

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, May 21, 2026
Time: 9:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Reem Karmali, MD, MS
Protocol: Juno Therapeutics, Inc., a wholly owned subsidiary of Celgene Corporation, **JCAR017-EAP-001**
NCT Number: NCT04400591
Meeting Type: Continuing Review of Protocol and Site
Title: Expanded Access Protocol (EAP) for Subjects Receiving Lisocabtagene Maraleucel that is Nonconforming for Commercial Release

1. Call to order:

The Meeting was called to order at 9:22 am Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were four 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: 5 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.

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for JCAR017, since it consists of autologous T cells modified by a 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 JCAR017 locally**, provided all other criteria for study closure are 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: 5 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.

Point of Discussion:

1. The Biosafety Officer confirmed that biohazardous waste generated in studies under IBC review is disposed of in the red biohazardous waste containers available in the Olson Pavilion dosing areas.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:26 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 3.0, dated 03-20-2024
Investigator's Brochure, Version 13, dated 02-04-2026
Product Administration Manual, Version 1.0, dated 08-12-2020
Sponsor Letter, dated 03-19-2024
Sponsor Letter, FDA Extended Approval, dated 12-12-2025
Research Modification Evaluation, Investigator's Brochure, Version 13
Research Modification Evaluation, Sponsor Letter, FDA Extended Approval, dated 12-12-2025
Biological Risk Assessment and Summary, updated 03-12-2026
Site Map, Olson, 1st Floor, dated 01-23-2026
Site Map, Prentice, 5th Floor, Rube Walker Blood Center, dated 03-07-2023
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, Olson MCCT, dated 02-20-2026
Biohazard Sign, Prentice and Olson, dated 04-01-2026
Biological Safety Cabinet Certifications, Olson MCCT, expires 09-2026
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 02-02-2026
Prior Meeting Minutes, Continuing, dated 05-28-2025