

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, July 11, 2025
Time: 11:00 am Pacific Time
Location: Zoom Teleconference
Institution: Retina Consultants of Orange County, Orange, CA
Principal Investigator: Sean D. Adrean, MD, FAAO, FASRS
Protocol: AbbVie, Inc., RGX-314-3101
NCT Number: NCT05407636
Meeting Type: Continuing Review of Protocol and Site
Title: A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD

1. Call to order:

The Meeting was called to order at 11:17 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 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

Point of Discussion:

1. The Committee recommended that Item #8 in the Points of Discussion from the previous meeting minutes be revised to reference the correct section of the Biosafety SOP (5.1.4.i and not 5.4.i.).

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.

Point of Discussion:

1. The Institutional Representative confirmed that no subjects have been dosed.

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 other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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

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 IBC noted that preparation and dosing will occur at a separate facility not owned or directly affiliated with the Institution.
2. The Committee recommended that Biosafety SOP Section 5.1.4.ii. be revised to indicate that the surface, rather than the paper towels, should remain wet for a contact time of 10 minutes.
3. The Institutional Representative confirmed that the freezer labeled with the yellow biohazard sign, as shown in the Photos document, is used for study agent storage.
4. The Committee recommended that the biohazard sign be printed on fluorescent orange or orange-red paper per California Health and Safety Code Sections 118275 - 118320.
5. The Institutional Representative confirmed that the prefilled disposable eyewash bottles have an expiration date of October 2027 and that an updated photo would be provided to IBC Services.
6. The Institutional Representative confirmed that all biohazardous waste containers have been labeled with a biohazard symbol on the top and all visible sides.

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 11:23 am Pacific Time.