

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, July 21, 2025  
**Time:** 12:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** University of North Carolina at Chapel Hill, Chapel Hill, NC  
**Principal Investigator:** Natalie Grover, MD  
**Protocol:** Kite Pharma, Inc., KT-US-472-0141  
**NCT Number:** NCT05776134  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** Expanded access study for the treatment of patients with commercially out-of-specification Brexucabtagene Autoleucel.

### 1. Call to order:

The Meeting was called to order at 12:31 pm Eastern Time.

### 2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

### 3. Declaration of quorum:

Seven voting members were present, including three 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. Approval of previous meeting minutes:

Minutes Approved - YES: 7 NO: 0 ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of 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 KTE-X19, 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 KTE-X19 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: 7

NO: 0

ABSTAIN: 0

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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 the protocol number in the Storage section of the Site Inspection Checklist be changed from KT-US-472-014 to KT-US-472-0141.
2. An Institutional Representative confirmed that rooms [REDACTED] in the [REDACTED] are used for subject dosing.
3. An Institutional Representative could not confirm how frequently the plumbed eyewash station is flushed and whether a log of that action is maintained.
4. An Institutional Representative confirmed that they are aware that an updated Investigator's Brochure is available.

### **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: 7

NO: 0

ABSTAIN: 0

**13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 12:35 pm Eastern Time.