INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, December 15, 2025**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	The Christ Hospital, Cincinnati, OH
Principal Investigator:	**Gregory F. Egnaczyk MD, PhD, FACC**
Protocol:	Alexion Pharmaceuticals, Inc., **ALXN2350-DCM-201**
NCT Number:	NCT 07218887
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1/2, Open-Label, Multicenter, Dose Finding and Dose Expansion Study to Investigate the Safety, Tolerability, and Efficacy of ALXN2350 Gene Therapy in Adult Participants with BAG3 Mutation Associated Dilated Cardiomyopathy

1. Call to order:

The Meeting was called to order at 10:02 am Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Three voting members were present, including one local member 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. 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.

Point of Discussion:

1. The Committee noted that wildtype AAV is capable of integration into the human genome and recommended that the Biological Risk Assessment be revised to replace “Wildtype AAV” with “The AAV vector is replication-defective…”

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for ALXN2350, since it consists of an AAV 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 ALXN2350 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: 3 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

Points of Discussion:

1. An Institutional Representative confirmed that an addendum to Principal Investigator's CV with clinical trial experience will be finalized shortly.
2. The Committee recommended that this addendum be submitted to IBC Services.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative noted that a new dosing room in a different building will be used for dosing, and confirmed that this new room is set up similarly to the dosing room noted in the site-specific document. In addition, this new dosing room has a sink for washing hands inside the room, however no plumbed eyewash is available. The Committee recommended that the Institution submit additional information about this new room to IBC Services for evaluation. The Committee found this arrangement acceptable.
2. An Institutional Representative confirmed that a sharps container attached to a wall is available in both dosing locations.
3. The Committee recommended per best biosafety and hand hygiene practices that in rooms without a sink, staff members should use hand sanitizer prior to exiting and then wash their hands in the closest available sink.
4. An Institutional Representative confirmed that at a minimum a biohazard symbol will be placed on the Biological Safety Cabinet during preparation and agreed to follow-up with IBC Services to confirm whether or not a biohazard sign is placed at the entrance to the preparation room. The Committee recommended that the study agent-specific Biohazard Sign be placed on the entrance door to the preparation room during study agent preparation.
5. The Committee recommended that the refrigerator and freezer storage units be labeled with a biohazard symbol when the study agent is on site and in storage.
6. An Institutional Representative confirmed that the staff member complete annual Exposure Control Plan (ECP) training annually and that this includes OSHA BBP training.

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: 3 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:26 am Eastern Time.