clinical trials are requesting Biosafety Protocols.

B26-009 – Hematology/Oncology – Clinical Trial:
A Phase 3 Study of a arlocabtagene autoleucel, a GPRC5D-directed CAR T Cell Therapy (Quintessential 2 CA 088 clinical trial) in Participants with Relapsed or Refractory Multiple Myeloma and Refractory to Lenalidomide

B26-010 – Hematology/Oncology – Clinical Trial:
A phase 2, open-label, multicenter study of MB-105 in patients with CD5 positive (CD5+) relapsed / refractory T-cell lymphoma (r/r TCL).

The committee determined more time was required to adequately review the protocols and both were **TABLED with MODIFICATIONS REQUIRED** by unanimous vote.

V. CONTINGENT APPROVALS:

B25-007 –To date the has been no response to the committee's comments. She plans to submit her BSL3 revisions at a later date.

B26-004 – CONTINGENT APPROVAL MODIFICATIONS REQUIRED by unanimous vote with a quorum present. The PI has responded to the committee's comments and the protocol remains it the CONTIGENT APPROVAL category.

B26-008 –– INVESTIGATING AFFERENT BAROREFLEX DYSFUNCTION IN HYPERTENSION. The PI responded to the all committee comments and the protocol was moved to the **FULLY APPROVED category**.

VI. TERMINATIONS: None

VII. Old Business: None

VIII. NEW BUSINESS:

B15-088 – Modification to add plasmids form Addgene was approved.

IX. ANNUAL RENEWALS: Fully approved by unanimous vote:

B25-002 Neurology
B25-003 Microbiology
B25-005 Microbiology

X. NON-RESPONDER ANNUAL RENEWALS:

B23-001 Pathology

XI. ADD/DELETE MEMOS: All listed completed training and were approved by unanimous vote unless indicated. Contingent until complete.

B12-004 Anatomy ADD Research Associate
B20-007 Pharmacology ADD Transient Employee
B24-001 Neurosurgery ADD Gratis Faculty

XII. Contingent ADD MEMOS:

B21-002 Pathology
ADD: Resident (training incomplete)
ADD: Medical Student (training incomplete)
B22-001 Neurology
ADD: Postdoc (training incomplete)
B26-004 Microbiology
ADD: Two Postdocs
Training is complete for the above lab personnel. They will be added when the biosafety is approved.

Adjourn: 3:30pm

Respectfully submitted:

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Sarah Harold, B.S., Coordinator

Approved:

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Arrigo DeBenedetti, Ph.D.
Chairman, Biosafety Committee