

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, July 24, 2025  
**Time:** 12:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Erie Retina Research, LLC, Erie, PA  
**Principal Investigator:** David R.P. Almeida, MD, MBA, PhD, FRCSC, DABO  
**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 12:00 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 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: 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 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 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 noted that external transportation is not applicable anymore since all study agent-related activities will occur in the same building, and recommended that Biosafety SOP Section 3.4.2 be deleted.
2. The Committee recommended that a photo of the plumbed eyewash station located in the dosing location be provided to IBC Services.
3. The Committee recommended that the plumbed eyewash station in the dosing location be checked and flushed on a weekly and that this check/flush be documented via a log.
4. The Committee recommended that the Photos document be updated to include the location or address on each slide.
5. The Committee recommended that a representative photo showing the sharps and biohazardous waste containers in the preparation/dosing room be provided to IBC Services.
6. The Committee recommended that the Site Map of the dosing location be revised to indicate that the eyewash station is a "Plumbed Eyewash Station".
7. An Institutional Representative confirmed that a plumbed eyewash station will be installed in the near future in the location where the study agent is stored.
8. An Institutional Representative confirmed that eye protection and eyelid speculums are disposable.
9. An Institutional Representative confirmed that stud agent-specific Biohazard Sign is printed on red paper and agreed to provide an updated photo of the posted Biohazard Sign.

### **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: 4

NO: 0

ABSTAIN: 0

**13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 12:17 pm Eastern Time.