

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, May 18, 2026
Time: 10:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Reem Karmali, MD, MS
Protocol: Miltenyi Biomedicine, GmbH, M-2018-344
NCT Number: NCT04792489
Meeting Type: Continuing Review of Protocol and Site
Title: A multi-center single arm Phase II study to evaluate the safety and efficacy of genetically engineered autologous cells expressing anti-CD20 and anti-CD19 specific chimeric antigen receptor in subjects with relapsed and/or refractory diffuse large B cell lymphoma

1. Call to order:

The Meeting was called to order at 10:19 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 five 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. 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 noted changes since the last review.

Point of Discussion:

1. An Institutional Representative confirmed that there are no deviations or research-related incidents have occurred and that Section E in the Continuing Review Report Form should be marked as "No."

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for MBCART2019.1, since it consists of primary human cells modified with a recombinant lentiviral vector. 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 MB-CART2019.1 locally**, provided all other biosafety criteria required for study closure are met. The Committee reaffirmed this determination.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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

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 Biosafety Officer confirmed that the yellow chemotherapy containers shown in the Olson Pavilion Photos document are not typically used for biohazardous waste generated in IBC-reviewed studies and will verify with Olson Pavilion staff that such waste is not disposed of in these containers.

11. Site requirements:

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

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 10:24 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 8.0, dated 12-05-2025

Investigator's Brochure, Edition 10.0, dated 05-30-2025

Apheresis and Investigational Medicinal Product Manual, Version 7.1, dated 06-09-2025

Research Modification Evaluation, Protocol, Version 8.0

Research Modification Evaluation, Investigator's Brochure, Edition 10.0

Research Modification Evaluation, Apheresis and Investigational Med Prod Manual, Version 7.1

Biological Risk Assessment and Summary, updated 01-23-2026

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 02-20-2026

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, Prentice and Olson, dated 04-01-2026

Biohazard Sign, Olson MCCT, dated 02-20-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 03-17-2025

SOP Addendum, Biosafety for Autologous Cells, dated 02-20-2026

Training, Shipping Certification, expires 06-05-2027

CRRF, dated 03-03-2026

Prior Meeting Minutes, Continuing, dated 06-20-2025