

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, June 23, 2025  
**Time:** 2:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Norton Hospital, Louisville, KY  
**Principal Investigator:** Don Ambrose Stevens, MD  
**Protocol:** Allogene Therapeutics, ALLO-329-101  
**NCT Number:** N/A  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** A Phase 1 Study Evaluating The Safety And Preliminary Efficacy of ALLO-329, A Dual Anti-CD19 / Anti-CD70 Allogeneic CAR T Cell Product In Autoimmune Disease (Resolution)

### 1. Call to order:

The Meeting was called to order at 2:00 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 six 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 ALLO-329, since it consists of primary human cells modified using a recombinant adeno-associated viral vector and mRNAs.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of ALLO-329 locally**, provided that other biosafety criteria for study closure are also 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 a sign be posted above the eyewash in the [REDACTED] indicating the location of this eyewash station, and that an updated photo be submitted to IBC Services.
2. An Institutional Representative confirmed that sharps containers used within the Biological Safety Cabinet have lids affixed to them. The Committee recommended that a representative photo of these sharps containers be provided to IBC Services.
3. The Committee recommended that a photo of the waterbath used to thaw the study agent (which should be labeled with a biohazard symbol) be provided to IBC Services.

### **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 2:11 pm Eastern Time.