

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, September 2, 2025
Time: 12:00 pm Arizona Time
Location: Zoom Teleconference
Institution: HonorHealth, Scottsdale, AZ
Principal Investigator: Abraham S. Kanate, 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 12:02 pm 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 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: 4

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 the plumbed eyewashes be flushed on a weekly basis and recommended that the Institution follow-up with IBC Services about how often they are flushed.
2. The Committee noted that IATA/Shipping training for a study staff member expires in September 2025. The Committee recommended that the staff member complete training prior to the expiration date and the certification be provided to IBC Services, once available.

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 12:12 pm Arizona Time.