

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Tuesday, June 24, 2025  
**Time:** 10:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Prisma Health-Upstate, Greenville, SC  
**Principal Investigator:** Suzanne Fanning, DO  
**Protocol:** Kite Pharma, Inc., KT-US-484-0136  
**NCT Number:** NCT05605899  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** An Adaptive Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of Axicabtagene Ciloleucel versus Standard of Care Therapy as First-Line Therapy in Subjects with High-Risk Large B-Cell Lymphoma (ZUMA-23)

### 1. Call to order:

The Meeting was called to order at 10:15 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 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: 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 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 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 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: 5 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 Biosafety SOP Section 3.4.1 be revised to indicate that absorbent material will be added to the Ziploc-style bag.
2. The Committee noted that Biosafety SOP Section 5.1.4c appropriately describes how spills in the water bath will be handled.
3. The Committee recommended that site documents be revised to indicate that access to the storage rooms and biohazardous waste storage rooms is limited to institutional staff.
4. The Committee recommended that Site Inspection Checklist, item 21 be revised to "Not Applicable" for the use of hand sanitizer prior to exiting rooms where sinks are not available since all preparation and dosing rooms have sinks.
5. The Committee recommended that a photo of the water bath and the area (i.e. mobile cart, countertop) where the study agent is thawed be provided to IBC Services.
6. The Committee recommended that the internal transport container be labeled with a biohazard symbol and that a photo of the labeled container be provided to IBC Services. The Committee noted that it may be possible to use a magnetic biohazard symbol that can easily be applied and removed when study agent is present.
7. An Institutional Representative could not confirm whether there is a biohazard-labeled freezer for study agent storage in [REDACTED]. The Committee recommended that the Institution follows up with IBC Services.
8. The Committee recommended that biohazardous waste containers be kept covered when not in use and that updated photos be provided to IBC Services.
9. An Institutional Representative confirmed that the [REDACTED] rooms may be used as study agent storage locations. The Committee recommended that all site documents be revised accordingly.

### **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 10:21 am Eastern Time.