

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, June 2, 2026
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Corewell Health, Grand Rapids, MI
Principal Investigator: Sami Brake, MD
Protocol: Lyell Immunopharma, Inc., LYL314-101
NCT Number: NCT05826535
Meeting Type: Continuing Review of Protocol and Site
Title: A phase 1/2 multi-center study evaluating the safety and efficacy of IMPT-314, a CD19/20 bispecific chimeric antigen receptor (CAR) T cell therapy in participants with relapsed or refractory aggressive B-cell non-hodgkin lymphoma.

1. Call to order:

The Meeting was called to order at 1:00 pm 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. 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 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 LYL314, since it consists of human cells modified using a lentiviral vector administered in a clinical setting. The Committee reaffirmed this determination.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of LYL314 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: 5 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 Committee discussed the IBCS assessment for the deviation/research-related incident report and noted that it appears that it was submitted to the NIH.
2. The Committee discussed a photo of the water bath on the mobile cart in the Preparation/Dosing Room and noted that it appears that one photo might be super-imposed another. The Committee recommended that the photo be fixed.
3. The Institutional Representative confirmed that the study agent is not prepared in a Biological Safety Cabinet (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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:11 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 6.0, dated 03-11-2025

Investigator's Brochure, Edition 8, dated 02-25-2026

Drug Administration Manual, Revision 2, dated 11-03-2025

Research Modification Evaluation, Protocol, Version 6.0

Research Modification Evaluation, Investigator's Brochure, Edition 7

Research Modification Evaluation, Investigator's Brochure, Edition 8

Research Modification Evaluation, Drug Administration Manual, Revision 1

Research Modification Evaluation, Drug Administration Manual, Revision 2

Biological Risk Assessment and Summary, updated 03-27-2026

LYL314-101, Deviation Assessment, dated 10-13-2025

Research Modification Evaluation, Change in Preparation, dated 10-14-2025

Site Map, Butterworth Hospital, 5th Floor, dated 02-17-2026

Site Inspection Checklist, expires 01-09-2027, updated 02-17-2026

Photos, BW Hospital, Dosing Area, dated 02-18-2026

Biohazard Sign, dated 09-12-2025

SOP, Biosafety for LYL314, dated 09-12-2025

Training Shipping Certifications, expire 2026, 2027

CRRF, dated 03-13-2026

Prior Meeting Minutes, (frmly MPCT-012L), Continuing, dated 06-06-2025