

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, May 18, 2026  
**Time:** 10:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** Northwestern University, Chicago, IL  
**Principal Investigator:** Seema Singhal, 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 Idecabtagene Vicleucef that is Nonconforming for Commercial Release

### 1. Call to order:

The Meeting was called to order at 10:00 am Central Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Biosafety Officer. 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: 6 NO: 0 ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted 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 locally of ide-cel, 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: 6 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.

**Point of Discussion:**

1. The Biosafety Officer confirmed that the yellow chemotherapy containers shown in the Olson Pavilion Photos document are not typically used for biohazardous waste generated in IBC-reviewed studies and will verify with Olson Pavilion staff that such waste is not disposed of in these containers.

**11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer.

**12. Vote on the Site:**

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6                      NO: 0                      ABSTAIN: 0

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

**14. Meeting adjourned:** The meeting was adjourned at 10:09 am Central Time.

**15. Post-meeting notes:** None.

**Documents reviewed:**

- Agenda
- Protocol, Amendment 3, dated 05-07-2024
- Investigator's Brochure, Version 12, dated 03-25-2026
- Product Handling Manual, Version 4.0, dated 03-19-2025
- Research Modification Evaluation, Investigator's Brochure, Version 12
- Biological Risk Assessment and Summary, updated 04-21-2026
- Site Map, Olson, 1st Floor, dated 01-23-2026
- Site Map, Olson, 7th Floor, MCCT, Room 7-424, dated 02-27-2025
- Site Map, Prentice, 16th Floor, dated 04-12-2024
- Site Map, Feinberg and Olson Loading Docks, received 10-16-2018
- Site Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 02-20-2026
- Photos, Olson Pavilion, MCCT, dated 06-05-2025
- Photos, Prentice Hospital, dated 04-25-2025
- Photos, Feinberg and Olson Loading Dock, dated 03-25-2026
- Photos, Olson Pavilion, Dosing, dated 05-01-2025
- Biohazard Sign, Prentice and Olson, dated 04-01-2026
- Biohazard Sign, Olson MCCT, dated 02-20-2026
- SOP, Biosafety for Genetically Modified Human Cells, dated 03-17-2025
- SOP Addendum, Biosafety for Autologous Cells, dated 02-20-2026
- Training, Shipping Certification, expires 06-05-2027
- CRRF, dated 02-04-2026
- Prior Meeting Minutes, Continuing, dated 05-28-2025