INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: **Monday, November 24, 2025**
Time: 2:00 PM Eastern Time.
Location: Zoom Teleconference
Institution: Cincinnati Eye Institute, Cincinnati, OH
Principal Investigator: **Robert Sisk, MD**
Protocol: Beacon Therapeutics, **AGTC-RPGR-002**
NCT Number: NCT04850118
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 2/3, Randomized, Controlled, Masked, Multi-center Study to Evaluate the Efficacy, Safety and Tolerability of Two Doses of AGTC-501, a Recombinant Adeno-associated Virus Vector Expressing RPGR (rAAV2tYF-GRK1-RPGR), Compared to an Untreated Control Group in Male Subjects with X-linked Retinitis Pigmentosa Confirmed by a Pathogenic Variant in the RPGR Gene

1. Call to order:

The Meeting was called to order at 2:26 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. 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. 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 provided an overview of 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 AGTC-501, since it consists of an AAV vector administered in a clinical setting and to align with IBC-approved research with similar agents at the site. 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 AGTC-501 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

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 noted that the Biological Safety Cabinet (BSC) used to prepare the study agent is due for recertification this month. The Institutional Representative noted that the BSC was recently recertified and agreed to provide the report to IBC Services following the meeting.
2. The Committee recommended photos of the biohazardous waste containers for disposal of personal protective equipment (PPE) and other non-sharps waste in the Preparation and Dosing Rooms be provided to IBC Services.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:30 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 5.0, dated 12-17-2024
Protocol Clarification Letter, dated 02-11-2025
Protocol Clarification Letter, dated 02-14-2025
Investigator's Brochure, Version 6.0, dated 08-29-2023
Pharmacy Manual, Version 8.0, dated 02-11-2025
Addendum to Pharmacy Manual, Version 8.0, dated 04-14-2025
Surgical Procedure Manual, Version 4.0, dated 02-11-2025
Pharmacy Manual, Drug Product Formulation 3.1 (DP 3.1), Version 1.0, dated 04-28-2025
Research Modification Evaluation, Protocol, Version 5.0
Research Modification Evaluation, Protocol Clarification Letter, dated 02-11-2025
Research Modification Evaluation, Protocol Clarification Letter, dated 02-14-2025
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Research Modification Evaluation, Pharmacy Manual, Version 8.0
Research Modification Evaluation, Addendum to Pharmacy Manual, Version 8.0, dated 04-14-2025
Research Modification Evaluation, Pharmacy Manual, DPF 3.1, Version 1.0
Biological Risk Assessment and Summary, updated 05-27-2025
Site Map, updated 10-29-2024
Site Inspection Checklist, expires 10-29-2026, updated 10-10-2025
Photos, dated 10-24-2025
Biohazard Sign, all studies, dated 09-15-2025
Biological Safety Cabinet Certification, dated 05-2025
SOP, Main, Biosafety for Ophthalmic AAV Study Agents, dated 08-04-2025
SOP, Addendum Biosafety for AGTC-501, 08-04-2025
Training, Shipping Certification, expires 10-21-2026
CRRF, dated 11-13-2025
Prior Meeting Minutes, Continuing, dated 11-15-2024