

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, March 12, 2026
Time: 10:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: George Georges, MD
Protocol: Kite Pharma, Inc., KT-US-728-0204
NCT Number: NCT07304154
Meeting Type: Initial Review of Protocol and Site
Title: A phase 1 open-label, multiregional, multicenter, basket study evaluating the safety and efficacy of KITE-363, an autologous anti-CD19/CD20 CAR T-cell therapy in participants with relapsed/refractory autoimmune neurologic diseases.

1. Call to order:

The Meeting was called to order at 10:00 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 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. 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-363 since it consists of primary human cells modified using a recombinant lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of KITE-363 locally**, provided that all other criteria 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.

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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 there are multiple points of entry at the loading docks where full containers of biohazardous waste are stored. The Biosafety Officer confirmed that biohazard signage is posted closest to the loading dock full biohazardous waste storage area.
2. The Committee recommended that the Biosafety Officer confirm if a wall mounted plumbed eyewash sign is present near the plumbed eyewash station located in the Prentice 16-2114 (Clean Utility Room).

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with 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 10:10 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 1.0, dated 08-20-2025

Investigator's Brochure, Version 8.0, dated 10-15-2025

Investigational Product Manual, Version 7.0, dated 11-24-2025

Biological Risk Assessment and Summary, updated 02-24-2026

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

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

Site Map, 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 02-20-2026

Photos, Prentice Hospital, dated 04-25-2025

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

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

Photos, Feinberg and Olson Loading Dock, dated 03-05-2025

Biohazard Sign, Prentice and Olson, dated 03-02-2026

Biohazard Sign, Olson MCCT, dated 02-20-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 03-17-2025

SOP Addendum, Biosafety for Autologous Cells, dated 02-20-2026

Training, Shipping Certification, expires 06-05-2027

CV, Georges, G., signed 01-14-2026