INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, May 5, 2026**
Time:	2:00 pm Mountain Time
Location:	Zoom Teleconference
Institution:	Retina Associates of Utah, PC, Salt Lake City, UT
Principal Investigator:	**Robert Kwun, 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 2:00 pm 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 the Principal Investigator, 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 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 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

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 noted that IATA/Shipping training for a staff member expires in June 2026. The Committee recommended that the training be completed prior to the expiration and the certificate be provided to IBC Services.
2. The Institutional Representative confirmed that the plastic seals have been removed from pre-filled disposable eyewash bottles. The Committee recommended that an updated photo of these bottles be provided to IBC Services.
3. The Institutional Representative confirmed that sharps containers are readily available in study agent handing areas. The Committee recommended that Site Inspection Checklist (#13) be revised to indicate this.
4. The IBC noted that preparation and dosing will occur at a separate facility not owned or directly affiliated with the Institution.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative and the Principal Investigator.

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 2:08 pm 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 03-24-2026
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 Maps, dated 02-12-2026
Site Inspection Checklist, expires 04-20-2028
Photos, dated 02-12-2026
Biohazard Sign, dated 04-21-2026
SOP, Biosafety for ABBV-RGX-314, dated 02-12-2026
Training, Shipping Certification, expires 06-19-2026
CRRF, dated 02-02-2026
Prior Meeting Minutes, Continuing, dated 05-29-2025