

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, March 17, 2026
Time: 10:00 am Pacific Time
Location: Zoom Teleconference
Institution: The Retina Partners, Encino, CA
Principal Investigator: Amir H. Guerami, MD
Protocol: [REDACTED]
NCT Number: [REDACTED]
Meeting Type: Initial Review of Protocol and Site
Title: A Multi-Center, Randomized, Double-Masked, Active-Comparator-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of [REDACTED] in Participants with Neovascular Age-Related Macular Degeneration

1. Call to order:

The Meeting was called to order at 10:00 am Pacific 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, [REDACTED]. 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.

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 [REDACTED], since it consists of an 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** [REDACTED] 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: 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. An Institutional Representative stated that full waste containers are stored in and retrieved by the waste hauler from the waste closet. The Committee recommended that all site documents, including the Biosafety SOP, Site Inspection Checklist and Site map, be revised to indicate this.
2. An Institutional Representative stated that the waste closet is locked and that there is enough storage space for biohazardous waste and sharps containers.
3. An Institutional Representative will follow up with IBC Services on whether 10% bleach solution is used for spill clean-up. The Committee recommended that site documents be revised accordingly upon receipt of the follow-up information, including a photo of the bleach, if used.

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:09 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 0.0, dated 09-19-2025

Investigator's Brochure, Edition 9.0, dated 02-25-2026

Investigational Medicinal Product Manual, Version 1.0, dated 02-19-2026

Biological Risk Assessment and Summary, updated 02-27-2026

Site Map, The Retina Partners, Medical Office, dated 03-09-2026

Site Inspection Checklist, expires 07-08-2026, updated 03-09-2026

Photos, The Retina Partners, Medical Office, dated 03-09-2026

Biohazard Sign, [REDACTED], dated 04-07-2025

SOP, Biosafety for [REDACTED], dated 03-09-2026

Training, Shipping Certification, expires 06-25-2027

CV, Guerami, A., signed 03-06-2025