

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, August 11, 2026
Time: 9:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Reem Karmali, MD, MS
Protocol: AvenCell Therapeutics, Inc., **AVC-203-01**
NCT Number: NCT07284433
Meeting Type: Initial Review of Protocol and Site
Title: A single-arm, multicenter, open-label, Phase I/II trial of Allo-QuadCAR01-T, an allogeneic CAR-T-cell therapy targeting CD19 and CD20, for the treatment of relapsed or refractory B-cell malignancies

1. Call to order:

The Meeting was called to order at 8:59 am Central 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 the Institution's Biosafety Officer. Also present were three 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 Allo-QuadCAR01-T since it consists of donor-derived T-cells genetically modified using a targeted CRISPR/Cas9 system and a retroviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of Allo-QuadCAR01-T locally**, provided that other biosafety criteria for study closure are also 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: 6

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

10. Review of proposed facilities and practices:

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

Point of Discussion:

1. The Committee recommended that the Site Inspection Checklist, Item #22 be revised to add a comment that plumbed eyewash stations are flushed weekly.

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: 6

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:09 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 4.0, dated 01-28-2026

Investigator's Brochure, Version 2.0, dated 09-11-2025

Cell Therapy Manual, Version 1-0, dated 10-17-2025

Biological Risk Assessment and Summary, dated 03-04-2026

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Olson, 7th Floor, MCCT, Room 7-424, dated 02-27-2025

Site Map, Olson, 7th Floor, MCCT, Room 7-613, dated 02-19-2024

Site Map, Prentice, 16th Floor, dated 04-12-2024

Site Map, Feinberg and Olson Loading Docks, received 10-16-2018

Site Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 07-24-2026

Photos, Prentice Hospital, dated 04-25-2025

Photos, Olson Pavilion, MCCT, dated 06-05-2025

Photos, Olson Pavilion, Dosing, dated 05-01-2025

Photos, Feinberg and Olson Loading Dock, dated 03-25-2026

Biohazard Sign, Dosing Areas, dated 07-22-2026

Biohazard Sign, Olson MCCT, dated 07-22-2026

Biological Safety Cabinet Certifications, Olson MCCT, expires 03-2027

SOP, Biosafety for Genetically Modified Human Cells, dated 06-15-2026

SOP Addendum, Biosafety for Allogeneic Cells, dated 07-22-2026

Training, Shipping Certification, expires 06-05-2027

CV, Karmali, R, signed 01-25-2026