Minutes

FH & MCW Institutional Biosafety Committee
Institutional Biosafety Committee
8/12/2025
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:00 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 10 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
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
Qizhen Shi (Pediatrics)	R/SNA Technology Expert
Matthew Surdel (Medicine)	R/SNA Technology Expert
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
Lezi E (Cell Biology, Neurobiology and Anatomy)	R/SNA Technology Expert
Benjamin Gantner (Medicine)	Chair
Laura Stephens (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

7/8/2025 (Zoom)

Motion:	Minutes Approved
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10

4 New Business

1. Administrative Report

There was no Administrative Report.

5 Application Reviews

IBC20250021 BE-101

Principal Investigator:	Lynn Malec
Motion:	Approved
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-C-1, Section III-F-8 (C-I)
Biosafety Level(s):	BSL2

Deliberations: The Vice Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. This application will support a Phase 1/2 study which aims to evaluate the safety and tolerability of a single intravenous dose of BE-101 in adults with moderately severe to severe Hemophilia B. BE-101 is manufactured from autologous B cells that are initially isolated from leukapheresis units. The participant's B cells are modified using clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 targeting the C-C Chemokine Receptor 5 (CCR5) gene. Adeno-associated virus (AAV) is used as the DNA donor homology template. Leukapheresis of patient cells will occur in the Grace or Infusion Clinic by a Versiti Therapeutic Services nurse. Leukapheresis product will then be shipped directly to Contract Manufacturing Organization (CMO), Resilience Inc., for manufacture of the investigational product, BE-101. BE-101 will be shipped frozen in a liquid nitrogen (LN2) dry vapor shipper to the Cell Therapy Lab (CTL) where it will be stored until administration. Infusion of BE-101 will occur in the Day Hospital. Processing and shipping of research samples will be completed in the Medical College of Wisconsin (MCW) Adult Translational Research Unit (ATRU) under the ATRU core IBC application. 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 risk assessment and mitigation strategies are appropriate and they had no concerns. The Biological Safety Officer (BSO) had no concerns. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application.

5 Application Reviews

IBC20250028 Alexion AMR (CONCORD)

Principal Investigator:	Matthew Cooper
Motion:	Decision Pending Changes
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-C-1, Section III-F-8 (C-I)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Vice Chair introduced new Institutional Biosafety Committee (IBC) application. The Secondary Reviewer went on to explain the study, a Phase 2 clinical trial to evaluate the safety and efficacy of ALXN2030 in adult patients with antibody-mediated rejection (AMR) following kidney transplantation. The primary objective is to evaluate the efficacy of the investigational product compared with placebo and assessing microvascular inflammation as the primary clinical endpoint in participants with active or chronic active AMR at week 52. ALXN2030 is a double-stranded small interfering RNA (siRNA) designed to inhibit the hepatic expression of the human complement C3 protein. Knockdown of C3 in pre-clinical models has demonstrated the ability to reduce inflammation, extending graft survival, and reversing C3 kidney deposits. Alexion Pharmaceuticals will ship the investigational product to Froedtert Hospital (FH), where it will be stored and prepared in the Investigational Drug Service (IDS) pharmacy. The product will be transported from IDS to the Adult Translational Research Unit (ATRU) for outpatient administration via subcutaneous injection. Following administration, blood samples will be collected in the ATRU and processed according to procedures outlined in the ATRU core IBC protocol. 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 requested a few changes, including that the PI clarify if onsite or offsite transportation will occur, confirm whether waste will be generated in this study, and update locations where the investigational product will be prepared and stored. The Committee requested that the PI include the risks associated with working with human source materials. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

6 Adjournment

There being no further business, the meeting was adjourned at 1:20 pm. The next regularly scheduled meeting will be held on Tuesday, September 9, 2025 at 1:00 pm in Zoom.