INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, February 12, 2026**
Time:	9:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	OhioHealth Research Institute, Columbus, OH
Principal Investigator:	**Paige Sutton, MD**
Protocol:	TG Therapeutics, Inc., **TG-Azercel-101**
NCT Number:	NCT06680037
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1, Open-label Study to Evaluate the Safety and Clinical Activity of Azercabtagene Zapreleucel in Participants with B-cell Mediated Autoimmune Disorders

1. Call to order:

The Meeting was called to order at 9:01 am Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were eight Institutional Representatives and 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:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

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

The Committee determined that **BSL-2 containment facilities and practices** are required for PBCAR0191 since it consists of primary human cells modified using mRNA and an AAV vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of PBCAR0191 locally**, provided that all other criteria for study closure are met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 discussed that preparation and dosing for this study agent are not accurately described in the Biosafety SOP and recommended that Biosafety SOP Sections 3.3 and 3.5 be revised accordingly.
2. An Institutional Representative confirmed that germicidal agent will not be used to decontaminate spills in the water bath. The Committee recommended that Biosafety SOP Section 5.1.4c.i. be revised accordingly.
3. The Committee recommended that Biosafety SOP Section 5.2.5 be revised to indicate that, if required, staff members will be escorted to the plumbed eyewash station.
4. The Committee recommended that the Biohazard Sign be revised to list the study agent as “Genetically Modified Human T-Cells” since the sign is used for multiple protocols.
5. The Committee recommended that Site Inspection Checklist, Item #19 be revised to include bleach.
6. An Institutional Representative confirmed that prefilled disposable eyewash bottles are not used in any of the preparation or dosing locations. The Committee recommended that the Site Map be revised accordingly.
7. An Institutional Representative confirmed that the black waste container with a yellow biohazard sticker shown in the Inpatient 6 Blue dosing room photo is used for chemotherapy waste and that the red biohazardous waste containers are used for infectious waste.
8. An Institutional Representative confirmed that the sink and plumbed eyewash station in the Cell Therapy Lab is located in GTP Lab 2 but that there is no door separating GTP Lab 1 and GTP Lab 2.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:23 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 4.0, dated 10-18-2025
Investigator's Brochure, Autoimmune Disorders, Version 1.0, dated 01-23-2025
Pharmacy Manual, Version 2.0, dated 04-25-2025
Biological Risk Assessment and Summary, updated 02-10-2026
Site Maps, CART Cells, dated 11-11-2025
Site Inspection Checklist, CART Cells, expires 11-13-2027, updated 01-29-2026
Photos, CART, dated 12-17-2025
Biohazard Sign, Cells, dated 01-30-2026
Biological Safety Cabinet Certifications, expire 05-31-2026
SOP, Institutional Biosafety for CART, dated 01-30-2026
Training, Shipping Certifications, expire 2026, 2027
CV, Sutton, P., signed 08-05-2024