

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, December 5, 2025
Time: 11:00 am Mountain Time
Location: Zoom Teleconference
Institution: Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator: Daanish Hoda, MD
Protocol: Kite Pharma, Inc., **KT-US-728-0204**
NCT Number: NA
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 11:00 am Mountain 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 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: 5

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 recommended that "IV push infusion" be removed from Biosafety SOP Section 3.5 as this is not applicable.
2. The Committee recommended that the brackets referring to wipes and paper towels be removed from Biosafety SOP Section 5.1.6.
3. The Committee recommended that the reference to the eyewash in the [REDACTED] be removed from the [REDACTED] site map as this is not accurate.
4. An Institutional Representative confirmed that prefilled disposable eyewash bottles are not available in the preparation/dosing rooms but there are plumbed eyewash stations located on that same floor. The Committee found this to be acceptable.
5. An Institutional Representative confirmed that PDI Super Sani-Cloth wipes are used for spill clean-up. The Committee recommended that the Site Inspection Checklist (#19) be revised to reflect this.
6. The Committee discussed how disposable PPE is handled after use. An Institutional Representative stated that PPE that is not visibly soiled is disposed of as garbage and is not placed into a biohazardous waste container. The Committee recommended that all disposable PPE be discarded into biohazardous waste containers per best biosafety practices.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:16 am Mountain Time.