INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, July 15, 2026**
Time:	9:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Michele Donato, MD**
Protocol:	Kite Pharma, Inc., **KT-US-471-0140**
NCT Number:	NCT05776160
Meeting Type:	Continuing Review of Protocol and Site
Title:	Expanded access study for the treatment of patients with commercially out-of-specification Axicabtagene Ciloleucel.

1. Call to order:

The Meeting was called to order at 9:01 am Eastern 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 was one Institutional Representative 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:

The Biosafety Officer 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 axicabtagene ciloleucel, since it consists of autologous T cells modified by a gammaretroviral 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 axicabtagene ciloleucel**, 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: 6 NO: 0 ABSTAIN: 0

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 recommended that Biosafety Guidelines, Addendum for Autologous Cells Section 2.5 be revised to remove the duplicate study agent description.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative and 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 9:08 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 2.0, dated 09-12-2025
Protocol Clarification Letter 1, dated 04-16-2026
Investigator's Brochure, Edition 16, dated 01-07-2026
Investigational Product Manual, Version 7.0, dated 05-29-2026
Research Modification Evaluation, Protocol, Version 2.0
Research Modification Evaluation, Protocol Clarification Letter 1, dated 04-16-2026
Research Modification Evaluation, Investigator's Brochure, Edition 16
Research Modification Evaluation, Investigational Product Manual, Version 6.0
Research Modification Evaluation, Investigational Product Manual, Version 7.0
Biological Risk Assessment and Summary, updated 06-22-2026
Site Maps, Genetically Modified Human Cells, updated 11-19-2025
Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 06-03-2026
Biohazard Sign, Donato, dated 07-02-2026
Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025
Biosafety Guidelines, Addendum for Autologous Cells, dated 07-02-2026
Training, Shipping Certifications, expire 10-2026, 11-2026, 12-2026, 2027
CRRF, dated 04-01-2026
Prior Meeting Minutes, Continuing, dated 07-30-2025