Minutes

FH & MCW Institutional Biosafety Committee
Institutional Biosafety Committee
4/14/2026
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:04 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 redacted meeting minutes will be made public, the information discussed should be considered confidential to protect the identity of individuals and the competitiveness of proprietary or technical information.

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 (Campus Operations)	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
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 (Non-MCW)	HGT Expert

Committee Members Absent

Kenneth Allen (Research Office)	Alternate Animal Containment Expert, Non-Voting
Kunal Gupta (Neurosurgery)	R/SNA Technology Expert
Nikki Lytle (Surgery)	R/SNA Technology Expert
Sandy Montes-Gruber (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

03/10/2026 (Zoom)

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

4 New Business

1. Review Best Practices

   The Chair first thanked the Committee for their hard work and dedication. He then stated there have been issues noted regarding delayed application reviews. The Chair noted three areas of concern during review that have been extending review times.

   - Missing deadlines before meetings
   - The amount of time to complete Designated Review (DR)
   - The number of rounds of DR for application(s)

   The Chair asked that the Committee be mindful of completing reviews in a timely manner. He also asked that Committee members make sure that critiques reflect the IBC's core mission to evaluate biosafety concerns and adherence to the *NIH Guidelines*. If a minor concern is found that is not related to the IBC's core mission, that concern may not need to be sent back if there are no other biosafety or NIH adherence concerns. The Vice Chair asked if examples of concerns that may not need to be routed back could be assembled. The Chair will discuss this possibility with the Biosafety Office and bring back the information back to the IBC if possible.

2. IBC Standard: *IBC Membership & Responsibilities*

   The Chair presented the revised Institutional Biosafety Committee (IBC) Standard, *IBC Membership & Responsibilities*. The revisions to the standard removed the two-term limit for Committee members. The Chair asked if there were any questions or concerns. There being none, upon a motion duly made by an IBC member and seconded, the Committee voted to approve the revision to the standard as written.

3. IBC Standard: *Establishing Standards and Position Statements*

   The Chair presented the Institutional Biosafety Committee (IBC) Standard, *Establishing Standards and Position Statements*. The NIH Guidelines require that institutions establish and implement policies that provide for the safe conduct of research with recombinant or synthetic nucleic acid molecules and ensure compliance with the NIH Guidelines. To that end, the IBC continuously evaluates its conduct and establishes Standards or Positional Statements as necessary to document its positions and processes with respect to various aspects under its purview, in part to maintain consistency in its decisions. The purpose of this document is to describe the purpose of and process for establishing IBC Standards and IBC Position Statements. The Chair asked if there were any questions or concerns. There being none, upon a motion duly made by an IBC member and seconded, the Committee voted to approve the standard as written.

4. IBC Standard: *Addressing Noncompliance/Reportable Events*

The Chair presented the Institutional Biosafety Committee (IBC) Standard, *Addressing Noncompliance/Reportable Events*. The role of the IBC is to review research involving the possession and use of biological toxins, microorganisms, human or non-human primate (NHP) tissue or cells, animal tissue or cells, and any use of recombinant DNA as described in the NIH Guidelines, and to assist investigative staff in establishing practices designed to protect the safety of personnel working with those agents. Failure to follow the practices described in an approved IBC Application ("noncompliance") can place the safety of personnel at risk and the institution out of compliance with the NIH Guidelines. The purpose of this document is to provide guidance with regards to addressing noncompliance and/or reportable events and bringing them to the attention of the IBC. The Chair asked if there were any questions or concerns. There being none, upon a motion duly made by an IBC member and seconded, the Committee voted to approve the standard as written.

5. IBC Standard: *Availability of IBC Meeting Minutes and Public Comment*

   The Chair presented the Institutional Biosafety Committee (IBC) Standard, *Availability of IBC Meeting Minutes and Public Comment*. Per Section IV-B-2-a-(7) of the NIH Guidelines, "an institution shall make available to the public all Institutional Biosafety Committee meeting minutes…If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Science Policy, National Institutes of Health." The purpose of this document is to document the process by which Institutional Biosafety Committee (IBC) Meeting Minutes will be made available to the public and public comments will be forwarded to the NIH Office of Science Policy. The Chair asked if there were any questions or concerns. There being none, upon a motion duly made by an IBC member and seconded, the Committee voted to approve the standard as written.

