

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Tuesday, October 7, 2025  
**Time:** 11:00 am Arizona Time  
**Location:** Zoom Teleconference  
**Institution:** Western Regional Medical Center, Inc. dba City of Hope Phoenix, Goodyear, AZ  
**Principal Investigator:** Aileen Go, MD  
**Protocol:** Celgene Corporation, BB2121-EAP-001  
**NCT Number:** NCT04771078  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** Expanded Access Protocol (EAP) for Subjects Receiving Idecabtagene Vicleucel that is Nonconforming for Commercial Release

### 1. Call to order:

The Meeting was called to order at 11:22 am Arizona Time.

### 2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

### 3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were two 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.

### Point of Discussion:

1. The Committee discussed whether study staff have experience with Expanded Access Protocols (EAPs). An Institutional Representative stated that there is an open EAP study at the institution in which no one has enrolled but study staff do have experience with the commercial product.

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

The Committee determined that **BSL-2 containment facilities and practices** are required for ide-cel, since it consists of primary human cells modified with a recombinant lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's, last dose locally of ide-cel**, provided all other biosafety criteria required 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: 4

NO: 0

ABSTAIN: 0

### 9. Review of Principal Investigator qualifications:

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

## INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

### **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 Section 2.3 be revised to indicate that an EpiPen is available in the event that someone goes into anaphylactic shock.
2. The Committee discussed eyewash signage for the storage room and recommended that the same eyewash signs that are used at the main location be used for the eyewash in the [REDACTED]
3. The Committee discussed a sign in the storage room that indicates a “dirty sink w/ eyewash station.” The Committee recommended that the institution follow up with IBC Services on what is meant by “dirty sink” as this sink also appears to be used as an eyewash.
4. The Committee recommended that prefilled disposable eyewash bottles be made available in the preparation/dosing rooms.
5. The Chair stated that disposable eyewash bottles come in multiple sizes, typically 4 or 32 oz, and that the institution could purchase either size but should ensure that a large quantity is on hand.
6. An Institutional Representative confirmed that biohazardous waste containers are kept lidded. The Committee recommended that a photo, showing a lidded biohazardous waste container, 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: 4

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

### **14. Meeting adjourned:** The meeting was adjourned at 11:27 am Arizona Time.