

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, November 13, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Atlantic Health System, Morristown, NJ
Principal Investigator: Mohamad Cherry, 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 1:01 pm 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 four 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 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: 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. The Committee recommended that Biosafety SOP Section 3.3 be revised to reflect that the study agent is thawed in a water bath on a countertop. The biological safety cabinet (BSC) will not be used for preparation as there are no open manipulations of the study agent.
2. The Committee recommended that the Biohazard Sign be revised to include a detailed description of the study agent, "bb2121, autologous T cells modified using a lentiviral vector expressing a BCMA-specific CAR."
3. An Institutional Representative confirmed that 16-ounce prefilled disposable eyewash bottles are stored in an office and brought to the dosing room when a subject is ready to be dosed. The Committee recommended that site documents be revised to reflect this.
4. An Institutional Representative confirmed that pharmacy and clinical staff undergo N95 fit testing annually.
5. An Institutional Representative confirmed that it is standard institutional policy to wear an N95 when cleaning spills.
6. An Institutional Representative confirmed that the BSC is scheduled to be recertified prior to the due date listed in the current report.
7. The Committee noted that special provisions or restrictions for entry only apply to the specific protocols listed in the Site Inspection Checklist, Item #4.

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 1:17 pm Eastern Time.