

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, November 7, 2025
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Associated Retinal Consultants, PC, Troy, MI
Principal Investigator: **Jeremy D. Wolfe, MD**
Protocol: AbbVie, Inc., M24-528
NCT Number: NCT07007065
Meeting Type: Initial Review of Protocol and Site
Title: Neovascular Age-Related Macular Degeneration (nAMD): A Phase 3b Study of Surabgene Lomparovovec Assessing the Injection Burden, Efficacy, Safety, and Long-Term Preservation of Visual Acuity in a Real-World Context

1. Call to order:

The Meeting was called to order at 12:02 pm Eastern 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for ABBV-RGX-314, since it consists of an AAV vector administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of ABBV-RGX-314 locally**, provided that all other biosafety criteria for study closure are also met.

8. 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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9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

Point of Discussion:

1. The Committee noted the Principal Investigator's curriculum vitae (CV) is over 4 years old and recommended that a more recent one be submitted to IBC Services. The Institutional Representative agreed to submit a more current version of the Principal Investigator's CV to IBC Services.

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 a subsection be added to Biosafety SOP 3.6 with details about how the reusable eyelid speculum is decontaminated.
2. The Committee recommended that regular waste trash containers be separated by a physical distance from biohazardous waste containers to avoid accidentally disposing biohazardous waste in a non-biohazardous waste container.
3. The Committee recommended that the Site Inspection Checklist, Item 13 be revised to reflect that needles are not used for study agent preparation or dosing.
4. The Institutional Representative confirmed that the refrigerator that will be used to store the study agent is labeled with a biohazard symbol/sign and that a newer photo was submitted to IBC Services. The Committee recommended that the Photos document be updated accordingly.

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 12:15 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 2.0, dated 05-16-2025

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

Pharmacy Manual, Version 2.0, dated 04-25-2025

Instructions for Administration of Investigational Product, Version 2.0, dated 05-19-2025

Biological Risk Assessment and Summary, dated 10-23-2025

Site Map, Truvista Surgery Center, dated 06-07-2021

Site Map, Associated Retinal Consultants, dated 10-27-2025

Site Inspection Checklist, expires 06-16-2027, updated 10-24-2025

Photos, dated 10-27- 2025

Biohazard Sign, All Protocols, dated 10-27-2025

SOP, Biosafety for ABBV-RGX-314, dated 10-27-2025

Training, Shipping Certifications, expire 03-2026, 07-2027

CV, Wolfe, J., signed 02-08-2021