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:	**Yvonne A. Efebera, MD, MPH**
Protocol:	Celgene Corporation, **BB2121-EAP-001**
NCT Number:	NCT04771078
Meeting Type:	Continuing 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 9:01 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 ide-cel, since it consists of primary human cells modified with 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 ide-cel locally**, provided all other biosafety criteria required 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. An Institutional Representative confirmed that a biological safety cabinet (BSC) will not be used for study agent preparation since the only preparation involved is thawing the infusion bag and that Biosafety SOP Section 3.3 was written broadly to cover all study agents.
2. An Institutional Representative confirmed that if the infusion bag was found to have a leakage, it would be placed inside the BSC until they received clarification from the Sponsor on how to handle the leaking bag.
3. 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.
4. An Institutional Representative confirmed that if the full dose in the infusion bag was not required to be administered to the subject, the appropriate volume would be infused, and the infusion bag would be discarded as biohazardous waste with the remaining volume still in the bag. The Committee recommended that Biosafety SOP Section 3.5 be revised accordingly.
5. The Committee recommended that Biosafety SOP Section 3.6.1 be revised to include the appropriate wet contact times for the listed disinfectants.
6. 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.
7. 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%.
8. 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.
9. 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.
10. 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.
11. 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. 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 9:26 am Eastern Time.