

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: Janssen Research and Development, 68284528MMY4006
NCT Number: NCT05346835
Meeting Type: Continuing Review of Protocol and Site
Title: Intermediate-Size Population Expanded Access Program (EAP) for Ciltacabtagene autoleucl (cilta-cel) Out-of-Specification (OOS) in patients with Multiple Myeloma.

1. Call to order:

The Meeting was called to order at 10:09 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 JNJ-68284528, since it consists of genetically modified primary human cells. 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 JNJ-68284528 locally**, provided that other biosafety criteria for study closure are also 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.

Points 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 10:13 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 4.0, dated 09-30-2024

Investigator's Brochure, Edition 10, dated 04-15-2025

Carvykti Prescribing Information, dated 10-2025

Research Modification Evaluation, Carvykti Prescribing Information, dated 06-2025

Research Modification Evaluation, Carvykti Prescribing Information, dated 10-2025

Biological Risk Assessment and Summary, updated 11-12-2025

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Prentice, 5th Floor, Rube Walker Blood Center, dated 03-07-2023

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, Prentice Hospital, dated 04-25-2025

Photos, Olson Pavilion, MCCT, dated 06-05-2025

Photos, Olson Pavilion, Dosing, dated 05-01-2025

Photos, Feinberg and Olson Loading Dock, dated 03-25-2026

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 03-03-2026

Prior Meeting Minutes, Continuing, dated 06-04-2025