SAINT LOUIS UNIVERSITY

Institutional Biosafety Committee
Meeting Minutes

June 25, 2025

Location: Zoom Meeting **Time:** 9:30 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, only present for the SSM SLUH eIBC# 2025-00022 review
Patricia Osmack, MLS(ASCP), M.A., RBP	IBC Manager, 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. The minutes for the May 28, 2025, SLU IBC meeting were fully approved: 11-yes/0-no/0-abstentions (Anna Schmidt was not present).

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:
   - Salvemini, Daniela, Ph.D., (Pharmacology & Physiological Science) 5-Yr. renewal eIBC Protocol ID: 2025-00019.
   - Abate, Getahun, M.D., Ph.D., (IM-Infectious Disease) eIBC Protocol ID: 2025-00023.
   - Dhindsa, Sandeep, M.D., (IM-Endocrinology) 5-Yr. renewal eIBC Protocol ID: 2025-00024.

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:
   - Toth, Karoly, Ph.D., (Molecular Microbiology & Immunology) eIBC Protocol ID: 2024-00023.

- Rafiei, Hossein, Ph.D., (Department: Nutrition and Dietetics) eIBC Protocol ID: 2025-00013.
- Touchette, Erin, M.S., (Comparative Medicine, Inotiv) eIBC Protocol ID: 2024-00057.
- Touchette, Erin, M.S., (Comparative Medicine, Inotiv) eIBC Protocol ID: 2025-00014.
- Touchette, Erin, M.S., (Comparative Medicine, Inotiv) eIBC Protocol ID: 2024-00017.
- Ungerleider, Nathan, Ph.D., (Molecular Microbiology & Immunology) eIBC Protocol ID: 2024-00043.
- Lin, Chien-Jung, M.D., (IM-Cardiology) eIBC Protocol ID: 2024-00005.

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:
   - Navia Pelaez, Juliana Maria, Ph.D., (Pharmacology & Physiological Science) eIBC Protocol ID: 2024-00009.
   - Syn, Wing-Kin, M.D., (IM-Gastroenterology) eIBC Protocol ID: 2023-00051.
   - Adolph, Madison, Ph.D., (Biochemistry & Molecular Biology) eIBC Protocol ID: 2024-00045.
   - Ferris, Stephen, Ph.D., (Molecular Microbiology & Immunology) eIBC Protocol ID: 2022-00036.
   - Hillman, Noah, M.D., (Pediatrics) eIBC Protocol ID: 2023-00011.
   - Antony, Edwin, Ph.D., (Biochemistry & Molecular Biology) eIBC Protocol ID: 2024-00055.
   - Jagger, Brett, M.D., Ph.D., (IM-Infectious Diseases) eIBC Protocol ID: 2024-00007.
   - Teague, Ryan, Ph.D., (Molecular Microbiology & Immunology) eIBC Protocol ID: 2021-00026.
   - Fisher, Jonathan, Ph.D., (Biology) eIBC Protocol ID: 2021-00011.
   - Miyata, Kana, Ph.D., (IM-Nephrology) eIBC Protocol ID: 2022-00020.
   - Montano, Adriana, Ph.D., (Pediatrics) eIBC Protocol ID: 2024-00030.
   - Montano, Adriana, Ph.D., (Pediatrics) eIBC Protocol ID: 2022-00004.
   - Hoft, Dan, M.D., Ph.D., (IM-Infectious Diseases) eIBC Protocol ID: 2025-00020.
   - Ungerleider, Nathan, Ph.D., (Molecular Microbiology & Immunology) eIBC Protocol ID: 2024-00043.
   - Hoft, Dan, M.D., Ph.D., (IM-Infectious Disease) eIBC Protocol ID: 2025-00020.
   - Lemaire, Laurence Anne, Ph.D., (Biology) eIBC Protocol ID: 2023-00028.
   - Nazzal, Mustafa, M.D., (Abdominal Transplant Center) eIBC Protocol ID: 2023-00048.
   - Sengupta, Mohini, Ph.D., (Biology) eIBC Protocol ID: 2023-00031.
   - Hoft, Dan, M.D., Ph.D., (IM-Infectious Disease) eIBC Protocol ID: 2025-00020.
   - Cifarelli, Vincenza, Ph.D., (Pharmacol0gy & Physiological Science) eIBC Protocol ID: 2022-00006.
   - Janowiak Mulligan, Blythe, Ph.D., (Biology) eIBC Protocol ID: 2023-00004.
   - Lin, Chien-Jung, M.D., (IM-Cardiology) eIBC Protocol ID: 2024-00005.
   - Teckman, Jeffrey, M.D., (Pediatrics) eIBC Protocol ID: 2022-00002.
   - Teckman, Jeffrey, M.D., (Pediatrics) eIBC Protocol ID: 2024-00060.

- Fleming, Robert, M.D., Ph.D., (Pediatrics) eIBC Protocol ID: 2021-00020.
- Jain, Ajay, M.D., (Pediatrics) eIBC Protocol ID: 2023-00039.

