

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	Monday, June 9, 2025
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Southeast Retina Center, PC, Augusta, GA
Principal Investigator:	Dennis M. Marcus, 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 1:16 pm 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 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: 4 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 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 all other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

Point of Discussion:

1. The Committee noted that there is a risk of bleeding after subretinal injection and discussed whether additional biosafety precautions should be implemented. The Committee determined that BSL-1 containment facilities and practices plus Standard Precautions is appropriate for minimizing the risk of exposure to the study agent or bloodborne pathogens after injection.

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9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

<input checked="" type="checkbox"/>	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

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 recommended that Biosafety SOP Section 3.3 be revised to include that the sterile cup will be lined with sterile gauze prior to expelling excess solution into the cup.
2. The Committee recommended that the address in the Site Inspection Checklist for the Outpatient Surgical Facility be revised to "Suite 202", as noted in the Site Map for this facility.
3. The Institutional Representative confirmed that the handwashing sink and plumbed eyewash station are located inside of OR1 in Suite 202.
4. The Committee recommended that a photo of the handwashing sink and the plumbed eyewash station in OR1 be provided to IBC Services.
5. The Institutional Representative confirmed that the 706-910-9792 phone number is monitored 24/7. The Committee recommended that the Biohazard Sign be revised to reflect this.
6. The Committee noted that IATA/DOT Shipping Training Certification expired in April 2025 and recommended that an updated certificate be provided to IBC Services.

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:

<input checked="" type="checkbox"/>	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 1:29 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 6.0, dated 05-15-2025

Research Modification Evaluation, Protocol, Version 10.0

Research Modification Evaluation, Protocol, Version 9.0

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, Pharmacy Manual, Version 5.0

Research Modification Evaluation, Subretinal Administration Manual, Version 6.0

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Biological Risk Assessment and Summary, updated 06-03-2025

Site Map, dated 05-19-2023

Site Inspection Checklist, dated 04-09-2024, updated 03-21-2025

Photos, dated 02-18-2025

Biohazard Sign, dated 11-12-2024

SOP, Biosafety for RGX-314, dated 09-06-2024

Training, Shipping Certification, expires 04-17-2025

CRRF, dated 05-09-2025

Prior Meeting Minutes, Continuing, dated 05-07-2024