

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, August 11, 2026
Time: 4:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Ophthalmic Consultants of Boston and Boston Eye Surgery and Laser Center, Boston, MA
Principal Investigator: Jeffrey S. Heier, 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 4:02 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. Also present were 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 noted changes since the last review.

Point of Discussion:

1. The Institutional Representative stated that enrollment for new subjects is closed but previously dosed subjects may be re-treated, so the study will remain open and under IBC Oversight.

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

The Committee previously determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for AGTC-501, since it consists of an adeno-associated viral (AAV) vector administered by injection in a clinical setting. 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 all other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 recommended that the Biohazard Sign be revised to read as: "The Following adeno-associated virus (AAV)-based Study Agents may be present ..."
2. The Committee discussed the eyelid speculum and how it is decontaminated after use wanting to ensure that it is done per the manufacturer's specifications. The Committee recommended that the institution follow up with IBC Services on whether the eyelid speculum is reusable or disposable, and if reusable, how it is decontaminated. The Committee recommended that site documents be revised as necessary upon receipt of the follow-up information.
3. The Committee noted that the cardboard biohazardous waste container in the biohazardous waste storage area does not appear to be fully closed. The Institutional Representative stated that the flaps of the container are usually closed and that it is taped shut when full and ready for vendor pick-up. The Committee recommended that the site photos be revised to reflect this.
4. The Institutional Representative stated that all PPE worn by study staff is disposable. The Committee recommended that Site Inspection Checklist (#9) be revised to remove the comments referencing reusable PPE as they are not applicable.

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 4:20 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, Edition 7.0, dated 12-08-2025

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

Research Modification Evaluation, Protocol Clarification Letter, dated 02-14-2025

Research Modification Evaluation, Protocol Clarification Letter, dated 02-11-2025

Research Modification Evaluation, Investigator's Brochure, Edition 7.0

Research Modification Evaluation, Addendum to Pharmacy Manual, Version 8.0, dated 04-14-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Biological Risk Assessment and Summary, updated 01-22-2026
Research Modification Evaluation, Additional Storage Location, dated 08-28-2025
Site Map, OCB, updated 07-31-2025
Site Map, BESLC, dated 11-12-2025
Site Inspection Checklist, expires 04-16-2028, updated 04-23-2026
Photos, dated 11-24-2025
Biohazard Sign, Ophthalmic AAV Study Agents, dated 04-20-2026
Biosafety SOP, Ophthalmic AAV Study Agents, dated 04-20-2026
Biosafety SOP, Addendum for AGTC-501, dated 08-28-2025
Training Shipping Certification, expires 02-27-2027
Prior Meeting Minutes, Continuing, dated 05-29-2025