

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, November 3, 2025
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: Children's National Research Institute of Children's National Medical Center, Washington, DC
Principal Investigator: Eugene Hwang, MD
Protocol: Pediatric Brain Tumor Consortium (PBTC), **PBTC-059**
NCT Number: NCT04903080
Meeting Type: Continuing Review of Protocol and Site
Title: Phase 1 trial of autologous HER2-specific CAR T cells in pediatric patients with refractory or recurrent ependymoma

1. Call to order:

The Meeting was called to order at 11:44 am Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and two of the Institution's Biosafety Officers. Also present were IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

A Biosafety Officer confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 6 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for HER2 CAR T cells, since they consist of genetically modified primary human cells. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of HER2 CAR T cells locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

| | |
|---|------------------------|
| X | APPROVED |
| | CONDITIONALLY APPROVED |
| | TABLED |
| | DISAPPROVED |

DETERMINATION VOTE - YES: 6 NO: 0 ABSTAIN: 0

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee recommended that Biosafety SOP Section 5.1.2 be revised to list the PPE required for handling spills.
2. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to read "Rinse the affected eye thoroughly for 15 minutes according to institutional policy using an eyewash..." and that language be added to indicate that in rooms without a plumbed eyewash station, individuals should use the prefilled disposable eyewash bottles and then be escorted to the plumbed eyewash handling spills.
3. The Committee discussed the use of the [REDACTED] as locations of dosing for genetically modified human cells and found these rooms to be acceptable for other similar studies at the Institution currently under this IBC's oversight.
4. The Committee recommended that eyewash station signage be placed above plumbed eyewash stations and that updated photos be submitted to IBC Services.
5. A Biosafety Officer confirmed that Biological Safety Cabinets (BSCs) are typically labeled with a biohazard symbol when staff members are handling biological agents within them, and an Institutional Representative noted that they will confirm that this practice is followed. The Committee noted that the biohazard symbol could be removable and only placed on the BSC when biologics are handled.
6. A Biosafety Officer confirmed that the plumbed eyewash stations are flushed on a weekly and monthly basis, per Institutional policies.
7. A Biosafety Officer confirmed that a glove on top of a biohazard waste container in a [REDACTED] was most likely misplaced and should have been discarded into the biohazardous waste stream.
8. An Institutional Representative confirmed that a child's toy awaiting disposal is on the cart in a photo of a [REDACTED].
9. The Committee recommended that an updated photo of the [REDACTED] in the [REDACTED] area be submitted to IBC Services.
10. An Institutional Representative confirmed that several internal transport containers may be used, which should be labeled with a biohazard symbol as appropriate. The Committee recommended that updated photos of biohazard-labeled internal transport containers be provided to IBC Services, if applicable.
11. A Biosafety Officer confirmed that the red biohazardous waste containers are typically labeled on top of the lid. The Committee suggested that these containers could also be labeled with a biohazard symbol on the side if top is left up.
12. An Institutional Representative noted that they will confirm that study staff members receive additional lab safety training from the [REDACTED] as required per the Institution's Exposure Control Plan.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officers.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

| | |
|---|------------------------|
| X | APPROVED |
| | CONDITIONALLY APPROVED |
| | TABLED |
| | DISAPPROVED |

DETERMINATION VOTE - YES: 6

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:50 am Eastern Time