INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, September 3, 2025**
Time:	12:00 pm Central Time
Location:	Zoom Teleconference
Institution:	Retina Foundation of the Southwest, Dallas, TX
Principal Investigator:	**David G. Birch, PhD**
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 12:31 pm Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and one affiliated Institutional Representative. 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. 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.

Point of Discussion:

1. An Institutional Representative confirmed that enrollment is closed and that the three subjects randomized to the control group may be dosed with the study agent in approximately one year.

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 adeno-associated viral (AAV) vector administered by injection in a clinical setting. The Committee reaffirmed this determination.

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.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6 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 reviewed the newest Biological Safety Cabinet (BSC) Certification and did not have any questions or concerns. An Institutional Representative confirmed that BSC [redacted] is the BSC used for study agent preparation.
2. The Committee noted that the IATA Shipping Training Certification for a study staff member expires in October 2025.
3. The Committee discussed the Coverage TB spray and determined that it does not appear to be effective against the non-enveloped AAV-based study agent. The Committee recommended that the Institution use a bleach-based or other commercially available disinfectant with proved efficacy against non-enveloped viruses, such as adenovirus, AAV, and/or poliovirus.
4. An Institutional Representative confirmed that a 10% bleach solution could be made fresh for decontaminating work surfaces.
5. The Committee recommended that the Institution confirm the effective disinfectant(s) that will be used for the preparation and dosing locations and that the Site Inspection Checklist Item 19 and Biosafety SOP Section 3.7 be updated accordingly.
6. An Institutional Representative confirmed that the preparation location uses reusable eye protection. The Committee recommended that the Site Inspection Checklist Item 9 be revised to reflect the disinfectant used to decontaminate reusable eye protection and that Biosafety SOP Section 3.7.2 be updated accordingly.
7. An Institutional Representative confirmed that plumbed eyewash stations at the preparation and dosing locations are flushed on a weekly basis and a log of flushing is maintained.
8. An Institutional Representative confirmed that closed sharps containers and sealed red biohazardous waste bags are placed into the larger red plastic-lined cardboard containers located in the biohazard waste storage room at the dosing location.
9. The Committee noted that the study agent storage room number noted in the Prior Meeting Minutes is incorrect.

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: 6 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:43 pm Central Time.