SAINT LOUIS UNIVERSITY

Institutional Biosafety Committee
Meeting Minutes

July 23, 2025

Location: Zoom Meeting **Time:** 9:30 am

IBC Members present

Laurie P. Shornick, Ph.D.	IBC Chairperson, Voting member
Christopher S. Eickhoff, M.S.	Biological Safety Officer, Voting member
Steven Cummings, M.D.	Occupational Health Program Manager, 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
Wayne A. Wilhelm, B.S.	Local Non-Affiliated, Voting member
Corey Ragsdale, Ph.D.	Local Non-Affiliated, 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
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
Frank Speck	Other: Comparative Medicine Manager, Non-voting
Steve Tinge, CPIA (Consultant)	Other: IACUC Manager, Non-voting

I. Old Business

A. Approval of Minutes

1. The minutes for the June 25, 2025, SLU IBC meeting were fully approved: 11-yes/0-no/0-abstentions.
2. The minutes for the June 25, 2025, SSM SLUH IBC meeting were fully approved: 12-yes/0-no/0-abstentions (Anna Schmidt, SSM ad hoc IBC representative, by email)

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:
   - Baum, Dana, Ph.D., (Chemistry) Five-year renewal, eIBC Protocol ID: 2025-00030.
   - Tavis, John, Ph.D., (Molecular Microbiology & Immunology), Five-year renewal, eIBC Protocol: 2025-00028.

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:
   - Hannan, Thomas, Ph.D., Ph.D., (Comparative Medicine, Fimbrion) eIBC Protocol ID: 2021-00024.

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:

- Jain, Ajay, M.D., (Pediatrics) eIBC Protocol ID: 2023-00039.
- Exil, Vernat M.D., (Pediatrics) eIBC Protocol ID: 2023-00048.
- Baldan, Angel, Ph.D., (Biochemistry & Molecular Biology) eIBC Protocol ID: 2024-00029.
- Hoft, Daniel, M.D., Ph.D., (IM-Infectious Diseases) eIBC Protocol ID: 2023-00001.
- Karunarathne, Welivitiya, Ph.D., (Chemistry) eIBC Protocol ID: 2022-00018.
- Lemaire, Laurence Anne, Ph.D., (Biology) eIBC Protocol ID: 2023-00028.
- Touchette, Erin, M.S., (Comparative Medicine, Inotiv) eIBC Protocol ID: 2024-00017.
- Touchette, Erin, M.S., (Comparative Medicine, Inotiv) eIBC Protocol ID: 2024-00017.
- Baldan, Angel, Ph.D., (Biochemistry & Molecular Biology) eIBC Protocol ID: 2021-00025.
- Montano, Adriana, Ph.D., (Pediatrics) eIBC Protocol ID: 2024-00030.
- Janowiak Mulligan, Blythe, Ph.D., (Biology) eIBC Protocol ID: 2023-00004.
- Yosten, Gina, Ph.D., (Pharmacology & Physiological Science) eIBC Protocol ID: 2024-00032.
- Lin, Chien-Jung, M.D., (IM-Cardiology) eIBC Protocol ID: 2024-00005.
- Korolev, Sergey, Ph.D., (Biochemistry & Molecular Biology) eIBC Protocol ID: 2024-00053.

