

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, February 6, 2026  
**Time:** 1:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Associated Retinal Consultants, PC, Troy, MI  
**Principal Investigator:** **Jeremy D. Wolfe, 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 1:00 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 were two Institutional Representatives 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:

An 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 noted 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, 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 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: 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.

#### **Point of Discussion:**

1. The Committee recommended that a photo of the study agent storage refrigerator, with a visible biohazard symbol, be provided to IBC Services.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

### **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 1:07 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

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, dated 10-27-2025

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

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

CRRF, dated 11-03-2025, updated 01-13-2026

Prior Meeting Minutes, Continuing, dated 02-18-2025