INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, September 2, 2026**
Time:	8:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Retina Northwest, PC, Portland, OR
Principal Investigator:	**Apurva Patel, MD**
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 8:00 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, including one local member 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: 4 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 adeno-associated viral (AAV) vector being 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 ABBV-RGX-314 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: 4 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 Institutional Representative confirmed that the Clinic Site where used study agent vials are stored is a separate location from Providence St. Vincent Outpatient Surgery Center and Providence Portland Medical Center. The Committee recommended that site documents be updated to include the location name and address for the Clinic Site.
2. The Institutional Representative could not confirm if the autoclave is validated using biological indicators. The Committee recommended that the Institution follows up with IBC Services regarding this.

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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:10 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, Clinical Site, dated 07-16-2026
Site Map, OR Rooms, dated 12-18-2025
Site Map, Pharmacy, dated 07-31-2025
Site Inspection Checklist, expires 07-31-2027, updated 07-15-2026
Photos, dated 12-18-2025
Biohazard Sign, dated 12-18-2025
SOP, Biosafety for ABBV-RGX-314, dated 07-16-2026
Training, Shipping Certifications, expire 2027, 2028
CRRF, dated 05-29-2026, updated 07-16-2026
Prior Meeting Minutes, Continuing, dated 09-08-2025