

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, December 11, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Norton Hospital, Louisville, KY
Principal Investigator: **Don Ambrose Stevens, MD**
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 Idecaracetagene Vicleucel that is Nonconforming for Commercial Release

1. Call to order:

The Meeting was called to order at 1:18 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 five 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

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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 noted they had previously confirmed with the Institution that the dirty utility closet at the [REDACTED] location is in a secure, controlled area. The Committee recommended that a comment be added to Slide 10 noting that this room is in a secure, controlled area.
2. The Committee noted that the photos of the rooms on Slides 10 and 11 appear to be the same, however, the locations noted on these slides differ. The Committee recommended that the Institution confirm with IBC Services what location these photos apply to. The Committee recommended that additional photos of the biohazardous waste storage areas be submitted to IBC Services as needed, and that the Photos document be updated accordingly.

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 1:22 pm Eastern Time.