

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, July 11, 2025
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Retina Vitreous Associates of Florida, Largo, FL
Principal Investigator: David A. Eichenbaum, 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 12:00 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 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 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 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

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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 Institutional Representative confirmed that the information in the Site Inspection Checklist is still accurate. The Committee recommended that the Site Inspection Checklist be updated to note that the Institutional Representative confirmed the information in the document is still accurate.
2. The Committee discussed posted biohazard signage at the entrance to the study agent storage and biohazardous waste storage rooms and recommended that the Institution submit photos of the outside of these rooms to IBC Services and that the Photos document be updated accordingly.
3. The Institutional Representative noted that the door to the study agent storage room has been removed, and that this area is limited to only staff members. The Committee recommended that a biohazard symbol or sign be posted on the wall next to the storage room.
4. The Committee recommended that a photo to the entrance of the limited access area where the study agent storage room is located be submitted to IBC Services and the Photos document be updated accordingly.
5. The Institutional Representative confirmed that staff members are current in their IATA shipping training and agreed to submit current/updated training certifications to IBC Services.
6. The Institutional Representative confirmed that the phone number ending in [REDACTED] on the Biohazard Sign is available 24/7. The Committee recommended that the Biohazard Sign is updated to indicate that this phone number is a "24/7 number".

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.