

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, October 15, 2025  
**Time:** 8:00 am US Arizona Time  
**Location:** Zoom Teleconference  
**Institution:** Banner Research, Gilbert, AZ  
**Principal Investigator:** Matthew Ulrickson, MD  
**Protocol:** Allogene Therapeutics, ALLO-501A-202  
**NCT Number:** NCT06500273  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A randomized, open-label study evaluating the efficacy and safety of Cemacabtagene Ansedgleucel in participants with minimal residual disease after response to first line therapy for Large B-Cell Lymphoma (ALPHA3).

### 1. Call to order:

The Meeting was called to order at 8:16 am US Arizona 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 one local member 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 ALLO-501A, since it consists of primary human cells modified using a recombinant lentiviral vector and mRNAs. 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 ALLO-501A locally**, provided that other biosafety criteria for study closure are also 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.

#### **Points of Discussion:**

1. The IBC Chair noted that updated biological safety cabinet (BSC) certification reports were provided to IBC Services shortly before the meeting and that one of the reports was for a Baker SG504 [REDACTED] Class II, A2 BSC rather than for the Thermo 1206 [REDACTED] Class II, A2 BSC already on file.
2. An Institutional Representative confirmed that the Thermo 1206 BSC was decommissioned and replaced with the Baker SG504 BSC. The Committee recommended that 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: 4

NO: 0

ABSTAIN: 0

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

**14. Meeting adjourned:** The meeting was adjourned at 8:22 am US Arizona Time.