

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, January 29, 2026
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Southeast Retina Center, PC, Augusta, GA
Principal Investigator: Dennis M. Marcus, MD
Protocol: AbbVie, Inc., RGX-314-2202
NCT Number: NCT04567550
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 2, Randomized, Controlled, Dose-escalation Study to Evaluate the Efficacy, Safety, and Tolerability of RGX-314 Gene Therapy Delivered via a Single Suprachoroidal Space (SCS) Injection in Participants With Diabetic Retinopathy (DR) With and Without Center Involved-Diabetic Macular Edema (CI-DME) (ALTITUDE)

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 noted 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 ABBV-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 ABBV-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 a sink-mounted eyewash station has not been installed in Suite 201. The Committee recommended that the Institution consider installing a sink-mounted eyewash station inside one of the dosing rooms in this suite.
2. The Institutional Representative confirmed that reusable sharps are not used for this protocol. The Committee recommended that Site Inspection Checklist, Item #14 be revised accordingly.
3. The Institutional Representative confirmed that preparation and dosing occur in Exam Room 9 or 10 and that both rooms have sinks.

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 12:11 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 10.0, dated 07-02-2024

Investigator's Brochure, Version 14, dated 03-24-2025

Pharmacy Manual, Version 11.0, dated 03-26-2025

Single Suprachoroidal Administration Manual, (1.5 x 10 12 GC), Version 4.0, dated 11-10-2025

Single Suprachoroidal Administration Manual, Version 3.0, dated 11-05-2020

Single Suprachoroidal Administration with IP Dilution (1.0 x10 12 GC), Version 1.0. dated 07-19-2021

Single Suprachoroidal Administration with IP Dilution (5.0x10 11 GC), Version 3.0, dated 05-25-2021

Suprachoroidal Admin Manual, Refrigerated IP Dilution (1.0x10 12 GC), Version 1.0, dated 07-17-2023

Suprachoroidal Administration Manual, Refrigerated IP Dilution (5.0x10 11 GC), Version 1.0, dated 10-25-2021

Research Modification Evaluation, Investigator's Brochure, Version 14

Research Modification Evaluation, Pharmacy Manual, Version 11.0

Research Modification Evaluation, Single SCS Admin Man (1.5x10 12 GC), Version 3.0

Research Modification Evaluation, Single SCS Admin Manual (1.5x10 12 GC), Version 4.0

Biological Risk Assessment and Summary, updated 11-20-2025

Site Map, Suite 201, dated 05-19-2023

Site Inspection Checklist, expires 01-21-2028

Photos, dated 02-18-2025

Biohazard Sign, dated 11-12-2024

SOP, Biosafety for RGX-314, dated 01-06-2026

Training, Shipping Certification, expires 05-27-2027

CRRF, dated 01-06-2025

Prior Meeting Minutes, Continuing, dated 12-03-2024