6. IBC Position Statement: *BRC Locations*

   The Chair presented the Institutional Biosafety Committee (IBC) Position Statement, *BRC Locations*, which states that individual room numbers should not be listed in IBC applications for areas in the Biomedical Resource Center (BRC). A member of the Biosafety Team requested a clarification to the description of the animal facility and the Committee concurred. Upon motion duly made and seconded, the Committee voted to approve the position statement with the requested clarification.

7. Continuing Education - Changes to Sections H and P of the IBC Application SmartForm

   The Research Safety Committees Manager presented updates to the Institutional Biosafety Committee (IBC) Application SmartForm that will go into effect in eBridge on April 18, 2026. The updates will affect Section H (Viral Vectors), which will add questions to clarify the risks associated with the vectors used and the mitigation strategies that will be used, and Section P (Engineering Controls and PPE), which will add questions to clarify when specific PPE will be used to perform certain procedures with a particular biological material. A Committee member asked if sample responses could be prepared to assist Principal Investigators in answering the questions added in Section H. The Biosafety Office noted that they have fact sheets for other biological agents in the IBC Application SmartForm and would look into developing something similar for this section as well.

8. Administrative Report

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

5 Application Reviews

IBC20260010 ZENITH

Principal Investigator: Sam Hooshmand

5 Application Reviews

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):	BSL2

Deliberations: The 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 1b trial evaluating the safety, tolerability, and preliminary efficacy of AZD0120, an autologous BCMA/CD19 dual targeting chimeric antigen receptor (CAR)+ T cell therapy in adults with refractory active relapsing or progressive multiple sclerosis. Patients will undergo leukapheresis onsite and the cells will be shipped externally to the manufacturing facility. The patient's T cells are genetically modified using a self-inactivating lentiviral vector, after which they are shipped back to the Cell Processing Lab (CPL). CPL staff will transport cells to the inpatient unit of the Center for Advanced Care (9CFAC) and the investigational product (IP) will be administered to study patients via infusion. Blood will be collected prior to administration of the IP and during subsequent study visits. The Primary and Secondary Reviewers stated the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the Principal Investigator (PI) reference all Core Laboratories that will be used and update the Hazard Communication forms for this study. The Biological Safety Officer (BSO) stated the PI needs to complete recombinant DNA (rDNA) training. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

IBC20260011 IIT-DHAKAL-FT836-DARA

Principal Investigator:	Binod Dhakal
Motion:	Approved
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):	BSL2

Deliberations: (A guest left the meeting at 1:52 pm due to a conflict of interest.) The Chair introduced this new Institutional Biosafety Committee (IBC) application. The Primary Reviewer went on to explain the study, which will support a Phase 1 study of a chimeric antigen receptor (CAR) T cell that targets major histocompatibility complex class I chain-related proteins A and B MICA/B in multiple myeloma. The product is a highly engineered allogeneic product generated from an induced pluripotent stem cell line. The product will be delivered cryopreserved to the Cell Therapy Lab (CTL) and administered by two intravenous (IV) infusions at the inpatient unit of the Center for Advanced Care (9CFAC). Post-infusion samples will be obtained and sent to the sponsor for analysis. 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 appropriate and they had no concerns with the study. 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

IBC20220116_REN01 PRECISION-PBCAR0191-01 (azer-cel)

Principal Investigator:	Nirav Shah
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):	BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, and the Primary Reviewer described the study. This application supports a clinical trial that uses the allogeneic chimeric antigen receptor (CAR) T cell product, Azer-cel. This investigational product is manufactured using recombinant adeno-associated virus serotype 6 (rAAV6). 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. The Reviewers requested that the Principal Investigator (PI) align the recommended PPE with guidance provided by Froedtert Hospital (FH). The Biological Safety Officer (BSO) requested the Hazard Communication forms be updated to the most current version. 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 2:00 pm. The next regularly scheduled meeting will be held on Tuesday, May 12, 2026 at 1:00 pm in Zoom.