

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Tuesday, January 13, 2026  
**Time:** 1:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** The West Clinic, Memphis, TN  
**Principal Investigator:** Jason Chandler, MD, MPH, FACP  
**Protocol:** Juno Therapeutics, a Celgene Company, JCAR017-EAP-001  
**NCT Number:** NCT04400591  
**Meeting Type:** Initial 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 1:14 pm 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 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

### 7. Determination for biosafety level and period of IBC oversight:

The Committee 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 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.

### 8. 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

### 9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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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. An Institutional Representative confirmed that plumbed eyewash stations are flushed weekly and a flush log is maintained.
2. An Institutional Representative confirmed that biohazard waste containers are closed when not in use.
3. An Institutional Representative confirmed that absorbent material will be placed inside the internal transport container.
4. An Institutional Representative confirmed that hand soap and paper towels are available near sinks.
5. The Committee recommended that the Photos document Slide 2 be revised to add a comment noting that hand soap and paper towels are available near sinks.
6. The Committee recommended that the Biohazard Sign be revised to read as, "Agents: bb2121; JCAR017; Genetically Modified Human Cells".

### **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 1:20 pm Central 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

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

Photos, Memphis, dated 01-02-2026

Site Map, Memphis, dated 01-02-2026

Site Inspection Checklist, expires 10-04-2026, updated 12-02-2025

Biohazard Sign, Genetically Modified Human Cells, dated 01-06-2026

SOP Biosafety for JCAR017, dated 12-17-2025

Training, Shipping Certification, expires 07-18-2027

CV, Chandler, J., signed 11-20-2025