INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, June 13, 2025**
Time:	12:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Cumberland Valley Retina Consultants, Hagerstown, MD
Principal Investigator:	**Allen Hu 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 12:11 pm Eastern 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 were 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 provided an overview of 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 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 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

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 confirmed that during preparation of the study agent, excess solution is expelled into a sterile cup that does not contain absorbent material. The Committee recommended sterile gauze be placed inside the sterile cup and that Biosafety SOP Section 3.4 be revised to add that "The syringe and cannula are tested and primed by expelling excess solution into a sterile cup inside covered with absorbent material."
2. The Committee noted that a study staff member is due to renew their IATA shipping training in 2025 and recommended that they submit their newer Shipping Certification to IBC Services upon retraining.

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 12:19 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 10.0, dated 02-28-2025
Investigator's Brochure, Version 14, dated 03-24-2025
Pharmacy Manual, Version 7.0, dated 04-07-2025
Subretinal Administration Manual, Version 5.0, dated 07-05-2023
Research Modification Evaluation, Protocol, Version 9.0
Research Modification Evaluation, Protocol, Version 10.0
Research Modification Evaluation, Investigator's Brochure, Version 14
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Research Modification Evaluation, Pharmacy Manual, Version 6.0
Research Modification Evaluation, Subretinal Administration Manual, Version 6.0
Biological Risk Assessment and Summary, updated 06-03-2025
Research Modification Evaluation, Site Location Changes, dated 08-06-2024
Site Map, Frederick Surgical Center, dated 06-04-2021
Site Map, Cumberland, dated 02-19-2025
Site Inspection Checklist, dated 02-24-2025, updated 05-28-2025
Photos, dated 02-19-2025
Biohazard Sign, All studies, dated 02-24-2025
SOP, Biosafety for RGX-314, dated 07-17-2024
Training, Shipping Certifications, expire 2025-2026
CRRF, dated 05-05-2025
Prior Meeting Minutes, Continuing, dated 06-20-2024