

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, October 13, 2025  
**Time:** 1:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** University Retina and Macula Associates, PC, Hinsdale, IL  
**Principal Investigator:** Veeral Sheth, MD, MBA, FACS  
**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 1:15 pm Central 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 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 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

## 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 biohazard sign be revised to indicate which phone number is available 24/7.
2. The Committee recommended that photos of the biohazardous waste storage room, including the inside and posted biohazard signage outside of the room, at the Hinsdale Surgical Center be provided to IBC Services.
3. The Committee discussed the photo of the Pharmacy which shows a laminar flow hood (LFH) and noted that it should not be used for study agent preparation as it does not protect the user. The Institutional Representative confirmed that the LFH in the Pharmacy is not used for this protocol as the study agent is prepared and dosed in the operating room at the Hinsdale Surgical Center.
4. The Institutional Representative confirmed that the study agent specific biohazard sign is posted at the entrance to the areas where the study agent is handled, including the pharmacy (where it is stored) and the operating room at the Hinsdale Surgical Center.

### **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 1:19 pm Central 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, Version 10.0

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

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, Lemont Location, dated 06-11-2025

Site Map, Hinsdale Surgical Center, dated 08-16-2021

Site Inspection Checklist, expires 09-17-2026, updated 06-11-2025

Photos, Lemont, dated 06-12-2025

Photos, Hinsdale Surgical Center, dated 09-26-2024

Biohazard Sign, RGX-314, dated 09-26-2024

SOP, Biosafety for RGX-314, dated 02-13-2025

Training, Shipping, Certification, expires 05-12-2027

CRRF, dated 07-01-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Prior Meeting Minutes, Continuing, dated 10-22-2024