



## Minutes

**FH & MCW Institutional Biosafety Committee  
Institutional Biosafety Committee  
7/14/2026  
1:00 pm  
Zoom**

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### 1 Statements of Confidentiality and Conflicts of Interest

**Quorum and Meeting Access:** The Chair called the meeting to order at 1:10 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.

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### 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   |
| 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

Nikki Lytle (Surgery)

R/SNA Technology Expert

Sandy Montes-Gruber (Non-MCW)

Non-Affiliated Member

Qizhen Shi (Pediatrics)

R/SNA Technology Expert

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### 3 Meeting Minutes Reviewed at this Meeting

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06/09/2026 (Zoom)

|                     |                  |
|---------------------|------------------|
| <b>Motion:</b>      | Minutes Approved |
| <b>Yes Votes:</b>   | 11               |
| <b>No Votes:</b>    | 0                |
| <b>Abstained:</b>   | 0                |
| <b>Recused:</b>     | 0                |
| <b>Total Votes:</b> | 11               |

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### 4 New Business

#### 1. IBC Membership Recommendations

The Chair notified the Institutional Biosafety Committee (IBC) members that there will be openings for new members in the near future. He requested that current IBC members contact him or the IBC Office if they know of anyone that would be interested in serving on the IBC.

#### 2. Hazard Communication Forms

##### ◦ Proposed revisions

The Chair notified the Institutional Biosafety Committee (IBC) that many amendments submitted for clinical trials that require Hazard Communication forms are to update room locations where the investigational product is used and noted that there was an opportunity to make the form more flexible. The Chair asked the Biological Safety Officer (BSO) to present the proposed revisions to the form. These changes include the removal of agent storage, disposal locations, specific room numbers, and transport routes; these changes would allow Froedtert and the study teams greater flexibility while not impacting safety. The goal would be to include the type of rooms that would be appropriate for the work, as opposed to specific room numbers. Froedtert's Office of Clinical Research and Innovative Care Compliance (OCRICC) would then be able to confirm that the work is being done in the appropriate locations within Froedtert. After discussion, the Committee voted to allow for greater flexibility in the Hazard Communication forms. The Biosafety Office will work with OCRICC to make the necessary changes.

##### ◦ HGT vs. Non-HGT Studies

The Chair continued the discussion about the Hazard Communication forms and reminded the Institutional Biosafety Committee (IBC) that Hazard Communication forms are currently only required for clinical trials that involve human gene transfer (HGT). Since the inception of the Hazard Communication form, there have been several non-HGT studies that have submitted these forms with their IBC Applications due to the nature of the studies. The Chair asked the IBC if the requirement for Hazard Communication forms should officially be extended to non-HGT clinical studies (clinical trials that don't involve the use of recombinant DNA). A Committee member noted that non-recombinant human cell products require Biosafety Level (BSL)2 precautions, which are standard, so there is no practical change in risk or precautions for the administration of such products. A representative from the Office of Clinical Research and Innovative Care Compliance (OCRICC) noted that the Hazard Communication forms are beneficial when providing guidance for procedures that are not the standard, such as when additional personal protective equipment (PPE) is required or when individuals with certain risk factors should not be present during preparation or administration of the product. After discussion, the Committee determined that further information would need

to be gathered from nursing and pharmacy staff in Froedtert to determine whether Hazard Communication forms would be useful for non-HGT studies before being brought back to an IBC Meeting for further discussion. The IBC voted to continue to request Hazard Communication forms for non-HGT studies, as has been the unofficial practice, until the Committee makes an official determination.

### 3. 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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## 5 Application Reviews

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### IBC20260021 IIT-SHAH-CAR-H20-19

Principal Investigator: Nirav Shah

**Motion:** Approved

**Yes Votes:** 11

**No Votes:** 0

**Abstained:** 0

**Recused:** 0

**Total Votes:** 11

**NIH Guidelines:** Section III-C-1, Section III-D-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 1, single-arm, open-label clinical trial designed to evaluate the safety of chimeric antigen receptor (CAR)-T cells in patients with B-cell malignancies that have failed prior therapies, including other CAR T-cell therapies. Apheresis will occur in the Grace Clinic of the Cancer Center, or a prior cryopreserved apheresis product may be used for patients previously treated with CAR T-cell therapy. The subject's blood will be transported to the Bone Marrow Transplant (BMT) and Cell Therapy Laboratories (CTL) where it will be used to manufacture the product. The fresh, frozen, or thawed cells will be transported to the Froedtert Hospital/MCW Center for Advanced Care (CFAC) 9th floor for administration as inpatient treatment on the day of cell infusion. The frozen cells may be thawed either at patient's bedside or within the CPL. The product will be administered by intravenous (IV) infusion. Research samples will be collected and processed as described in Cancer Center Clinical Trials Office (CC CTO) Laboratory Core IBC application. 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. 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.

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## 6 Adjournment

There being no further business, the meeting was adjourned at 2:07 pm. The next regularly scheduled meeting will be held on Tuesday, August 11, 2026 at 1:00 pm in Zoom.