

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, September 8, 2025
Time: 3:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Cincinnati Eye Institute, Cincinnati, OH
Principal Investigator: Robert Sisk, MD
Protocol: Beacon Therapeutics, RPGR-005
NCT Number: N/A
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 2 Open-label Study to Evaluate the Safety of Laruparetigene Zovaparvovec Administered Bilaterally in Male Participants with X-Linked Retinitis Pigmentosa

1. Call to order:

The Meeting was called to order at 3:00 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 was 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. 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 AGTC-501 since it consists of an adeno-associated viral (AAV) vector administered by injection in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of AGTC-501 locally**, provided all other 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: 4

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

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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 the biohazard sign be revised to include a 24/7 phone number.
2. The Committee discussed processing of post-dosing samples. The Institutional Representative stated that the samples are centrifuged in the [REDACTED]. The Committee noted that this room should have posted biohazard signage in accordance with the institution's policies and recommended that a photo of this room be provided to IBC Services.
3. The Institutional Representative confirmed that biohazardous waste is stored in the [REDACTED].
4. The Committee discussed the biohazardous waste container in the [REDACTED] as shown in site photos, and noted that it doesn't look like a biohazardous waste container. The Institutional Representative stated that the photo is of a regular trash can but that the lab does have biohazardous waste containers, which are labelled with biohazard symbols.
5. The Committee recommended that photos of the [REDACTED] including labelled biohazardous waste containers and posted biohazard signage, be provided to IBC Services.
6. The Committee recommended that a sharps container be placed inside the Biological Safety Cabinet (BSC) during study agent preparation.

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

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