

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, June 2, 2025
Time: 10:00 am Eastern Time.
Location: Zoom Teleconference
Institution: Southern Vitreoretinal Associates, PL, Tallahassee, FL
Principal Investigator: Harold L. Brooks Jr., 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 10:03 am Eastern 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: 3 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 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 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: 3 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 Biosafety SOP Section 3.6.2 be revised to indicate that “Super” Sani-Cloth Wipes are used to decontaminate reusable PPE.
2. The Institutional Representative confirmed that prefilled disposable eyewash bottles are available inside the preparation and dosing room. The Committee recommended that the Site Map be revised to reflect this.
3. The Committee recommended that 32-ounce prefilled disposable eyewash bottles, designed to specifically flush eyes in the event of an exposure, be purchased and made available in the preparation and dosing room.
4. The Committee recommended that photos showing the sharps container and biohazardous waste container inside the preparation and dosing room be provided to IBC Services.
5. The Institutional Representative confirmed that the study agent storage unit labeled as a refrigerator in the Photos document is a freezer and that the refrigerated formulation of the study agent has not been used at the site. The Committee recommended that the photo be renamed as “Study Agent Freezer.”
6. The Committee recommended that the study agent storage freezer be labeled with a biohazard sticker, similar to the one used on the internal transport container.
7. The Institutional Representative confirmed that the internal transport container without a biohazard symbol, as shown in the Photos document, is used to transport supplies and is not used to transport the study agent. The Committee recommended that this photo be removed from the document.

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 10:19 am Eastern Time.