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:
   - Hurley, Maria, M.D., (Dermatology) SSM SLUH eIBC Protocol ID: 2024-00008.
   - Exil, Vernat, M.D., (Pediatrics) eIBC Protocol ID: 2023-00038.
   - Toth, Karoly, Ph.D., (Molecular Microbiology & Immunology) eIBC Protocol ID: 2024-00023.

5. Protocols Closed (at the request of the PI):
   - Abate, Getahun, M.D., Ph.D., (IM-Infectious Disease) eIBC Protocol ID: 2015-00002.

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.

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 Maraleucal (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
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.

Principle Investigator	Tavis, John, Ph.D.,
Department	Molecular Microbiology & Immunology
Protocol #	2025-00028
Title	Tavis Lab Standard Hepatitis B Virus Biosafety Protocol (5 year renewal of 2020-00022)
Protocol Description	This protocol details Hepatitis B virus (HBV) studies to evaluate the molecular biology and biochemistry of HBV reverse transcription, and further, to determine if hamsters transduced with the human cellular receptor for HBV support productive HBV replication.
Types of manipulation	Laboratory & animal
Agents	Human blood products, tissue, and cell lines, HBV, plasmids, and replication-defective adenovirus
Containment level	BSL-2
Applicable section of NIH Guidelines	III-D-1, III-D-4
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 IBC requested clarification about safely transporting biological agents within the building, the type of container used to precipitate HBV virions, and animal specimen collection.
IBC Decision	The IBC provided contingent approval of the protocol (11-yes 0-no/0-abstention). Follow-up action: designated review by the BSO or designee.

2.

Principle Investigator	Baum, Dana, Ph.D.,
Department	Chemistry
Protocol #	2025-00030
Title	In Vitro Selection and Investigations of Functional Nucleic Acids (Aptamers, Deoxyribozymes, Ribozymes, and Aptazymes) - 5 year renewal of Protocol 2015-24498
Protocol Description	Various *E. coli* expression systems will be used to identify and characterize DNA and RNA sequences capable of binding (aptamers) or catalysis (deoxyribozymes and ribozymes).
Types of manipulation	Laboratory
Agents	*Escherichia coli* strains and plasmids
Containment level	BSL-1
Applicable section of NIH Guidelines	III-E, III-F-3
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 IBC requested that the description for treating liquid waste be updated for consistency and to state that the secondary container for transporting gels stained with ethidium bromide be leak-proof and puncture resistant.
IBC Decision	The IBC provided contingent approval of the protocol (11-yes 0-no/0-abstention). Follow-up action: designated review by the BSO or designee.

C. Amendments & Continuing Reviews of Approved eIBC Protocols:

1.

Principle Investigator	Spencer, Susan, Ph.D.,
Department	Biology
Protocol #	2023-00016
Title	Investigation of the spindle-associated protein CG10126/Calcyphosine in Drosophila and in cultured human cells (5-year renewal of 2018-00011)
Protocol Description	The IBC approved protocol describes studies in Drosophila melanogaster and human cell lines to study genes expressed in response to EGFR signaling. This amendment updates personnel and adds new plasmids.
Types of manipulation	Amendment: Laboratory
Agents	Amendment adds new plasmids
Containment level	Amendment: BSL-1
Applicable section of NIH Guidelines	Amendment: III-D-2
IBC Review	The committee performed a risk assessment based on the changes made in relation to the approved protocol 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 IBC did not have any comments or concerns.
IBC Decision	The IBC provided full approval of the protocol (11-yes 0-no/0-abstention, Anna Schmidt was not present). Follow-up action: designated review by the BSO or designee.

2.

Principle Investigator	Hannan, Thomas, Ph.D.,
Department	Comparative Medicine, Fimbrion
Protocol #	2021-00024
Title	Anti-virulence therapies for the treatment and prevention of bacterial infections (5-year renewal of 2016-24575)
Protocol Description	The IBC approved protocol details the study of new molecules against various bacteria. The amendment adds a new non-recombinant bacterium (*Pseudomonas aeruginosa)* used with a new infection model.
Types of manipulation	Amendment: Animal
Agents	Amendment adds *Pseudomonas aeruginosa (non-recombinant)*
Containment level	Amendment: ABSL-2
Applicable section of NIH Guidelines	Approved protocol: III-D-4-b Amendment: None (no rsNA)
IBC Review	The committee performed a risk assessment based on the changes made in relation to the approved protocol 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 IBC requested further details on the proposed *Pseudomonas aeruginosa* stains (source, antibiotic susceptibility testing, signs and symptoms of accidental exposure, and preparation of challenge doses). Clarification on the surface disinfection methodology is also required.
IBC Decision	The IBC provided contingent approval of the protocol (11-yes 0-no/0-abstention, Anna Schmidt was not present.) Follow-up action: designated review by the BSO or designee.

D. Protocols in Pre-Review:

1. New protocols: 3
2. Amendments: 4
3. Annual continuing reviews: 0

E. Other Business:

1. None

The meeting was adjourned at approximately 9:55 am.

Respectfully Submitted:

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

Reviewed:

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