INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, June 25, 2026**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Lori Leslie, 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 10:09 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 and the Intuition's Biosafety Officer. 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:

The Biosafety Officer 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 noted 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 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

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. The Committee noted the biological safety cabinet (BSC) certification reports expired in May of 2026 and recommended that the most recent BSC certification be provided to IBC Services.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer.

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 10:14 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 2, dated 07-25-2025
Investigator's Brochure, Edition 6.0, dated 03-21-2025
Investigational Product Manual, Version 3.0, dated 04-25-2025
Research Modification Evaluation, Protocol, Amendment 1
Research Modification Evaluation, Protocol, Amendment 2
Research Modification Evaluation, Protocol Clarification Letter, dated 04-17-2025
Research Modification Evaluation, Investigator's Brochure, Edition 6.0
Research Modification Evaluation, Investigational Product Manual, Version 3.0
Biological Risk Assessment and Summary, updated 10-13-2025
Site Maps, Genetically Modified Human Cells, updated 11-19-2025
Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 05-04-2026
Biohazard Sign, Leslie, dated 03-27-2026
Biological Safety Cabinet Certifications, CTMF, expire 05-31-2026
Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025
Biosafety Guidelines, Addendum for Allogeneic Cells, dated 04-28-2025
Training, Shipping Certifications, expire 10-2026, 11-2026, 12-2026, 2027
CRRF, dated 05-15-2026
Prior Meeting Minutes, Continuing, dated 06-16-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, June 25, 2026**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Michele Donato, MD**
Protocol:	Autolus, Inc., **AUTO1-OS1**
NCT Number:	NCT06799221
Meeting Type:	Continuing Review of Protocol and Site
Title:	Expanded Access Program (EAP) for Obecabtagene Autoleucel (obe-cel) Out-of-specification (OOS) in Adult Patients with Acute Lymphoblastic Leukemia

1. Call to order:

The Meeting was called to order at 10:00 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 and the Intuition's Biosafety Officer. 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:

The Biosafety Officer 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 noted 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 obe-cel since it consists of primary human cells modified using a recombinant, replication-defective lentiviral vector. 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 obe-cel locally**, provided that all other 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: 5 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 noted the biological safety cabinet (BSC) certification reports expired in May of 2026 and recommended that the most recent BSC certification be provided to IBC Services.
2. The Committee acknowledged that the Biosafety Guidelines Addendum contains adequate details about gravity flow versus IV push infusion.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer.

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 10:09 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 1.0, dated 11-22-2024
Investigator's Brochure, Version 6.0, dated 10-23-2024
Prescribing Information, dated 11-2024
Biological Risk Assessment and Summary, dated 02-13-2025
Site Maps, Genetically Modified Human Cells, updated 11-19-2025
Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 05-04-2026
Biohazard Sign, Donato, dated 11-13-2025
Biological Safety Cabinet Certifications, CTMF, expire 05-31-2026
Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025
Biosafety Guidelines, Addendum for Autologous Cells, dated 05-04-2026
Training, Shipping Certifications, expire 10-2026, 11-2026, 12-2026, 2027
CRRF, dated 04-17-2026
Prior Meeting Minutes, Initial, dated 06-16-2025