

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, May 27, 2026
Time: 11:00 am Mountain Time
Location: Zoom Teleconference
Institution: Black Hills Regional Eye Institute, Rapid City, SD
Principal Investigator: Prema Abraham, 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 11:04 am Mountain 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 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: 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 Committee recommended that a photo of the biohazardous waste container used for disposal of PPE and other non-sharps items in OR4 be provided to IBC Services.
2. The Institutional Representative confirmed that the Lab Room is used for biohazardous waste storage. The Committee recommended that the Site Inspection Checklist be revised to reflect this.
3. The Institutional Representative confirmed that the freezer is used to store the study agent. The Committee recommended that the Institution consider replacing the biohazard sign on the freezer as it is curling up at the edges.

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 11:13 am Mountain 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 3 Letter, dated 07-23-2025

Research Modification Evaluation, Protocol Administrative Change 4, 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 6.0

Research Modification Evaluation, Subretinal Administration Manual, Version 7.0

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

Site Map, 2nd and 3rd Floors, dated 05-21-2025

Site Inspection Checklist, expires 05-09-2027, updated 05-12-2026

Photos, dated 05-22-2025

Biohazard Sign, dated 05-12-2026

SOP, Biosafety for ABBV-RGX-314, dated 05-12-2026

Training, Shipping Certification, expires 03-05-2027

CRRF, dated 02-20-2025

Prior Meeting Minutes, Continuing, dated 05-28-2025