

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, August 6, 2025
Time: 12:00 pm Mountain Time
Location: Zoom Teleconference
Institution: Vision Research Center Eye Associates of New Mexico, Albuquerque, NM
Principal Investigator: John D. Pitcher III, 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 12:09 pm Mountain Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Six voting members were present, including three local members unaffiliated with the institution. IBC Services was also present. 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 was not present to confirm notice of the public posting. The Committee recommended that notice of the meeting be publicly posted for a week after today's meeting and that any comments or questions received by the institution be sent to IBC Services.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 6 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 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 other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

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9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6

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 discussed a previous IBC recommendation requesting that a biohazard symbol be placed on the top lid of the biohazardous waste container in [REDACTED] and that a new photo of this be provided to IBC Services. The Committee noted that this photo had not been provided.
2. The Committee discussed and determined that this recommendation should be a condition of approval and that IBC Services must receive the requested photo before research activities can continue. However, after discussion, it was discovered that an Institutional Representative had sent a photo of the biohazardous waste container in [REDACTED] labelled with a biohazard symbol on the lid. The photo was shown during the meeting, and the Committee found it to be acceptable.

11. Site requirements:

The Chair did not review training and communication requirements for maintaining IBC approval as an Institutional Representative was not present.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:28 pm Mountain Time.