Minutes

FH & MCW Institutional Biosafety Committee
Institutional Biosafety Committee
6/10/2025
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:02 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 9 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
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
Nikki Lytle (Surgery)	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
Lezi E (Cell Biology, Neurobiology and Anatomy)	R/SNA Technology Expert

3 Meeting Minutes Reviewed at this Meeting

5/13/2025 (Zoom)

Motion:	Minutes Approved
Yes Votes:	9
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	9

4 New Business

1. IBC Membership – Non-Affiliated Member replacement

   The Chair notified the Institutional Biosafety Committee (IBC) that one of the non-affiliated IBC members will be stepping down from the Committee by the end of summer. The Chair requested that the Committee send any recommendations they may have for potential non-affiliated IBC members to the Research Safety Committees Manager.

The following Business Items were discussed after the FH Applications.

2. Scope of reviews for Amendments vs. Renewals/New Applications

   The Chair reminded the Committee that when they review amendments, the focus of the review should be on the changed sections. Committee members are not expected to review the entire IBC Application. Renewals, on the other hand, should be reviewed in their entirety, similar to New Applications. After discussion, the Chair encouraged reviewers to bring amendments to the attention of the Committee if there are changes in the amendment that may impact the safety of the application as a whole, but reiterated that is not an expectation of amendment review.

3. IBC Position Statement: *Biosafety Level Classification for Urine*

   The Chair reminded the Committee that IBC Standards and Position Statements are reviewed on a periodic basis so that they can be revised as needed in response to programmatic evolution. The current IBC Standard on the biological safety level (BSL) for Urine was revised in the form of a Position Statement to align with the IBC's new approach to Position Statements vs. Standards. The Committee reviewed the IBC Position Statement: *Biosafety Level Classification for Human Bodily Fluids* which was created to replace that Standard. After brief discussion, upon a motion duly made by the Biological Safety Officer (BSO) and seconded, the Committee voted to accept the new IBC Position Statement.

4. Agents to be included on IBC Applications/Training Requirements

   (A Committee member joined the meeting at 1:37 pm. Quorum was maintained with 11 voting members.) The Chair posed the question to the Committee on whether non-pathogenic Escherichia (E.) coli should be listed on IBC applications as this material poses a minimal safety risk. After discussion, the Committee determined that these strains of E. coli should continue to be listed on IBC applications when they are used in a study to give IBC reviewers sufficient information to ensure that strains the Principal Investigator (PI) states are exempt are truly non-pathogenic. The Chair reminded the Committee that only agents requiring IBC Approval should be included in IBC Applications and should form the basis for training requirements. If a biological material that is not under the IBC's purview (such as recombinant animal tissue) is listed in the application, that material should not be considered when determining the safety training

that Study Team members listed on the application are required to have. During the Pre Review, the Biosafety Office should request any such material be removed from the application; if they are unsure, they should post a comment in the IBC SmartForm for Committee consideration.

5. Administrative Report

There was no Administrative Report.

5 Application Reviews

IBC20220016_REN01 SOTIO-BOXR1030

Principal Investigator:	Jonathan Thompson
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):	BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. This application supports a Phase 1/2 trial of BOXR1030 T cells in subjects with advanced GPC3-positive solid tumors. Cells are collected from the consented subject in the Grace Clinic and transported to the study sponsor where the cells are genetically modified ex vivo using a gammaretrovirus vector encoding an anti-GPC3 chimeric antigen receptor (CAR) and a 1030-GOT2 protein to become BOXR1030. This autologous engineered T-cell therapy is designed to target GPC3 on tumor cells. After the manufacturing process is complete, the cells are then cryopreserved and shipped to Froedtert Hospital/Medical College of Wisconsin (FH/MCW) to be stored in the Cell Therapy Lab until use. On the day of infusion, the investigational product is transported to the inpatient unit of the Center for Advanced Care (9CFAC) for administration. Blood is collected following administration and research samples are processed in the Cancer Center Clinical Trials Office (CC CTO) lab then shipped 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 that the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the Principal Investigator (PI) indicate that blood collected after administration of the product will be recombinant, confirm whether blood will be collected in 9CFAC, and remove a location that is not used in the study. The Biological Safety Officer (BSO) had no additional concerns. 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.

IBC20190032_REN02 JUNO Transcend-CLL 017004

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)

5 Application Reviews

Biosafety Level(s): BSL2

Deliberations: (2 Committee member joined the meeting at 1:13 pm. Quorum was maintained with 11 voting members.) The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to explain the study. This application supports a gene therapy trial which uses the investigational product JCAR017. Apheresis cell collection takes place from consented subjects in the Grace Clinic. The collected peripheral blood mononuclear cells (PBMCs) are shipped offsite and undergo sequential positive selection for CD8+ and CD4+ T cells which will be used to create the JCAR017 investigational product. The T cells are transduced with a lentiviral vector encoding the CD19-specific chimeric antigen receptor (CAR) and truncated epidermal growth factor receptor (EGFRt). JCAR017 is cryopreserved and shipped to Froedtert Hospital/Medical College of Wisconsin (FH/MCW) following quality control testing. On infusion day, the product is thawed in the Cell Therapy Lab (CTL) and transported to the inpatient unit of the Center for Advanced Care (9CFAC) or Day Hospital for infusion. Following administration, patient samples are collected and processed for research or shipped to the sponsor. 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 protocol is well written, and the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the Principal Investigator (PI) list the Food and Drug Administration (FDA)-approved name in the research objectives and the Hazard Communication sign. The Biological Safety Office had no additional concerns. 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 1:57 pm. The next regularly scheduled meeting will be held on Tuesday, July 8, 2025 at 1:00 pm in Zoom.