INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

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| **Meeting Date:** | **Friday, November 6, 2026** |
| **Time:** | 11:00 am Eastern Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | OhioHealth Research Institute, Columbus, OH |
| **Principal Investigator:** | **Basem William, MD, MRCP, FACP** |
| **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 11:00 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 three 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 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 Committee recommended that Biosafety SOP Sections 3.3.1, 3.3.2, and 3.3.3 be revised to indicate which study agent the preparation method applies to.
2. The Committee recommended that Biosafety SOP Sections 3.3.1 and 3.3.2 be revised by removing references to discarding the needle without recapping as the safety needle is recapped by engaging the safety mechanism, then removed, and replaced with a syringe cap.
3. The Committee recommended that Biosafety SOP Section 5.1.4 be revised to indicate that surfaces will be wiped down with either 70% alcohol or water after the initial decontamination using PDI Super Sani-Cloth wipes or 10% bleach solution.
4. An Institutional Representative stated that sharps containers are not kept inside Biological Safety Cabinets (BSCs) per institutional policy. The Committee recommended that site documents be revised to reflect this.
5. The Committee noted that the BSCs used for study agent preparation are due for re-certification in November 2026 and recommended that the new BSC certifications be provided to IBC Services when available.
6. The Committee recommended that a biohazard symbol be placed on top of the biohazardous waste container in the 6 Blue dosing room.
7. An Institutional Representative stated that disposable eyewash bottles are no longer used per institutional policy.
8. The Committee recommended that the photo of the LN2 storage tank that is not labelled with a biohazard symbol be removed from the site photos.

**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 11:17 am Eastern 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, 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 Maps, CART Cells, dated 09-25-2026

Site Inspection Checklist, CART Cells, expires 11-13-2027, updated 09-25-2026
Photos, CART, dated 12-17-2025
Biohazard Sign, Genetically Modified Human T-Cells, dated 09-30-2026
Biosafety Cabinet Certifications, CART Cells, expire 11-30-2026
SOP, Institutional Biosafety for CART, dated 11-02-2026
Training, Shipping Certifications, expire 2027, 2028
CRRF, dated 09-21-2026
Prior Meeting Minutes, Continuing, dated 12-15-2025