INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, January 21, 2026**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Virginia Oncology Associates, Norfolk, VA
Principal Investigator:	**Scott Cross, MD, PhD**
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 1:01 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 was one Institutional Representative 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:

The 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 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

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 Institutional Representative confirmed that only safety needles will be used for this study. The Committee recommended that Biosafety SOP, Addendum Section 2.2 be revised accordingly.
2. The Committee noted that Biosafety SOP, Addendum Section 2.2 indicates an 18-gauge needle will be used to withdraw the study agent from the vial but that sponsor documents note that a 20-gauge needle should be used. The Committee recommended that the Institution confirm whether an 18-gauge needle is acceptable and revise Biosafety SOP, Addendum Section 2.2 as needed.
3. The Committee recommended that the Biosafety SOP and Biosafety SOP, Addendum be reviewed at least annually and that the date on the SOP be updated to reflect the most recent reviewed date.
4. The Committee recommended that the institution provide IBC Services with a site map that shows the storage and preparation/dosing rooms in more detail. The Institutional Representative confirmed that they do not have more detailed blueprints available but that a hand-drawn map could be provided. The Committee determined this to be acceptable and recommended that the map includes items such as sinks, eyewashes, and benchtop preparation areas.
5. The Committee recommended that Site Inspection Checklist, Item #22 be revised to indicate that there is no eyewash in the preparation and dosing room.
6. The Institutional Representative confirmed that the study agent arrives in a sponsor-provided dewar for “just in time” dosing and there is no permanent storage unit on site.
7. The Institutional Representative confirmed that an SOP training log is available and will be provided to IBC Services.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

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 1:21 pm 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, dated 01-06-2026
Site Inspection Checklist, expires 10-14-2026, updated 01-06-2026
Photos, dated 10-14-2024
Biohazard Sign, dated 10-07-2021
SOP, Biosafety for Genetically Modified Human Cells, dated 12-15-2021
SOP, Addendum Biosafety for JCAR017, dated 09-15-2021
Training, Shipping Certification, expires 04-17-2027

CRRF, dated 08-11-2025, updated 01-16-2026
Prior Meeting Minutes, Continuing, dated 10-29-2024