

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, February 17, 2026
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: Northside Hospital, Atlanta, GA
Principal Investigator: Scott R. Solomon, MD
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 11:00 am Eastern 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 two 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: 4 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: 4 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.

Points of Discussion:

1. The Committee noted that a new Site Inspection Checklist Autoclave Addendum is due to be completed prior to the end of March 2026.
2. The Committee recommended that the second line of personal protective equipment (PPE) listed on the Biohazard Sign be revised to read as, "Use the following PPE for handling at all other times and for spill clean-up: gloves, gown, mask and eye protection".
3. An Institutional Representative noted that full containers of biohazardous waste generated in the Pharmacy is kept within the HSC Laboratory under a counter where it is picked up directly two times per week by the commercial biohazardous waste hauler. The Committee determined that this is acceptable.
4. The Committee recommended that the Site Map be revised to note where in the HSC Laboratory the biohazardous waste container is stored and that a photo of this area be submitted to IBC Services.

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 11:13 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 03, dated 01-06-2025

Investigator's Brochure, Edition 14, dated 03-27-2025

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

Research Modification Evaluation, Investigator's Brochure, Edition 14

Biological Risk Assessment and Summary, updated 04-16-2025

Site Map, BMT Unit, 4th Floor, dated 01-29-2024

Site Map, HSC Laboratory, dated 01-29-2024

Site Inspection Checklist, GMHC, expires 01-29-2028

Site Inspection Checklist, Autoclave Addendum, dated 02-11-2025, updated 02-24-2025

Photos, HSC Lab, BMT Unit, dated 07-03-2025

Biohazard Sign, Genetically Modified Human Cells, dated 01-26-2026

Biological Safety Cabinet Certifications, HSC Lab, expire 06-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 01-26-2026

SOP Addendum, Biosafety for Autologous Cells, dated 01-26-2026

Training, Shipping Certifications, expire 03-10-2026, 04-30-2026

CRRF, dated 11-03-2025

Prior Meeting Minutes, Continuing, dated 02-21-2025