

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, June 1, 2026  
**Time:** 8:00 am US Mountain Time  
**Location:** Zoom Teleconference  
**Institution:** Spectra Eye Institute, LLC, Phoenix, AZ  
**Principal Investigator:** Neal Palejwala, 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 8:00 am US Mountain 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 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: 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 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 AAV vector being 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: 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 the Institution (and surgical center) consider decontaminating reusable eyelid speculums with PDI Super Sani-Cloth Wipes prior to rinsing in water. If this recommendation is implemented, Biosafety SOP Section 3.6.2 and Item 14 of the Site Inspection Checklist should be updated accordingly.
2. The Institutional Representative confirmed that prefilled disposable eyewash bottles are available in the OR.

### **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 8:14 am US Mountain Time.

### **15. Post-meeting notes:** None.

#### **Documents reviewed:**

Agenda

Protocol, Version 7.0, dated 10-10-2025

Investigator's Brochure, Version 15, dated 04-24-2026

Pharmacy Manual, Version 11.0, dated 10-27-2025

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

Research Modification Evaluation, Protocol, Version 7.0

Research Modification Evaluation, Investigator's Brochure, Version 15

Research Modification Evaluation, Pharmacy Manual, Version 11.0, reviewed 05-26-2026

Research Modification Evaluation, Subretinal Administration Manual, Version 7.0

Biological Risk Assessment and Summary, updated 05-26-2026

Site Maps, dated 01-21-2025

Site Inspection Checklist, expires 12-18-2026

Photos, dated 06-05-2025

Biohazard Sign, dated 01-12-2026

SOP, Biosafety for ABBV-RGX-314, dated 01-12-2026

Training, Shipping Certification, expires 07-21-2027

CRRF, dated 03-12-2026

Prior Meeting Minutes, Continuing, dated 06-11-2025