Minutes

FH & MCW Institutional Biosafety Committee
Institutional Biosafety Committee
11/11/2025
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 11 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
Tyce Kearl (Medicine)	HGT Expert R/SNA Technology Expert
Angela Mathison (Surgery)	R/SNA Technology Expert
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
Eric Jensen (Research Office)	Animal Containment Expert
Nikki Lytle (Surgery)	R/SNA Technology Expert
Sandy Montes-Gruber (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

10/14/2025 (Zoom)

Motion:	Minutes Approved
Yes Votes:	11
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11

4 New Business

1. IBC Consultant

   The Chair notified the Institutional Biosafety Committee (IBC) that the Medical College of Wisconsin (MCW) Cancer Center (CC) has submitted a Cancer Center Support Grant (CCSG) and is pursuing a National Cancer Institute (NCI) Cancer Center designation. One of the concerns that was raised by the NCI in their initial review of MCW Cancer Center's request was the time to activation of clinical trials; IBC review is one component of the activation. With that in mind, the Office of Research has requested that an independent consultant review IBC processes. The consultant is from a firm that had been used previously to evaluate the processes of MCW's Institutional Review Board (IRB). The Chair stated that the consultant is expected to come in early December to begin the evaluation. The Chair will keep the IBC informed of the process and if anyone wishes to discuss the evaluation, they can contact either him or the Biological Safety Officer (BSO).

2. Review of Amendments

   The Chair reminded the Committee that review of amendments does not require the review of the application as a whole, and that the focus should be on the changes made within the SmartForm. The IBC Coordinator demonstrated how to compare the different versions in the application's SmartForm to assist with identifying where changes have been made in an amendment. The Chair stated that the IBC Review Standard will be updated to clarify the focus of amendment review. The updated Review Standard will be brought for the Committee to review at a future meeting.

3. Administrative Report

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

5 Application Reviews

IBC20250031 Zamto-Cel M-2024-423

Principal Investigator:	David Gazeley
Motion:	Decision Pending Changes
Yes Votes:	11

5 Application Reviews

No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11
NIH Guidelines:	Section III-C-1, Section III-F-8 (C-I)
Biosafety Level(s):	BSL2

Deliberations: The Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to explain the study. This IBC application will support a Phase I, multicenter study of autologous chimeric antigen receptor (CAR) T cells with dual CD19 and CD20 targets. The investigational product, Zamto-cel (MB-CART2019.1), will be administered to subjects with progressed and/or refractory autoimmune disease after receiving standard therapy. Subjects will undergo a single-day non-mobilized leukapheresis to retrieve cells for manufacture of Zamto-Cel. The leukapheresis product will be collected and transported to a Sponsor-centralized manufacturing facility. The activated cells will then be transduced with a lentiviral vector to introduce a CAR that will externally express antibody binding regions to CD19 and CD20. On the day of infusion, Zamto-Cel will be transported by Cell Processing staff to the inpatient (Bone Marrow Transplant) BMT and Cellular Therapy unit Center for Advanced Care (9CFAC) for infusion. Blood samples that need to be analyzed onsite or shipped to the sponsor-contracted central laboratory will be collected and processed in the Adult Translational Research Unit (ATRU) and the Cancer Center Clinical Trials Office (CC CTO) labs. The Primary and Secondary Reviewers stated the risk assessment and mitigation strategies are appropriate. The Reviewers noted that a study team member needs to renew shipping training for exempt patient specimens. The Reviewers requested a few clarifications, including that the Principal Investigator (PI) update the CC CTO IBC application identification (ID), clarify where blood will be drawn and processed, and update the location on the Hazard Communication form that the investigational product will be prepared. The 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 application pending the requested changes.

IBC20250032 IMUNON - Ovation 3

Principal Investigator:	William Bradley
Motion:	Decision Pending Changes
Yes Votes:	11
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11
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, allowing the Primary Reviewer to elaborate on the study. This IBC application will support a Phase III clinical trial to evaluate the safety and efficacy of IMNN-001 (an IL-12 plasmid formulated with PEG-PEI-Cholesterol (PPC) Lipopolymer) administered with chemotherapy in newly diagnosed patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. The application uses recombinant DNA (human interleukin-12 (hIL:-12) DNA plasmid) and human source material (ascites, blood, tumor tissue). Handling of tumor and ascites samples obtained before administration of IMNN-001 will be handled under IBC20210029. Minimal processing and shipping of serum samples obtained after administration of IMNN-001 will be handled under this 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 stated the risk assessment and mitigation strategies are adequate. The Reviewers requested several changes, including that the Principal Investigator (PI) clarify whether biological safety level (BSL)2 precautions are required for the preparation of IMNN-001 for administration, update locations where IMNN-001 will be prepared and where blood will be processed and/or stored, and confirm transport routes of the materials described

5 Application Reviews

in this application. The Biological Safety Officer (BSO) stated the Hazard Communication form will need to be updated so the name of the investigational product and the locations where it will be used align with that given in the IBC application. After brief discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve the application pending the requested changes.

6 Adjournment

There being no further business, the meeting was adjourned at 1:39 pm. The next regularly scheduled meeting will be held on Tuesday, December 9, 2025 at 1:00 pm in Zoom.