INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, July 7, 2026**
Time:	3:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Muna Qayed, MD, MSc**
Protocol:	Autolus Limited UK, **AUTO1-PY1**
NCT Number:	NCT06173518
Meeting Type:	Initial Review of Protocol and Site
Title:	A Single-Arm, open-label, multicenter, phase 1b/2 study evaluating the safety and efficacy of AUTO1 (obecabtagene autoleucel [obe-cel]) in pediatric patients with CD19-positive Relapsed/Refractory (R/R) B cell Acute Lymphoblastic Leukemia (B ALL) or R/R Aggressive Mature B Cell Non–Hodgkin Lymphoma (B NHL).

1. Call to order:

The Meeting was called to order at 3:01 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 two local members unaffiliated with the institution. Also present were one Institutional Representative 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 Institutional Representative confirmed that the notice of the meeting was not publicly posted per Institutional policy.

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 primary human cells modified using a recombinant, replication-defective 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 that 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: 4 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.

Points of Discussion:

1. The Committee discussed the institution's reluctance to keep a sharps container inside the Biological Safety Cabinet (BSC), suggesting there may be some differing perspectives on the BSC's containment role and a concern that the container itself could be a potential contamination source. The Committee recommends that a puncture-resistant, leak-proof, lidded sharps container be placed within the BSC during all study agent preparation activities that may generate sharps, consistent with the CDC/NIH BMBL, 6th Edition (BSL-2 Standard Practices A5 and A5-c), the NIH Guidelines (Appendix G-II-B-2-j), and 29 CFR 1910.1030(d)(4)(iii)(A). To address the Institution's Infection Control's concerns, the Committee endorses the use of a small, single-use sharps container introduced at the start of the procedure and removed, closed, at its conclusion. This would further preserve the BSC's air curtain while eliminating any perceived cross-contamination risk.
2. The Committee suggested that the Institution's Infection Prevention staff consider reaching out to the Biosafety Officer or biosafety professionals at their affiliated academic center for additional perspective on the containment role of the biological safety cabinet and the rationale for point-of-generation sharps disposal.
3. The Committee recommended that Biosafety SOP Sections 3.2.5 and 3.4.2 be revised to change the protocol number (AUTO-PY1) to the study agent (obe-cel).
4. The Institutional Representative confirmed that a handwashing sink is located inside the Outpatient dosing room.
5. The Committee noted that the (*) asterisk on the Site Map indicates that the Cellular Lab location contains a sink and a BSC.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

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.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 5.0, dated 09-30-2025
Investigator's Brochure, Version 6.0, dated 10-23-2024
Product Handling Manual, Version 3.0, dated 10-24-2023
Biological Risk Assessment and Summary, dated 06-23-2026
Site Maps, dated 06-04-2026
Site Inspection Checklist, Cellular Therapy Lab, BMT Inpatient Outpatient, expires 01-14-2027, updated 06-29-2026
Photos, dated 06-03-2026
Biohazard Sign, Genetically Modified Human Cells, dated 06-25-2026
Biological Safety Cabinet Certifications, Cell Therapy Lab, expires 09-2026
SOP, Biosafety for Genetically Modified Human Cells, dated 05-08-2026
SOP Addendum, Genetically Modified Human cells, dated 06-25-2026
Training, Shipping Certifications, expire 10-2026, 12-2026
CV, Qayed, M., signed 08-27-2025