

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, December 15, 2025  
**Time:** 9:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** OhioHealth Research Institute, Columbus, OH  
**Principal Investigator:** Basem M. William, MD, MRCP, FACP  
**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 9:27 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 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 discussed that study agent preparation and dosing is not adequately described in Biosafety SOP Sections 3.3 and 3.5 as the study agent is withdrawn from vials into a syringe and the prepared syringe is used for dosing.
2. The Committee recommended that Biosafety SOP 3.3 be revised to include subsections that clarify the specific preparation procedures used for study agent infusion bags versus study agent vials.
3. The Committee recommended that Biosafety SOP Section 3.5 be revised to include dosing procedures for syringes, including that used syringes will be discarded into a biohazardous waste container immediately after use.
4. The Committee recommended that Biosafety SOP Section 3.6.1 be revised to include the appropriate wet contact times for the listed disinfectants.
5. An Institutional Representative confirmed that only Super Sani-Cloth wipes would be used for small spills. The Committee recommended that Biosafety SOP Section 5.1.4a.i. be revised accordingly.
6. The Committee recommended that Biosafety SOP Section 5.1.4b.1 be revised to specify that the final concentration of bleach used for treating large spills should be 10%.
7. An Institutional Representative could not confirm whether any of the phone numbers listed on the Biohazard Sign are monitored 24/7. The Committee recommended that the Institution follow up with IBC Services regarding this and ensure that a 24/7 phone number is listed on the sign.
8. The Committee recommended that the door to the biohazardous waste storage room be labeled with a biohazard symbol and that a photo of the labeled door be provided to IBC Services.
9. An Institutional Representative confirmed that prefilled disposable eyewash bottles are no longer used in any areas where study agent handling activities occur as plumbed eyewash stations are available in each of these areas. The Committee recommended that site documents be revised accordingly.
10. An Institutional Representative confirmed that all the study agents listed in the Biosafety SOP are associated with protocols that the Institution expects to participate in in the future. The Committee determined this to be acceptable.
11. An Institutional Representative confirmed that sharps containers are located within arm's reach underneath the biological safety cabinets (BSCs) during study agent preparation.
12. An Institutional Representative confirmed that study agent preparation will only occur in the [REDACTED] inside a BSC for this protocol.

### **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 9:36 am Eastern Time.