

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, July 24, 2026
Time: 11:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Reem Karmali, MD, MS
Protocol: Novartis Pharmaceuticals, CCTL019B2003I
NCT Number: NCT03601442
Meeting Type: Continuing Review of Protocol and Site
Title: Managed Access Program (MAP) to provide access to CTL019, for acute lymphoblastic leukemia (ALL) or large B-cell lymphoma patients with out of specification leukapheresis product and/or manufactured tisagenlecleucel out of specification for commercial release

1. Call to order:

The Meeting was called to order at 11:09 am Central 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. 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 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 CTL019, since it consists of autologous T cells modified by a 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 CTL019 locally**, provided all other criteria 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

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 Committee discussed that the biological safety cabinet (BSC) certification reports for the Cellular Therapy Lab indicate that certification is performed on an annual basis but that the Biosafety Officer previously noted these are typically certified on a semi-annual basis. The Committee recommended that the Institution confirm whether the BSCs are certified on an annual or semi-annual basis and that future certification reports indicate the correct certification schedule.

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 11:14 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 03, dated 01-06-2025

Investigator's Brochure, Edition 15, dated 03-31-2026

Novartis CAR-T Cells, Product Handling Manual, Version 1.0, dated July 2023

Research Modification Evaluation, , Investigator's Brochure, Edition 15

Biological Risk Assessment and Summary, updated 04-17-2026

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

Site Map, Olson, 7th Floor, MCCT, Room 7-424, dated 02-27-2025

Site Map, Olson, 7th Floor, MCCT, Room 7-613, dated 02-19-2024

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 07-01-2026

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

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

Photos, Prentice Hospital, dated 04-25-2025

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

Biohazard Sign, Dosing Areas, dated 07-13-2026

Biohazard Sign, Olson MCCT, dated 07-13-2026

Biological Safety Cabinet Certifications, Olson MCCT, expires 03-2027

SOP, Biosafety for Genetically Modified Human Cells, dated 06-15-2026

SOP Addendum, Biosafety for Autologous Cells, dated 07-13-2026

Training, Shipping Certification, expires 06-05-2027

CRRF, dated 04-28-2026

Prior Meeting Minutes, Continuing, dated 08-27-2025