

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, June 27, 2025
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Northside Hospital, Atlanta, GA
Principal Investigator: Scott R. Solomon, MD
Protocol: Juno Therapeutics, a Celgene Company, 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 10:33 am Eastern 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 two 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 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 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 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: 5

NO: 0

ABSTAIN: 0

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

10. Review of proposed facilities and practices:

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

Points of Discussion:

1. An Institutional Representative confirmed that used personal protective equipment (PPE) is disposed of into an appropriate container. The Committee recommended that the Institution confirm the specific type of container used and the Main Biosafety SOP Section 4 be updated accordingly.
2. The Committee recommended that the following language be added to the Main Biosafety SOP Section 5.2.4, "If a plumbed eyewash is not readily available, immediately start rinsing the affected eye using a prefilled disposable eyewash bottle, and escort the exposed individual to the closest eyewash station."
3. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to include the amount of time an eye must be flushed according to the Institution's policy.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:37 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 3.0, dated 03-20-2024

Investigator's Brochure, Version 12, dated 02-03-2025

Product Administration Manual, Version 1.0, dated 08-12-2020

Sponsor Letter, dated 03-19-2024

Research Modification Evaluation, Investigator's Brochure, Version 12

Biological Risk Assessment and Summary, updated 02-25-2025

Site Map, HSC Laboratory, dated 01-29-2024

Site Map, BMT Unit, 4th Floor, dated 01-29-2024

Site Inspection Checklist, GMHC, expires 02-10-2027, updated 06-11-2025

Site Inspection Checklist, Autoclave Addendum, dated 02-11-2025, updated 02-24-2025

Photos, HSC Lab, BMT Unit, dated 02-12-2025

Biohazard Sign, Genetically Modified Human Cells, dated 06-11-2025

Biological Safety Cabinet Certifications, HSC Lab, expires 06-2025

SOP, Biosafety for Genetically Modified Human Cells, dated 06-18-2025

SOP Addendum, Biosafety for Autologous Cells, dated 06-11-2025

Training, Shipping Certification, expires 03-10-2026

CRRF, dated 03-03-2025, updated 06-25-2025

Prior Meeting Minutes, Continuing, dated 06-21-2024