

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, July 25, 2025  
**Time:** 8:00 am US Mountain Time  
**Location:** Zoom Teleconference  
**Institution:** Banner Research, Gilbert, AZ  
**Principal Investigator:** Matthew Ulrickson, MD  
**Protocol:** Kite Pharma, Inc., KT-US-471-0140  
**NCT Number:** NCT05776160  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** Expanded access study for the treatment of patients with commercially out-of-specification Axicabtagene Ciloleucel.

### 1. Call to order:

The Meeting was called to order at 8:00 am US Mountain Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Four voting members were present, including two local members unaffiliated with the institution. Also present were five 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: 4 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-C19, 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-C19 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: 4 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.

#### **Point of Discussion:**

1. An Institutional Representative confirmed that biohazard-labeled red bags are placed in red biohazardous waste containers, which should be labeled with a biohazard symbol. The Committee recommended that the Photos document be revised to indicate biohazard waste containers are labeled. The Committee recommended that the Institution submit an updated/representative photo to IBC Services of a biohazard-labeled biohazardous waste container available in the dosing room.

### **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: 4

NO: 0

ABSTAIN: 0

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

### **14. Meeting adjourned:** The meeting was adjourned at 8:09 am US Mountain Time.