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:
   - Fleming, Robert, M.D., Ph.D., (Pediatrics) eIBC Protocol ID: 2024-00026.
   - Montano, Adriana, Ph.D., (Pediatrics) eIBC Protocol ID: 2024-00028.
   - Montano, Adriana, Ph.D., (Pediatrics) eIBC Protocol ID: 2024-00029.
   - Montano, Adriana, Ph.D., (Pediatrics) eIBC Protocol ID: 2024-00030.
   - Montano, Adriana, Ph.D., (Pediatrics) eIBC Protocol ID: 2024-00033.
   - Sell, Scott, Ph.D., (Biomedical Engineering) eIBC Protocol ID: 2024-00020.
   - Tavis, John, Ph.D., (Molecular Microbiology & Immunology) eIBC Protocol ID: 2023-00023.
   - Montano, Adriana, Ph.D., (Pediatrics) eIBC Protocol ID: 2024-00034.
   - Tetri, Brent, M.D., (IM-Gastroenterology) eIBC Protocol ID: 2024-00012.
   - Samson, Willis, Ph.D., (Pharmacology & Physiological Science) eIBC Protocol ID: 2024-00032.
   - Francois-Moutal, Liberty, Ph.D., (Pharmacology & Physiological Science) eIBC Protocol ID: 2024-00018.
   - Goyal, Sagun, M.D., (IM-Hematology/Oncology) SSM SLUH eIBC Protocol ID: 2023-00025.
   - Wang, Yuqi, Ph.D., (Biology) eIBC Protocol ID: 2023-00017.

5. Protocols Closed (at the request of the PI):
   - Ray, Ranjit, Ph.D., (IM-Infectious Diseases) eIBC Protocol ID: 2020-00014.

6. Draft Protocols Withdrawn (after review by the BSO per NIH Guidelines):
   - None

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	Donlin, Maureen, Ph.D.
Department	Biochemistry & Molecular Biology
Protocol #	2025-00032
Title	Storage of fungal species for future drug screening and biological assessment
Protocol Description	Various fungal species will be stored frozen and will be propagated only for purposes of sharing strains with other researchers.
Types of manipulation	Laboratory
Agents	Fungal species
Containment level	BSL-2
Applicable section of NIH Guidelines	N/A (no rsNA agents added)
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 an update to the title and general purpose of this protocol to reflect the work which will be done, clarification on the PPE which will be worn for different activities and when a BSC will be used, and documentation on the specific disinfectant used.
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	Mohammed, Bassem, Ph.D.
Department	Biochemistry & Molecular Biology
Protocol #	2025-00025
Title	Biochemistry and Immunobiology of Coagulation Proteins
Protocol Description	The PI is studying the structure and function of coagulation proteins with the aim of understanding physiology, treating pathologic clotting, and bleeding. The experimental approach merges classical enzymology for structural function study of coagulation proteins using plasma derived and recombinant proteins.
Types of manipulation	Laboratory & animal
Agents	Human blood products, insect, animal and human cell lines, bacteria and plasmids
Containment level	BSL-1, BSL-2, ABSL-1 & ABSL-2
Applicable section of NIH Guidelines	III-D-4, III-E, III-F8
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 information about source and volumes of human blood products used. The IBC also requests clarification on specific PPE worn for different activities, when a BSC will be used, agent transport, and asked the PI to copy specific gene information to another location in the protocol.
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.

B. Five Year Renewals of eIBC Protocols:

1.

Principle Investigator	Di Cera, Enrico, Ph.D.
Department	Biochemistry & Molecular Biology
Protocol #	2025-00027
Title	Mutagenesis of serine proteases (5-year renewal for eIBC protocol# 2020-00030)
Protocol Description	The PI is studying the structure and function of serine proteases. Specifically, the interaction of prothrombin with prothrombinase leading to generation of thrombin and blood clotting, and the interaction of the thrombin-thrombomodulin complex with protein C initiating the negative feed-back loop that shuts down the coagulation response.
Types of manipulation	Laboratory
Agents	Human cell lines, human blood products, bacteria and plasmids
Containment level	BSL-2
Applicable section of NIH Guidelines	III-E, III-F-8
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 on the specific PPE worn for different activities, when a BSC will be used, how biological agents are transported between lab spaces, specifics of equipment decontamination, and the maximum volume of human plasma used.
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	Vankayalapati, Rama Krishna, Ph.D.
Department	IM-Infectious Diseases
Protocol #	2024-00013
Title	Immune responses to *Mycobacterium tuberculosis* infection
Protocol Description	The PI is amending the scope of work to describe sample collection and tissue homogenization and is updating PPE details described in the protocol.
Types of manipulation	Amendment: Laboratory & animal
Agents	Amendment: Human blood products, bacteria
Containment level	Amendment: ABSL-2, ABSL-3, BSL-2 & BSL-3
Applicable section of NIH Guidelines	Amendment: N/A (no rsNA agents added)
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 correction of a couple of typos.
IBC Decision	The IBC provided full approval of the protocol (11-yes 0-no/0-abstention). Follow-up action: designated review by the BSO or designee.

