

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, August 25, 2025
Time: 12:00 pm Central Time
Location: Zoom Teleconference
Institution: Retina Consultants of Texas - San Antonio, San Antonio, TX
Principal Investigator: Richard Gary Lane, 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 12:16 pm Central 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:

An 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 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: 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 discussed the biohazardous waste container in [REDACTED] as shown in site photos, and whether it is used for sharps or non-sharps biohazardous waste. The Institutional Representative stated that it is a sharps container but that it is used for both sharps and non-sharps, such as PPE. The Institutional Representative also stated that any PPE worn by study staff will be discarded into a regular garbage container as the risk of bodily fluids or study agent exposure is considered low by the surgery staff.
2. The Committee noted that site documents (Site Inspection Checklist #3 and #9) specifically state that an OSHA-required Exposure Control Plan is in place at the institution and that disposable PPE is discarded as biohazardous waste. The Committee stated that per OSHA sharps and non-sharps biohazardous should be placed into separate containers. The Committee stated that the institution must follow this practice and recommended that photos of both sharps and non-sharps containers be provided to IBC Services.
3. The Committee noted the "Soiled Linen" sign and biohazard symbol on the door to the [REDACTED] and discussed what is stored in that room. The Institutional Representative stated that the room is used for storage of both full and empty biohazardous waste containers and that site staff are aware that the room is not used only for storage of soiled linens. The Committee found this to be acceptable.
4. The Committee recommended that a larger photo of the biohazard signage on the study agent storage room door be provided to IBC Services.
5. The Institutional Representative confirmed that the study agent specific biohazard sign will be posted at the entrance to the areas where the study agent is handled.
6. The Committee recommended that the Site Map for the [REDACTED] be revised to include [REDACTED] as the preparation and dosing location.
7. The Institutional Representative confirmed that the plumbed eye wash is flushed weekly and a flush log is kept.

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 12:34 pm Central Time.