INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, July 27, 2026**
Time:	9:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Northside Hospital, Atlanta, GA
Principal Investigator:	**Lizamarie Bachier-Rodriguez, MD**
Protocol:	Kite Pharma, Inc., **KT-US-499-0150**
NCT Number:	NCT04989803
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 1/2 Open-label, Multicenter Study Evaluating the Safety and Efficacy of KITE-363, an Autologous Anti-CD19/CD20 CAR T-cell Therapy, in Subjects with Relapsed and/or Refractory B-cell Lymphoma

1. Call to order:

The Meeting was called to order at 9:11 am Eastern 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 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 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 KITE-363 and KITE-753, since they consist 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 KITE-363 and KITE-753 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

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 SOP Addendum, Biosafety for Autologous Cells Section 3.2.2 be revised to remove KITE-753 and that both KITE-363 and KITE-753 be added to Section 3.2.4 since the study agent may be withdrawn from the infusion bag into a syringe for dosing.
2. The Committee recommended that SOP Addendum, Biosafety for Autologous Cells Section 3.4.2 be revised to add KITE-363 since it may be administered via IV push infusion.
3. The Institutional Representative confirmed that enrollment is open and two subjects have been dosed.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

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 9:19 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 6.0, dated 02-13-2026
KITE-363, Investigator's Brochure, Version 8.0, dated 10-15-2025
KITE-753, Investigator's Brochure, Edition 3.0, dated 09-12-2025, Corrected
KITE-363, Investigational Product Manual, Version 8.0, dated 05-29-2026
KITE-753, Investigational Product Manual, Version 7.0, dated 05-29-2026
Research Modification Evaluation, Protocol, Amendment 5.0
Research Modification Evaluation, Protocol, Amendment 6.0
Research Modification Evaluation, KITE-363, Investigator's Brochure, Version 7.0
Research Modification Evaluation, KITE-363, Investigator's Brochure, Version 8.0
Research Modification Evaluation, KITE-753, Investigator's Brochure, Edition 3.0
Research Modification Evaluation, KITE-753, Investigator's Brochure, Edition 3.0, Corrected
Research Modification Evaluation, KITE-363, Investigational Product Manual, Version 7.0
Research Modification Evaluation, KITE-363, Investigational Product Manual, Version 8.0
Research Modification Evaluation, KITE-753, Investigational Product Manual, Version 6.0
Research Modification Evaluation, KITE-753, Investigational Product Manual, Version 7.0
Biological Risk Assessment and Summary, updated 06-10-2026
Site Map, BMT Unit, 4th Floor, dated 01-29-2024
Site Map, HSC Laboratory, dated 06-01-2026
Site Inspection Checklist, GMHC, expires 01-29-2028, updated 04-17-2026
Site Inspection Checklist, Autoclave Addendum, expires 04-20-2028
Photos, HSC Lab, BMT Unit, dated 04-23-2026
Biohazard Sign, Genetically Modified Human Cells, dated 07-13-2026
Biological Safety Cabinet Certifications, HSC Lab, expire 12-2026
SOP, Biosafety for Genetically Modified Human Cells, dated 07-13-2026
SOP Addendum, Biosafety for Autologous Cells, dated 07-13-2026
Training, Shipping Certification, expires 01-2028
CRRF, dated 04-02-2026
Prior Meeting Minutes, Continuing, dated 07-03-2025