

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, September 17, 2025
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Retina Consultants San Diego, Escondido, CA
Principal Investigator: Nikolas JS London, MD, FACS
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 8:32 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

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 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.

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 the phone number on the Biohazard Sign is available 24/7. The Committee recommended that the Biohazard Sign be updated to indicate that the phone number is available "24/7".
2. The Committee recommended that the Institution purchase prefilled disposable eyewash bottles designed specifically for flushing eyes (these should contain 16-32 ounces of liquid)
3. The Institutional Representative confirmed that the carpet under the freezer is entirely covered by plastic. The Committee recommended that an updated photo be provided to IBC Services.
4. The Institutional Representative confirmed that no study agent is stored in the refrigerator. The Committee recommended that the photo of the refrigerator be removed from the Photos document.
5. The Committee recommended that the Photos document be updated to note that only the storage slides apply to the [REDACTED].
6. The Committee noted that per the State of California Medical Waste Management Act, red biohazardous bags not inside a hard-sided container in operating room settings must be removed after every procedure. The Committee recommended that the Institution replace the hanging disposable red biohazardous bag in the dosing room after every procedure, per the State of California Medical Waste Management Act.
7. The IBC noted that preparation and dosing will occur at a separate facility not owned or directly affiliated with the Institution.

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 8:35 am Pacific Time.