Minutes

FH & MCW Institutional Biosafety Committee
Institutional Biosafety Committee
10/14/2025
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
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
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
Kunal Gupta (Neurosurgery)	R/SNA Technology Expert

3 Meeting Minutes Reviewed at this Meeting

9/9/2025 (Zoom)

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

4 New Business

1. IBC CE: NIH Biosafety Modernization Initiative

   The Biological Safety Officer (BSO) notified the Institutional Biosafety Committee (IBC) that the National Institute of Health (NIH) has launched an initiative to modernize and strengthen biosafety policy in order to keep pace with science and technology advances. As part of this effort, the framework of the NIH Guidelines may be revamped to become risk-based rather than technique-based; in some cases, the scope of the Guidelines may be expanded while at the same time reducing oversight for recombinant experiments which are now considered low-risk. The BSO explained that this effort is expected to unfold over the next year and that the research community, biosafety professionals and the public are encouraged to participate in regional listening sessions and submit comments through an online portal. The Committee was encouraged to contact the Biosafety Office with questions.

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

IBC20250042 MODERNA-MRNA-2808-P101

Principal Investigator:	Binod Dhakal
Motion:	Decision Pending Changes
Yes Votes:	13
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	13
NIH Guidelines:	Section III-C-1, Section III-F-8 (C-I)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to explain the study. This application will support a Phase 1/2 clinical trial which will test the safety and tolerability of mRNA-2808 in patients with relapsed or refractory (R/R) Multiple Myeloma. The investigational product, mRNA-2808, consists of a lipid nanoparticle (LNP) formulation encapsulating four (4) mRNA sequences that encodes for three

5 Application Reviews

(3) T cell engagers (TCEs). The investigational product will be stored and prepared on the 3rd floor of the Cancer Center. The IP will be administered to subjects via intravenous (IV) infusion in either the inpatient unit of the Center for Advanced Care (9CFAC) or as an outpatient in the Cancer Center Translational Research Unit (CC TRU). Following infusion, biospecimens (including blood, urine, bone marrow) will be collected during the initial inpatient stay and during study visits in either 9CFAC or the Cancer Center Laboratories. Standard of care (SOC) samples will be processed in Wisconsin Diagnostic Laboratories (WDL). Research samples will be processed in the Medical College of Wisconsin's (MCW) Cancer Center Clinical Trials Office (CC CTO) by MCW research staff and shipped to the study sponsor for analysis. The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are appropriate. The Reviewers stated that a study staff member needs to renew their recombinant DNA (rDNA) training. The Reviewers also requested that the Principal Investigator (PI) confirm where the IP will be stored and prepared, and clarify the transportation route the IP will travel from storage to preparation and administration. The Biological Safety Officer (BSO) stated one of the study team members should be listed on the application as administrative staff, a blank document needs to be removed, the clinical attestation needs to be uploaded, and the Hazard Communication form needs to be updated. After brief discussion, upon a motion duly made by the Secondary 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 1:28 pm. The next regularly scheduled meeting will be held on Tuesday, November 11, 2025 at 1:00 pm in Zoom.