

Minutes

BRI Institutional Biosafety Committee Institutional Biosafety Committee 9/9/2025 1:00 pm Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:01 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 12 voting members present. A guorum was maintained for the entire meeting.

Confidentiality: The Chair reminded the committee that while the meeting is open to the public, the information discussed during the meeting should be treated as confidential.

Conflict of Interest: The Chair asked the committee if any members needed to declare a conflict of interest with respect to any matter on the agenda. The Chair notified committee members that if they had a conflict of interest, they must leave the room during the final discussion and voting on that IBC submission.

2 Attendees

Committee Members Present

Lewis Bowen III (Finance and Administration)
Lezi E (Cell Biology, Neurobiology and Anatomy)

Benjamin Gantner (Medicine) Kunal Gupta (Neurosurgery) Anna Huppler (Pediatrics) Eric Jensen (Research Office) Tyce Kearl (Medicine)

Nikki Lytle (Surgery)
Angela Mathison (Surgery)
Sandy Montes-Gruber (Non-MCW)
Qizhen Shi (Pediatrics)
Laura Stephens (Non-MCW)

Committee Members Absent

Biological Safety Officer R/SNA Technology Expert

Chair

R/SNA Technology Expert R/SNA Technology Expert Animal Containment Expert R/SNA Technology Expert HGT Expert

R/SNA Technology Expert R/SNA Technology Expert Non-Affiliated Member R/SNA Technology Expert Non-Affiliated Member 3

Kenneth Allen (Research Office)

James Case (Non-MCW) Matthew Surdel (Medicine) Alternate Animal Containment Expert, Non-Voting Non-Affiliated Member

R/SNA Technology Expert

Meeting Minutes Reviewed at this Meeting

8/12/2025 (Zoom)

Motion: Minutes Approved

Yes Votes: 12
No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 12

4 New Business

1. IBC Oversite Considerations: Human Source Material

The Chair reminded the Institutional Biosafety Committee (IBC) that IBC approval is currently required for processing of human source material for research purposes regardless of whether that material is recombinant. However, work with human source material also requires approval through the Institutional Review Board (IRB); the IRB submission captures whether study staff will be handling these materials and if they have completed bloodborne pathogens training. He asked the Committee to consider whether requiring an IBC Application for studies that are only processing non-recombinant human source material increased safety or caused duplicative work for Principal Investigators (PIs) and study staff. The Chair noted that these IBC Applications are not reviewed by the full committee, as they do not fall under Sections IIIA-IIID of the National Institute of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), or include select agents or Risk Group 2 or higher microorganisms. Several IBC members agreed that requiring IBC Applications for such work is duplicative and they supported removing this requirement. The Biosafety Office voiced a concern that if IBC Applications are not required for this work and the samples are shipped, the shipping training of individuals performing shipping would be difficult to verify. After discussion, the Chair asked the Biosafety Officer to reach out to the IRB Office and others in the Environmental Health and Safety Office to determine if either Office has a way to track shipping training. The BSO will bring this information back to a later meeting for further discussion.

2. Administrative Report

(A Committee member rejoined the meeting at 1:40 pm. Quorum was maintained with 12 Committee members.) The Chair asked the Committee Members to review the Administrative Report and then invited discussion. No concerns were raised.

3. Exempt Rodent Report

The Exempt Rodent Report was provided to the Committee members.

5 Application Reviews

IBC20170013 AME02 Studies in VCMB

Principal Investigator: Peter Newman

Motion: Decision Pending Changes

Yes Votes: 12

5 Application Reviews

No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 12

NIH Guidelines: Section III-D-1, Section III-D-2, Section III-D-4, Section III-E,

Section III-F-1, Section III-F-8 (C-I), Section III-F-8 (C-II),

Section III-F-8 (C-VII)

Biosafety Level(s): BSL1, BSL2

Deliberations:

The Chair introduced this amendment of an Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to describe the study. The Principal Investigator (PI) is adding Chimeric Autoantigen/Alloantigen Receptor T cells (CAAR-T) to the protocol to eliminate B cells that secrete platelet-targeting autoantibodies or alloantibodies responsible for immune thrombocytopenia. Lentiviral vectors will be used to deliver CAAR constructs into Jurkat cells or primary T cells isolated from peripheral blood mononuclear cells (PBMCs). CAAR-T cell efficacy will be assessed through in vitro cytotoxicity assays. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers stated that the protocol is well written, and the risk assessment and mitigation strategies are comprehensive. The Primary Reviewer requested that the PI clarify if CAAR-T cells will be used in vivo. The Secondary Reviewer and Biological Safety Officer (BSO) had no additional concerns. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

6 Adjournment

There being no further business, the meeting was adjourned at 1:44 pm. The next regularly scheduled meeting will be held on Tuesday, October 14, 2025 at 1:00 pm in Zoom.