Minutes

FH & MCW Institutional Biosafety Committee
Institutional Biosafety Committee
2/10/2026
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:00 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 12 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 (Campus Operations)	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
Angela Mathison (Surgery)	R/SNA Technology Expert
Sandy Montes-Gruber (Non-MCW)	Non-Affiliated Member
Qizhen Shi (Pediatrics)	R/SNA Technology Expert
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
James Case (Non-MCW)	Non-Affiliated Member
Nikki Lytle (Surgery)	R/SNA Technology Expert
Laura Stephens (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

1/13/2026 (Zoom)

Motion:	Minutes Approved
Yes Votes:	12
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	12

4 New Business

1. BSL2+ PPE Requirements

   The Chair and the Biological Safety Officer informed the Institutional Biosafety Committee (IBC) that tissue culture spaces are shared between multiple labs in the new Center for Cancer Discovery (CCD) building. A lab performing work requiring biological safety level (BSL)2+ containment (such as with oncogenic lentiviral vectors) could be working in a biosafety cabinet (BSC) right next to a lab performing standard BSL2 tissue culture. The concern with this arrangement is that staff only working with BSL2 agents do not have or use respirators. The Biosafety Office evaluated the situation and recommended that work with BSL2+ agents in the CCD can be done without respirators as long as that work is confined to BSCs. All other personal protective equipment (i.e. double gloves, dedicated lab coat (either a cuffed lab coat or a standard lab coat with sleeve protectors for added skin protection), and surgical mask or face shield) would still be required, and PIs would need to submit an amendment to their IBC application to reflect this change. The Chair made a motion to remove the respirator requirement for BSL2+ work in the CCD. The motion was seconded, and the Committee voted to approve this change for the CCD location.

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

IBC20260001 IIT-DHAKAL-TGF-BETA-BCMA

Principal Investigator:	Binod Dhakal
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

5 Application Reviews

Deliberations: (A Committee member left the meeting at 1:19 pm due to a conflict of interest. Quorum was maintained with 11 voting members.) The Chair introduced this new Institutional Biosafety Committee (IBC) application and the Primary Reviewer elaborated on the study. This IBC application supports a Phase 1 clinical trial to determine the safety and feasibility of BCMA-TGFb Armored chimeric antigen receptor (CAR) T cells in patients with relapsed and/or refractor (R/R) multiple myeloma. The autologous product is manufactured on-site and may be administered fresh or frozen on the day of harvest for later thaw and infusion. This IBC application covers the transport and administration of the product to patients. The manufacturing and processing of the CAR T product on site and blood drawn before, during, and after transduction are covered by other IBC applications. 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. The Reviewers had no concerns. The Biological Safety Officer (BSO) requested several updates to the Hazard Communication forms for this study, including correcting the Principal Investigator (PI) listed on the form, clarifying whether the product will be administered to both inpatients and outpatients, and confirming locations where the product may be thawed. After brief discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

IBC20250057 BMS-CA0881007

Principal Investigator:	Othman Akhtar
Motion:	Decision Pending Changes
Yes Votes:	12
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	12
NIH Guidelines:	Section III-C-1, Section III-F-8 (C-I)
Biosafety Level(s):	BSL2

Deliberations: (A Committee member rejoined the meeting at 1:27 pm. Quorum was maintained with 12 Committee members.) 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 III clinical trial which will assess the efficacy of GPR5D chimeric antigen receptor (CAR) T versus standard therapy in patients with relapsed refractory multiple myeloma. The apheresis product is shipped to the study sponsor for CAR T manufacturing and the cryopreserved product is shipped back to the Cell Therapy Lab. The product is then thawed and administered in the inpatient unit of the Center for Advanced Care (CFAC9) or the Day Hospital. Post-infusion samples will be processed and shipped by the Cancer Center Clinical Trials Office (CC CTO); this work is covered by the CC CTO core IBC Application. The Primary and Secondary Reviewers stated the risks and mitigation strategies are well described and appropriate to the product. The Reviewers requested that the Principal Investigator (PI) indicate that single gloves will be used for the administration of the investigational product. The Biological Safety Officer (BSO) stated a study team member needs to renew bloodborne pathogens training. He also requested that the PI confirm the transport route listed on the Hazard Communication (HazCom) form for the investigational product. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

IBC20200012_REN02 IIT-Shah-CAR-T-20/19-IL7-IL15

Principal Investigator:	Nirav Shah
Motion:	Decision Pending Changes

5 Application Reviews

Yes Votes:	12
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	12
NIH Guidelines:	Section III-C-1, Section III-D-1
Biosafety Level(s):	BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to describe the study. This IBC application supports a Phase I/II clinical trial utilizing bispecific anti-CD19/20 chimeric antigen receptor (CAR)-T cells in patients with relapsed and/or refractory (R/R) B Cell Malignancies. Apheresis occurs in the Cancer Center Grace Clinic. The subject's blood is then transported to Bone Marrow Transplant (BMT) and Cell Therapy Laboratories onsite, where T cells will be isolated and transduced with a lentiviral vector to produce CAR-T cells. The product will then be transported in sealed collection bags, then aliquoted for immediate infusion or cryopreserved for storage and later infusion. On the day of cell infusion, the fresh or thawed CAR-T 20/19 cells will be transported to the inpatient unit of the Center for Advanced Care (9CFAC) or Cancer Center Day Hospital for administration as either inpatient or outpatient treatment. 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. The Reviewers requested that the Principal Investigator (PI) confirm where the investigational product will be prepared. The Biological Safety Officer (BSO) requested that the Hazardous Communication (HazCom) forms be updated with the correct PI. After brief discussion, 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, March 10, 2026 at 1:00 pm in Zoom.