

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, August 28, 2026
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Retina Consultants San Diego, Escondido, CA
Principal Investigator: **Nikolas London, MD FACS**
Protocol: AbbVie, Inc., **RGX-314-2104**
NCT Number: NCT04704921
Meeting Type: Continuing Review of Protocol and Site
Title: A Randomized, Partially Masked, Controlled, Phase 2b/3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ATMOSPHERE)

1. Call to order:

The Meeting was called to order at 8:24 am Pacific 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 noted changes since the last review.

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 ABBV-RGX-314, since it consists of an AAV-vector administered 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 ABBV-RGX-314 locally**, provided that all 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

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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 IBC noted that preparation and dosing will occur at a separate facility not owned or directly affiliated with the Institution.
2. The Institutional Representative confirmed that the red biohazardous waste bag hanging from the rack in the dosing room is removed after every procedure, per the State of California Medical Waste Management Act.
3. The Institutional Representative confirmed that 16-ounce prefilled disposable eyewash bottles are brought from the Retina Consultants San Diego offices to Scripps Memorial Hospital La Jolla when a subject is being dosed. The Committee recommended that the Photos document be revised to replace the photo of the 4-ounce prefilled disposable eyewash bottles with the photo of the 16-ounce prefilled disposable eyewash bottles.
4. The Institutional Representative confirmed that the plumbed eyewash station outside, and not inside, the OR rooms. The Committee recommended that the Site Map be revised accordingly.

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 8:32 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 11.0, dated 10-14-2025

Protocol Administrative Change 4 Letter, dated 01-30-2026

Investigator's Brochure, Version 15, dated 04-24-2026

Pharmacy Manual, Version 8.0, dated 10-27-2025

Subretinal Administration Manual, Version 7.0, dated 10-30-2025

Research Modification Evaluation, Protocol, Version 11.0

Research Modification Evaluation, Protocol Administrative Change 4 Letter, dated 01-30-2026

Research Modification Evaluation, Investigator's Brochure, Version 15

Research Modification Evaluation, Pharmacy Manual, Version 8.0

Research Modification Evaluation, Subretinal Administration Manual, Version 7.0

Biological Risk Assessment and Summary, updated 04-03-2026

Site Map, Monte Vista Rd, Suite 104 & 209, dated 08-02-2024

Site Map, Scripps Memorial Hospital LaJolla, dated 12-11-2023

Site Inspection Checklist, expires 08-18-2028

Photos, 12630 Monte Vista Rd, dated 09-17-2025

Photos, Scripps Memorial Hospital La Jolla, dated 10-13-2023

Biohazard Sign, ABBV-RGX-314, dated 08-10-2026

SOP, Biosafety for ABBV-RGX-314, dated 08-10-2026

Training, Shipping Certification, expires 07-08-2028

CRRF, dated 06-05-2026

Prior Meeting Minutes, Continuing, dated 09-17-2025