2.

Principle Investigator	Ungerleider, Nathan, Ph.D.
Department	Molecular Microbiology & Immunology
Protocol #	2024-00043
Title	The Epstein Barr Virus in cancer
Protocol Description	The PI is adding new plasmids and genes for use in vitro.
Types of manipulation	Amendment: Laboratory
Agents	Amendment: plasmids and new genes
Containment level	Amendment: BSL-2
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 requested an updated research space floor plan.
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.

3.

Principle Investigator	Elliott, Melissa, Ph.D.
Department	Molecular Microbiology & Immunology
Protocol #	2024-00046
Title	Understanding approaches for using natural killer cells for treating cancer and infections.
Protocol Description	The PI is adding de-identified human tissues, updating lab personnel, and adding a new research location.
Types of manipulation	Amendment: Laboratory
Agents	Amendment: Human tissue
Containment level	Amendment: BSL-2
Applicable section of NIH Guidelines	Amendment: N/A (no rsNA agents added)
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 1) clarification on where the human breast cancer tissue will be obtained, 2) additional details on the attached IRB exemption letter, and 3) further information on tissue processing. The IBC Manager updated the training spreadsheet.
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.

4.

Principle Investigator	Touchette, Erin, M.S.
Department	Comparative Medicine, Inotiv
Protocol #	2024-00057
Title	Developing adenovirus gene therapy vectors optimized for the treatment of renal diseases
Protocol Description	The PI is adding a new route of adenoviral delivery.
Types of manipulation	Amendment: Laboratory & animal
Agents	Amendment: Recombinant virus
Containment level	Amendment: BSL-2 and ABSL-2
Applicable section of NIH Guidelines	Amendment: III-D-4, III-D-1
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). Follow-up action: none.

5.

Principle Investigator	Touchette, Erin, M.S.
Department	Comparative Medicine, Inotiv
Protocol #	2025-00014
Title	Characterization and evaluation of cell and gene therapy compounds in rodent models.
Protocol Description	The PI is adding human selected renal cells and updating personnel.
Types of manipulation	Amendment: Laboratory & animal
Agents	Amendment: Addition of human selected renal cells (SRC)
Containment level	Amendment: BSL-2 (CM OR) and ABSL-2
Applicable section of NIH Guidelines	Amendment: No rsNA modifications.
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 clarification on the specific PPE worn for injection of human selected renal cells and the attachment of an updated draft AUP including the new hazard class.
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.

D. Protocols in Pre-Review:

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

E. Other Business:

1. The committee voted on a motion to allow the following with regard to RG1 AAV in animals.
   - Allow ABSL1 spaces to be listed on the protocol as general ABSL1 facilities in specific buildings rather than listing individual rooms.
   - Allow the use of previously approved RG1 AAVs at ABSL1 using new waste procedures developed by Comparative Medicine.
     The motion was approved (11-yes 0-no/0-abstention).
2. The committee discussed how to reduce redundancy in eIBC protocols.
   - Describing PPE for the various research activities should be addressed in the protocol summary question 3 and not on the PPE checklist text box on page 6.
   - Transport and shipping should be described on page 7 question 2.a, which can be referenced in the protocol summary question 3.

The meeting was adjourned at approximately 10:46 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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Christopher S. Eickhoff, M.S.
Biological Safety Officer & Executive Secretary Institutional Biosafety Committee

Approved:

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