

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, April 14, 2026
Time: 1:00 pm Central Time
Location: Zoom Teleconference
Institution: Allina Health System, Minneapolis, MN
Principal Investigator: [REDACTED]
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 1:00 pm Central 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 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:

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: 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 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: 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 recommended that Biosafety SOP Section 3.5 be revised to indicate how the dosing needle is primed prior to administration.
2. An Institutional Representative could not confirm the type of material for the covering on the bed in the dosing room, whether it's cloth or paper. The Committee recommended that the institution follow up with IBC Services on this and that site documents, including Site Inspection Checklist (#17), be revised accordingly.
3. The Committee recommended that the institution confirm whether biohazardous waste is stored in the operating rooms for any protocols listed on the Site Inspection Checklist.
4. An Institutional Representative could not confirm if the mobile cart that contains disposable eyewash bottles will be brought into the dosing room during administration. The Committee recommended that the institution follow up with IBC Services on this.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:13 pm Central 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

Site Map, ANW, Pharmacy, dated 10-09-2025

Site Map, ANW, 3rd Floor Cath Labs, dated 10-09-2025

Site Inspection Checklist, ANW, expires 11-04-2026, updated 10-27-2025

Photos, ANW Hospital, Pharmacy, dated 10-07-2025

Photos, ANW Hospital, Cath Lab, dated 10-07-2025

Biohazard Sign, XC001, dated 10-09-2025

Compounding Aseptic Isolator Certification, ANW Pharmacy, expires 04-2026

SOP, Biosafety for XC001, dated 10-10-2025

Training, Shipping Certification, expire 02-05-2027

CRRF, dated 01-02-2026

Prior Meeting Minutes, Initial, dated 04-14-2025