Minutes

FH & MCW Institutional Biosafety Committee
Institutional Biosafety Committee
7/8/2025
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:03 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
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
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

Tyce Kearl (Medicine)	HGT Expert R/SNA Technology Expert
Nikki Lytle (Surgery)	R/SNA Technology Expert
Laura Stephens (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

6/10/2025 (Zoom)

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

4 New Business

1. NOT-OD-25-127 - Dangerous Gain-of-Function Research

   The Chair provided the Institutional Biosafety Committee (IBC) with an update regarding the Executive Order NOT-OD-25-127, which was released on June 18, 2025. Per this order, the National Institute of Health (NIH) required that institutions review all research to identify projects involving dangerous gain-of-function research and notify the NIH of any such project by June 30, 2025. The Chair, Biosafety Officer, and Research Safety Committees (RSC) Manager reviewed all work with biological materials performed at Versiti Blood Research Institute (BRI), Children's Wisconsin (CW), Froedtert (FH), and the Medical College of Wisconsin (MCW). Principal Investigators (PIs) with work involving risk group (RG)2 microorganisms were contacted to attest whether they were performing any gain-of-function research. As of the July 8, 2025 IBC Meeting, there is no research in any of the institutions that IBC oversees that falls under this category. The Chair thanked the BSO and RSC Manager for their hard work and notified the IBC that he would bring any further developments before the Committee.

2. Administrative Report

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

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IBC20250024 Gene therapy for Temporal Lobe Epilepsy (GenTLE)

Principal Investigator:	Kunal Gupta
Motion:	Decision Pending Changes
Yes Votes:	9
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	9
NIH Guidelines:	Section III-C-1
Biosafety Level(s):	BSL1, BSL2

Deliberations: (A Committee member left the meeting at 1:09 pm due to a conflict of interest. Quorum was maintained with 9 voting members.) The Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. This application will support an early-phase study of a drug for patients with

5 Application Reviews

certain types of epilepsy. The drug is a replication-deficient recombinant adeno-associated virus (AAV)9 encoding two miRNAs under the hyman synapsin 1 promotor. The aim is to downregulate expression of specific proteins in the hippocampus for improved seizure control. The drug is manufactured by the study sponsor and received frozen by the Cancer Center Investigational Drug Services (IDS) Pharmacy. The IDS Pharmacy will thaw and prepare the product prior to administration. It will be administered in the neurosurgical operating room (OR) via a magnetic resonance imaging (MRI)-guided cannula into the hippocampus. The Principal Investigator (PI) notes that DNA shedding is not anticipated based on pre-clinical non-human primate studies. Cerebral spinal fluid (CSF) and blood samples will be drawn at various timepoints after administration, processed in the Adult Translational Research Unit (ATRU) and then shipped to the study sponsor. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary Reviewer requested that the PI indicate that samples are recombinant and address the potential risks of exposure to AAV. 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.

IBC20240011_AME01 NEOGENE-NT-112-301

Principal Investigator:	Mandana Kamgar
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: (A Committee member rejoined the meeting at 1:12 pm. Quorum was maintained with 10 Committee members.) The Chair introduced this amendment of an Institutional Biosafety Committee (IBC) application. The Secondary Reviewer went on to explain the study, which is a multi-center clinical trial testing autologous T cell receptor (TCR)-edited T cells. The amendment adds an additional cell product, AZD0240, to the initial investigational cell product, NT-112. Both investigational cell products target KRAS G12D. Autologous cells are collected by apheresis and shipped to the study sponsor where the drug product is manufactured using electroporation to deliver clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 ribonucleoprotein (RNP) complexes. Cryopreserved product will be received by the Cell Therapy Lab (CTL) and then thawed prior to infusion in the inpatient unit of the Center for Advanced Care (9CFAC). Blood samples will be drawn post-infusion and sent by the Cancer Center Clinical Trials Office (CC CTO) to the study 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 agreed that the proposal is well written and the risk assessment and mitigation strategies are appropriate. The Reviewers had no concerns, nor did the Biological Safety Officer (BSO). Upon a motion duly made by the Secondary Reviewer and seconded, the Committee voted to approve this amendment.

IBC20220033_REN01 ARCELLX Core IBC CART-ddBCMA product

Principal Investigator:	Binod Dhakal
Motion:	Approved
Yes Votes:	10

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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 Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and the Primary Reviewer elaborated on the study. The Principal Investigator (PI) oversees several clinical trials which utilize the investigational product, CART-ddBCMA, to treat patients with relapsed or refractory multiple myeloma. The product consists of autologous T cells that have been genetically modified ex vivo by a replication deficient lentiviral vector to target BCMA. Following apheresis in the Cancer Center Grace Clinic, the patient's cells are shipped offsite to a good manufacturing practice (GMP) facility where the product is manufactured. The CART-ddBCMA product is then cryopreserved and shipped back to Froedtert where it is stored in the Cell Therapy Lab (CTL) prior to infusion. On the day of infusion, the product is thawed and transported to the inpatient unit of the Center for Advanced Care (9CFAC) for intravenous (IV) infusion. Post-infusion, blood is collected for processing. Research samples are shipped to the sponsor for further 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 that the risk assessment and mitigation strategies are well described. The Reviewers had no concerns, nor did the Biological Safety Officer (BSO). Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal.

6 Adjournment

There being no further business, the meeting was adjourned at 1:16 pm. The next regularly scheduled meeting will be held on Tuesday, August 12, 2025 at 1:00 pm in Zoom.