INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, August 28, 2026**
Time:	9:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Yukiko Kimura, MD**
Protocol:	Autolus Limited UK, **AUTO1-SL2**
NCT Number:	NCT07053800
Meeting Type:	Initial Review of Protocol and Site
Title:	A Single-arm, Open-label, Phase II Study to Determine the Safety and Efficacy of Obecabtagene Autoleucel (Obe-cel) In Participants with Severe, Refractory Systemic Lupus Erythematosus with Active Lupus Nephritis

1. Call to order:

The Meeting was called to order at 9:01 am Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution, and the Institution's Biosafety Officer. 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:

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. 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 obe-cel since it consists of autologous human cells modified using a lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of obe-cel locally**, provided all other 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: 6 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 recommended that a photo of the hard-sided internal transport container used to transport prepared syringes from the preparation room to the dosing rooms be provided to IBC Services.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 6 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:10 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 5.0, dated 02-24-2026
Protocol Clarification Letter, dated 07-22-2026
Investigator's Brochure, Version 7.0, dated 05-15-2026
Product Handling Manual, Version 1.0, dated 03-10-2025
Biological Risk Assessment and Summary, updated 08-26-2026
Site Maps, Genetically Modified Human Cells, updated 11-19-2025
Site Map, Joseph M. Sanzari Children's Hospital, Ground Floor (Reuten Clinic), dated 12-16-2025
Site Map, Joseph M. Sanzari Children's Hospital, 5th Floor, dated 12-23-2025
Site Inspection Checklist, Sanzari Children's Hospital, expires 12-19-2027, updated 08-19-2026
Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2028
Photo, Sanzari Children's Hospital, Medical Cart, dated 12-05-2022
Biohazard Sign, Kimura, dated 07-20-2026
Biological Safety Cabinet Certifications, CTMF, expire 11-30-2026
Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025
Biosafety Guidelines, Addendum for obe-cel, dated 08-19-2026
Training, Shipping Certifications, expire 10-2026, 11-2026, 12-2026, 2027
CV, Kimura, Y., signed 10-07-2024