Minutes

FH & MCW 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 13 voting members present. A quorum 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)	Biological Safety Officer
Lezi E (Cell Biology, Neurobiology and Anatomy)	R/SNA Technology Expert
Benjamin Gantner (Medicine)	Chair
Kunal Gupta (Neurosurgery)	R/SNA Technology Expert
Anna Huppler (Pediatrics)	R/SNA Technology Expert
Eric Jensen (Research Office)	Animal Containment Expert
Tyce Kearl (Medicine)	HGT Expert R/SNA Technology Expert
Nikki Lytle (Surgery)	R/SNA Technology Expert
Angela Mathison (Surgery)	R/SNA Technology Expert
Sandy Montes-Gruber (Non-MCW)	Non-Affiliated Member
Qizhen Shi (Pediatrics)	R/SNA Technology Expert
Laura Stephens (Non-MCW)	Non-Affiliated Member
Mindy Waggoner (FH Pharmacists (no MCW faculty appt))	HGT Expert

Committee Members Absent

Kenneth Allen (Research Office)	Alternate Animal Containment Expert, Non-Voting
James Case (Non-MCW)	Non-Affiliated Member
Matthew Surdel (Medicine)	R/SNA Technology Expert

3 Meeting Minutes Reviewed at this Meeting

8/12/2025 (Zoom)

Motion:	Minutes Approved
Yes Votes:	13
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	13

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

   The Chair asked the Committee Members to review the Administrative Report and then invited discussion. No concerns were raised.

5 Application Reviews

IBC20220051_REN01 BTX-AUT-001 (BEAM 101)

Principal Investigator:	Mary Eapen
Motion:	Decision Pending Changes
Yes Votes:	12
No Votes:	0
Abstained:	0
Recused:	0

5 Application Reviews

Total Votes: 12

NIH Guidelines: Section III-C-1, Section III-F-8 (C-I)

Biosafety Level(s): BSL2

Deliberations: (A Committee member left the meeting at 1:33 pm due to a conflict of interest. Quorum was maintained with 12 voting members.) The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to explain the study. This application supports a Phase 1/2 clinical trial to evaluate the safety and efficacy of a single dose of autologous CD34+ base edited hematopoietic stem cells in patients with Sickle Cell Disease and Severe Vaso-Occlusive Crises. The patient's cells are collected in the Cancer Center and sent to the Cell Therapy Lab for processing. The remainder of the cells are shipped to an off-site manufacturing facility where the CD34+ cells undergo base editing via electroporation of clustered regularly interspaced short palindromic repeats (CRISPR) components. The investigational product is called BEAM-101. The product is shipped frozen back to Froedtert Hospital (FH) Cell Therapy Lab, and on the day of infusion, the product is thawed and transported to the inpatient unit of the Center for Advanced Care (9CFAC) for IV infusion. Research samples are collected and analyzed as outlined in the Cancer Center Clinical Trials Office (CC CTO) lab core IBC protocol. The Primary and Secondary Reviewers agreed that the proposal is well written, and the risk assessment and mitigation strategies are appropriate. The Reviewers had no concerns. The Biological Safety Officer (BSO) stated a study team member needs to renew his recombinant DNA training. Upon a motion by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the renewal of training.

IBC20220049_REN01 BMT CTN 2001 (GRASP)

Principal Investigator: Mary Eapen

Motion: Decision Pending Changes

Yes Votes: 12

No Votes: 0

Abstained: 0

Recused: 0

Total Votes: 12

NIH Guidelines: Section III-C-1

Biosafety Level(s): BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and the Primary Reviewer elaborated on the study. This supports an an open-label, multi-center, Phase 2, single arm clinical trial involving a single infusion of autologous CD34+ hematopoietic stem cells (HSC) transduced with a lentiviral vector containing a short hairpin RNA (shRNA) targeting BCL11a. The primary objective is to determine if treatment with a single infusion of these transduced cells will lead to a complete absence of severe Vaso-occlusive events (VOEs) in the period from Month 6 to Month 24 after gene therapy. Patient's CD34+ HSPCs will be collected in the Cancer Center and sent to the Cell Therapy lab. The cells will be shipped out to Dana-Farber Cancer Institute for transduction. The transduced cells will be cryopreserved until all quality control (QC) testing results are available and pass specification. The drug product will then be released for infusion and shipped frozen to the Cell Processing Lab. Cells will be thawed according to the standard operating procedure outlined in the manual of operations and then transported by Cell Processing Lab staff to the inpatient Bone Marrow Transplant (BMT) and Cellular Therapy unit Center for Advanced Care (9CFAC) for infusion by BMT and Cellular Therapy Program (9CFAC) nurses. Research samples will be collected and processed as outlined in the Cancer Center Clinical Trials Office (CC CTO) Lab core protocol then will be analyzed on-site or shipped to the sponsor-contracted central laboratory. The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are appropriate. The Primary and Secondary Reviewers noted that a study team member needs to renew his recombinant DNA (rDNA) training. The Reviewers also requested that the Principal Investigator (PI)

5 Application Reviews

include a completed training and hazard communication attestation and clarify if shipping will be done under this application. The Biological Safety Officer (BSO) stated that the PI needs to include an entry for blood collected after transfusion of the product and indicate this blood will contain recombinant material. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

6 Adjournment

There being no further business, the meeting was adjourned at 1:40 pm. The next regularly scheduled meeting will be held on Tuesday, October 14, 2025 at 1:00 pm in Zoom.