



Meeting Minutes

June 25, 2025

Location: Zoom Meeting

Time: 9:55 am

IBC Members present

Laurie P. Shornick, Ph.D.	IBC Chairperson, Voting member
Adriana M. Montano, Ph.D.	IBC Vice Chairperson, Voting member
Christopher S. Eickhoff, M.S.	Biological Safety Officer, Voting member
Tamara P. Blevins, M.S.	Assistant Biological Safety Officer, Alternate BSO voting member
Geoffrey J. Gorse, M.D.	Other: Emeritus, Voting member
Karoly Toth, D.V.M.	Lab Rep, Animal Expert, Voting Member
Paul M. Loewenstein, B.S.	Other: Emeritus, Voting member
Corey Ragsdale, Ph.D.	Local Non-Affiliated, Voting member
Melinda S. Darnell, B.S.	Plant expert, Voting member
Kathleen Donovan, D.V.M.	Animal expert, Voting member
Andrew J. Lechner, Ph.D.	Lab Rep, Voting Member
Ella M. Swierkosz, Ph.D.	Other: Emerita Professor, Voting member
Anna Schmidt, Pharm.D., BCPS	Ad hoc SSM SLUH, Voting member
Patricia Osmack, MLS(ASCP), M.A., RBP	IBC Manage, IBC RMS Contact, Non-voting
Renee Knoll, M.S., CHMM (Consultant)	Other: EHS Director & Chemical Hygiene Officer, Non-voting
Steve Tinge, CPIA (Consultant)	Other: IACUC Manager, Non-voting

I. Old Business

A. Approval of Minutes

- 1. None

B. Closed Items (Protocols fully approved between meetings):

1. New protocols previously granted contingent approval by the full IBC where the PI responses were reviewed and approved between meetings by the BSO or designee:
 - o Hamilton, Zachary, M.D., (Surgery-Urology) New SSM SLUH eIBC Protocol ID: 2024-00060.
2. Amendments or continuing reviews with changes previously granted contingent approval by the full IBC where the PI responses were reviewed and approved by the BSO or designee:
 - o None
3. Amendments not meeting threshold of requiring full committee review based on NIH guidelines and SLU IBC Policy that were reviewed and approved by the BSO or designee:
 - o Goyal, Sagun, M.D., (IM-Hematology/Oncology) Two amendments to SSM SLUH eIBC Protocol ID: 2023-00049.
 - o Lentine, Krista, M.D., (IM-Nephrology) Amendment to SSM SLUH eIBC Protocol ID: 2024-00059.

4. Continuing reviews not meeting threshold of requiring full committee review based on NIH guidelines and SLU IBC Policy that were reviewed and approved by the BSO or designee:
 - Goyal, Sagun, M.D., (IM-Hematology/Oncology) Amendment to SSM SLUH eIBC Protocol ID: 2023-00049.

5. Protocols Closed (at the request of the PI):
 - None

6. Draft Protocols Withdrawn (after review by the BSO per NIH Guidelines):
 - Rischall, Ariel, M.D., (IM-Hematology/Oncology) New SSM SLUH eIBC Protocol ID: 2025-00021.
 - Goyal, Sagun, M.D., (IM-Hematology/Oncology) Amendment to SSM SLUH eIBC Protocol ID: 2023-00049.

C. Open Items (Protocols reviewed by the IBC but not fully approved)

1. New protocols previously granted contingent approval by the full IBC where the PI responses have not yet been approved:
 - None

II. New Business

A. New Protocols

1.

Principle Investigator	Goyal, Sagun, M.D.,
Department	IM-Hematology/Oncology
Protocol #	2025-00022
Title	JCAR017 EAP-001: Expanded Access Protocol (EAP) For Subjects Receiving Lisocabtagene Maraleucel (Breyanzi / Liso-Cel) That Is Nonconforming for Commercial Release
Protocol Description	Lisocabtagene Maraleucel (Breyanzi / Liso-Cel) is a CAR-T cell therapy used for adults with various cancers. The purpose of this study is to provide access to and collect data on subjects receiving this therapy that is nonconforming for commercial product release.
Types of manipulation	Humans
Agents	CAR-T cells: Human Nonconforming Lisocabtagene Maraleucel
Containment level	BSL-2
Applicable section of NIH Guidelines	III-C-1
IBC Review	The committee performed a risk assessment to determine the biocontainment levels, and reviewed training, facilities (locations and inspections), procedures and practices, agent characteristics, and if used, rsNA details (gene sources, nature, hosts and vectors, and attempts of expression and function of any transgenes).
IBC comments (to be addressed by PI)	The SSM SLUH IBC did not have any comments or concerns.
IBC Decision	The SSM SLUH IBC provided full approval of the protocol (12-yes 0-no/0-abstention). Follow-up action: None.

B. Five Year Renewals of eIBC Protocols:

1. None

C. Amendments & Continuing Reviews of Approved eIBC Protocols:

1. None

D. Protocols in Pre-Review:

1. New protocols: 0
2. Amendments: 1
3. Annual continuing reviews: 0


E. Other Business:

1. None


The meeting was adjourned at approximately 10:00 am.

Respectfully Submitted:

Reviewed:

Signed by:

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Patricia A. Osmack, MLS(ASCP), M.A., RBP(ABSA)
Institutional Biosafety Committee Manager

DocuSigned by:

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Christopher S. Eickhoff, M.S.
Biological Safety Officer & Executive
Secretary Institutional Biosafety Committee

Approved:

Reviewed:

DocuSigned by:

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Laurie P. Shornick, Ph.D.
Institutional Biosafety Committee Chairperson

DocuSigned by:

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Lee Seabrooke, M.B.A.
Associate Vice President for Research