

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, December 1, 2025
Time: 3:00 pm Eastern Time.
Location: Zoom Teleconference
Institution: Ophthalmic Consultants of Boston and Boston Eye Surgery and Laser Center, Boston, MA
Principal Investigator: Jeffrey S. Heier, MD
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 3:00 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including one local member 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: 4 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 ABBV-RGX-314, because it consists of a recombinant adeno-associated viral vector. 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: 4 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 all applicable site-specific documents be revised to replace the former name of the study agent (RGX-314) with the current name which is ABBV-RGX-314.
2. The Institutional Representative confirmed that only one member of the study staff prepares and doses the study agent.
3. The Committee noted that eye protection in the sense of personal protective equipment consists of ANSI-approved eyewear, per OSHA standards.
4. The Committee recommended that the Institution confirm if ANSI-approved eye protection is worn during study agent handling (for all of the open studies using ABBV-RGX-314), and that the Biosafety SOPs and Biohazard Sign be updated accordingly.
5. If ANSI-approved eye protection is not worn, the Committee recommended that it be worn during study agent handling since ABBV-RGX-314 is based on an AAV-vector which is transmissible via the aerosol route (e.g., mucous membranes).

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 3:15 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 6.1.1 (US only), dated 03-10-2025

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

Pharmacy Manual, Version 10.0, dated 03-24-2025

Subretinal Administration Manual, Version 7.0, dated 10-30-2025

Research Modification Evaluation, Protocol, Version 6.1.1 (US only)

Research Modification Evaluation, Investigator's Brochure, Version 14

Research Modification Evaluation, Pharmacy Manual, Version 10.0

Research Modification Evaluation, Subretinal Administration Manual, Version 6.0

Research Modification Evaluation, Subretinal Administration Manual, Version 7.0

Biological Risk Assessment and Summary, updated 11-10-2025

Research Modification Evaluation, Additional Storage Location, dated 08-28-2025

Site Map, OCB, updated 07-31-2025

Site Map, BESLC, dated 11-12-2025

Site Inspection Checklist, expires 05-21-2026, updated 07-15-2025

Photos, dated 11-24-2025

Biohazard Sign, Ophthalmic AAV Study Agents, dated 06-04-2025

Biosafety SOP, Ophthalmic AAV Study Agents, dated 06-04-2025

Biosafety SOP, Addendum for RGX-314, dated 08-28-2025

Training Shipping Certification, expires 02-27-2027

CRRF, dated 09-03-2025

Prior Meeting Minutes, Continuing, dated 12-20-2024