INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, July 29, 2025**
Time:	3:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	AdventHealth Orlando, Orlando, FL
Principal Investigator:	**Rushang Patel, 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 Ansegedleucel 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 3:08 pm Eastern 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 three 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

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 photo of the [redacted] entry door, labeled with a biohazard symbol, be provided to IBC Services.
2. The Committee recommended that a representative photo of the biohazardous waste containers available in the dosing rooms be provided to IBC Services.
3. An Institutional Representative stated that used study agent infusion bags are transported back to [redacted] and not discarded as biohazardous waste in the dosing room. The Committee recommended that the institution follow up with IBC Services on the process for this, including the container the infusion bags will be transported in.

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 3:21 pm Eastern Time.