

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, January 9, 2026
Time: 9:00 am Pacific Time
Location: Zoom Teleconference
Institution: California Retina Consultants - Bakersfield, Bakersfield, CA
Principal Investigator: Dilsher Dhoot, 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 9:11 am Pacific 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 were three Institutional Representatives 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

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 an eyewash sign be placed on the wall above the plumbed eyewash station and that a photo of this be provided to IBC Services.
2. An Institutional Representative stated that there is a new biohazardous waste storage area, located on the [REDACTED]. The Committee recommended that photos of this area be provided to IBC Services and that all site documents be updated to reflect the additional biohazardous waste storage area.
3. The Committee recommended that applicable sections of the Biosafety SOP be updated to reflect the revised study agent name, ABBV-RGX-314.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

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 9:16 am Pacific Time.