INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, September 2, 2026**
Time:	9:00 am Central Time
Location:	Zoom Teleconference
Institution:	Northwestern University, Chicago, IL
Principal Investigator:	**Reem Karmali, MD, MS**
Protocol:	Kite Pharma, Inc., a Gilead Company, **KT-US-740-0603**
NCT Number:	NCT07479797
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicabtagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy

1. Call to order:

The Meeting was called to order at 9:00 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 three 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for KITE-753 and axicabtagene ciloleucel, since they consist of genetically modified primary human cells.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of KITE-753 and axicabtagene ciloleucel locally**, provided all other biosafety criteria required for study closure are met.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 recommended that the study agent description for KITE-753 be revised in the SOP Addendum, Biosafety for Autologous Cells to read “autologous T cells modified using a lentiviral vector encoding CD19- and CD20-specific CARs.”
2. The Biosafety Officer previously confirmed that the biological safety cabinets (BSCs) in the MCCT are certified on a semi-annual basis. The Committee noted that the BSC certification reports provided by the certifier are marked as being certified on an annual schedule and recommended 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 Biosafety Officer and 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: 6 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:10 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Original, dated 01-09-2026
Investigator's Brochure, KITE-753, Edition 3.0, dated 09-12-2025
Investigator's Brochure, Axicabtagene ciloleucel, Edition 16, dated 01-07-2026
Investigational Product Manual, KITE-753, Version 8.0, dated 08-14-2026
Investigational Product Manual, Axicabtagene ciloleucel, Version 13.0, dated 05-29-2026
Biological Risk Assessment and Summary, updated 08-25-2026
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 08-24-2026
Photos, Olson Pavilion, Dosing, dated 05-01-2025
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
Biohazard Sign, Dosing Areas, dated 08-24-2026
Biohazard Sign, Olson MCCT, dated 08-24-2026
Biological Safety Cabinet Certifications, Olson MCCT, dated 03-27-2026
SOP, Biosafety for Genetically Modified Human Cells, dated 06-15-2026
SOP Addendum, Biosafety for Autologous Cells, dated 08-24-2026
Training, Shipping Certification, expires 06-05-2027
CV, Karmali, R, signed 02-17-2026