

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, October 7, 2025
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Salehi Retina Institute, Inc. dba Retina Associates of Southern California, Los Alamitos, CA
Principal Investigator: Hani Salehi-Had MD
Protocol: AbbVie, Inc., RGX-314-2104
NCT Number: NCT04704921
Meeting Type: Continuing Review of Protocol and Site
Title: A Randomized, Partially Masked, Controlled, Phase 2b/3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ATMOSPHERE)

1. Call to order:

The Meeting was called to order at 8:01 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 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.

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 non-sharps biohazardous waste is disposed of into designated non-sharps biohazardous waste containers that are lined with a red bag (e.g., Photos, Slide 7). The Committee recommended that the Photos document be updated to indicate that the photo on the right of Slide 6 is a sharps container and the photo on the right of Slide 7 is a "non-sharps biohazardous waste container".
2. The Institutional Representative confirmed that hand sanitizer is used before leaving rooms without a handwashing sink. The Committee recommended that the last question in Site Inspection Checklist Item #21 be revised to indicate "Yes".
3. The Institutional Representative confirmed that prefilled disposable eyewash bottles are located in the dosing rooms. The Committee recommended that Site Inspection Checklist Item #22 be revised accordingly.
4. The Institutional Representative confirmed that the alternate phone number on the Biohazard Sign is a "24/7" number. The Committee recommended that the alternate phone number on the Biohazard Sign be updated to indicate it is a "24/7" number.
5. The Committee recommended that a log of the eyewash flushing be kept and that ideally, flushing should be done weekly.
6. The Institutional Representative confirmed that soap and paper towels are near the sinks in the preparation/dosing area.
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 8:20 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 10.0, dated 02-28-2025

Protocol Administrative Change 3 Letter, dated 07-23-2025

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

Pharmacy Manual, Version 7.0, dated 04-07-2025

Subretinal Administration Manual, Version 6.0, dated 05-15-2025

Research Modification Evaluation, Protocol Admin Change 3 Letter, dated 07-23-2025

Research Modification Evaluation, Protocol, Version 10.0

Research Modification Evaluation, Investigator's Brochure, Version 14

Research Modification Evaluation, Pharmacy Manual, Version 6.0

Research Modification Evaluation, Pharmacy Manual, Version 7.0

Research Modification Evaluation, Subretinal Administration Manual, Version 6.0

Biological Risk Assessment and Summary, updated 08-01-2025

Site Map, Salehi Retina, dated 07-19-2023

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Site Map, Operating Rooms, dated 07-19-2023
Site Inspection Checklist, expires 09-11-2027
Photos, dated 07-20-2023, updated 09-14-2023
Biohazard Sign, dated 07-18-2023
SOP, Biosafety for RGX-314, dated 07-20-2025
Training, Shipping Certifications, expires 2026, 2027
CRRF, dated 09-11-2025
Prior Meeting Minutes, Continuing, dated 08-29-2024