INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, November 3, 2025**
Time:	3:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	The Ohio State University, Columbus, OH
Principal Investigator:	**Kukbin Choi, MD**
Protocol:	XyloCor Therapeutics, Inc., **XC001-1003**
NCT Number:	NCT07118449
Meeting Type:	Initial Review of Protocol and Site
Title:	A 26-Week (with 26 Week Extension) Randomized, Multi-Center, Double-Blind Phase 2 Study to Evaluate the Efficacy and Safety of XC001 Gene Therapy as an Adjunct to Coronary Artery Bypass Graft Surgery for Patients with Symptomatic Coronary Artery Disease with Left Ventricular Dysfunction at Risk for Incomplete Revascularization

1. Call to order:

The Meeting was called to order at 3:02 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 and the Institution's Biosafety Officer. Also present were five Institutional Representatives, an Independent Consultant, 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. 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 XC001 since it consists of a genetically modified adenoviral vector administered in a clinical setting.

The Committee 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.

8. 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

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 Biological Safety Cabinet for the Class II Type B2 cabinet that will be used to prepare the study agent and noted that it appears to have been tested to CETA CAG-014:22 standards which focus only on airflow visualization studies. The Committee noted the following that this cabinet should be certified to NSF/ANSI 49 standards and are missing the following: airflow smoke pattern test, HEPA filter integrity leak test, site installation assessment and alarm calibration, blower interlock (critical to verify the proper operation of the blower interlock system), exhaust system performance, and cabinet integrity test.
2. The Committee noted that other Class II Type B2 BSCs at the Institution certified by the same company have undergone complete NSF/ANSI 49 testing. The Biosafety Officer noted that there it is likely that we do not have the full Certification report available for review, and that the BSC has most likely undergone full certification.
3. Since this is the first time the Committee is reviewing this particular Class II Type B2 BSC, the Committee determined as a **Condition of Approval** that a current (<12 months old) certification report for the Class II Type B2 Biological Safety Cabinet that will be used to prepare the study agent must be provided to IBC Services. The report must include passing results for the following NSF/ANSI 49-required tests:
    a. Downflow velocity profile test
    b. Inflow velocity test
    c. Airflow smoke pattern tests
    d. HEPA filter leak test
    e. Alarm function verification
    f. Blower interlock Exhaust system performance
4. The Committee recommended that a small sharps container be placed within the BSC during preparation of the study agent per best biosafety practices, and that Site Inspection Checklist Item 11 be updated accordingly.
5. An Institutional Representative confirmed that staff members use hand sanitizer prior to exiting the dosing room and then they wash their hands in a nearby sink.
6. The Committee recommended that the [redacted] Site Inspection Checklist Item 21 be revised to uncheck “Yes” for the third question and to check “Yes” for the fourth question.
7. The Committee recommended that [redacted] Site Inspection Checklist Item 22 be revised to change “Yes” to “N/A” in the first question.
8. The Committee recommended that the location of the sink near the dosing room be annotated on the [redacted] Site Map.
9. An Institutional Representative confirmed that the distance from the preparation room to the dosing room is not very far (within a few minutes) and that internal walkways are used.
10. The Committee discussed biohazard signage in the [redacted] and the Biosafety Officer noted that their policies are different than a typical lab setting. The Committee noted that it does not appear that any of the rooms used to store biohazardous waste are labeled with a biohazard symbol, however, an Institutional Representative confirmed that these rooms are limited to only staff members. The Committee recommended that these rooms be labeled with a biohazard symbol per best biosafety practices.
11. The Committee recommended that prepared syringes be placed in a small hard-sided sealable container for transportation from the preparation room to the dosing room and that the container be labeled with a biohazard symbol. An Institutional Representative agreed to confirm this information.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

	APPROVED
X	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

For a vote of CONDITIONALLY APPROVED, the following condition must be met before the proposed research can proceed:

a. A current (<12 months old) certification report for the Class II Type B2 Biological Safety Cabinet that will be used to prepare the study agent must be provided to IBC Services. The report must include passing results for the following NSF/ANSI 49-required tests:

- Downflow velocity profile test
- Inflow velocity test
- Airflow smoke pattern tests
- HEPA filter leak test
- Alarm function verification
- Blower interlock
- Exhaust system performance

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 3:30 pm Eastern Time.