

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, September 11, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Norton Hospital, Louisville, KY
Principal Investigator: Don Ambrose Stevens, 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 1:15 pm 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 nine 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 primary human cells modified using 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 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.

Points of Discussion:

1. The Committee recommended that, per best biosafety practices, a sharps container be placed inside the Biological Safety Cabinet (BSC) during study agent preparation for immediate disposal of used needles and vials.
2. The Committee recommended that if it is institutional policy not to have a sharps container inside the BSC, an explanation of this be provided in the Site Inspection Checklist, Item 11 comments.
3. The Committee recommended that biohazardous waste containers for disposal of personal protective equipment (PPE) and other non-sharp items be made available in the dosing rooms and that a representative photo of these containers be provided to IBC Services.

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 1:23 pm Eastern Time.