

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, April 22, 2026
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Lehigh Valley Health Network, Allentown, PA
Principal Investigator: Apurva Vyas, MD
Protocol: XyloCor Therapeutics, Inc., XC001-1002
NCT Number: NCT07048808
Meeting Type: Continuing Review of Protocol and Site
Title: Endocardial Delivery of XC001 Gene Therapy for Refractory Angina Coronary Treatment: A 26-Week (with 26 Week Extension) Phase 2b Randomized, Multi-Center, Double-Blind, Sham Controlled Study to Evaluate Efficacy and Safety (The EXACT-2 Trial)

1. Call to order:

The Meeting was called to order at 12:00 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 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 XC001, since it consists of a recombinant adenoviral 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 XC001 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

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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 Biosafety SOP Section 5.1.4a.i be revised to indicate that the spill will be overlaid with paper towels and the paper towels will then be saturated with the appropriate disinfectant and allowed to stand for the required wet contact time.

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 12:09 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 7.1, dated 02-25-2026

Investigator's Brochure, Version 17, dated 10-03-2025

Pharmacy Manual, Version 3, dated 12-18-2025

Research Modification Evaluation, Protocol, Version 5.0

Research Modification Evaluation, Protocol, Version 6.0

Research Modification Evaluation, Protocol, Version 7.0

Research Modification Evaluation, Protocol, Version 7.1

Research Modification Evaluation, Investigator's Brochure, Version 16

Research Modification Evaluation, Investigator's Brochure, Version 17

Research Modification Evaluation, Pharmacy Manual, Version 2

Research Modification Evaluation, Pharmacy Manual, Version 3

Biological Risk Assessment and Summary, updated 03-17-2026

Research Modification Evaluation, Change in PI, dated 08-25-2025

CV, Vyas, A., signed 5-13-2024

Site Maps, dated 03-14-2025

Site Inspection Checklist, expires 03-13-2027, updated 02-23-2026

Photos, dated 03-10-2025

Biohazard Sign, dated 08-20-2025

Biological Safety Cabinet Certification, expires 09-2026

SOP, Biosafety for XC001, dated 02-20-2025

Training, Shipping Certification, expires 7-12-2026

CRRF, dated 01-12-2026

Prior Meeting Minutes, Initial, dated 04-03-2025