

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, December 11, 2025  
**Time:** 1:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Norton Hospital, Louisville, KY  
**Principal Investigator:** **Don Ambrose Stevens, MD**  
**Protocol:** Kite Pharma, Inc., **KT-US-499-0150**  
**NCT Number:** NCT04989803  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** A Phase 1/2 Open-label, Multicenter Study Evaluating the Safety and Efficacy of KITE-363, an Autologous Anti-CD19/CD20 CAR T-cell Therapy, in Subjects with Relapsed and/or Refractory B-cell Lymphoma

### 1. Call to order:

The Meeting was called to order at 1:00 pm 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 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. 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 and KITE-753, since they consist of genetically modified primary human cells.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of KITE-363 and KITE-753 locally**, provided 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. An Institutional Representative confirmed that sharps containers are not placed inside of the Biological Safety Cabinet (BSC) due to limited space in the BSC. The Committee noted that small single-use size sharps container are available commercially and recommended that the Institution considers purchasing these smaller containers.
2. The Committee recommended that a small sharps container be placed inside of the Biological Safety Cabinet (BSC) for the immediate disposal of preparation supplies.
3. The Committee noted they had previously confirmed with the Institution that the dirty utility closet at the [REDACTED] location is in a secure, controlled area. The Committee recommended that a comment be added to Slide 10 noting that this room is in a secure, controlled area.
4. The Committee noted that the photos of the rooms on Slides 10 and 11 appear to be the same, however, the locations noted on these slides differ. The Committee recommended that the Institution confirm with IBC Services what location these photos apply to. The Committee recommended that additional photos of the biohazardous waste storage areas be submitted to IBC Services as needed, and that the Photos document be updated 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 1:17 pm Eastern Time.