

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, June 5, 2025  
**Time:** 1:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** Charles Retina Institute, Memphis, TN  
**Principal Investigator:** Stephen Huddleston, 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 1:15 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 were 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 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

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### **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 word “would” in the second to last sentence in Biosafety SOP Section 3.3.2 be deleted and to change “occur” to “occurs”.
2. The Institutional Representative confirmed that they are current in their shipping training and agreed to submit their certification to IBC Services at the recommendation of the Committee.
3. The Institutional Representative confirmed that a biohazard symbol is posted on the door to the biohazardous waste storage area door and agreed to submit a photo of door with the posted signage to IBC Services.
4. The Institutional Representative confirmed that a sink for washing hands and a plumbed eyewash station are available outside of the dosing room. The plumbed eyewash station is located in [REDACTED] and the sink is available immediately outside the dosing room. The Committee recommended that the Site Map be updated accordingly and that photos of the plumbed eyewash station and sink be submitted to IBC Services.
5. The Committee recommended that the site location table on the 1<sup>st</sup> page of the Site Inspection Checklist be revised to replace “[REDACTED]” with “[REDACTED]”.
6. The Committee recommended that Site Inspection Checklist Item 13 revised to note that “All Protocols” use a needle-free system”.
7. The Committee recommended that Site Inspection Checklist Items 21 and 22 be revised to indicate that the dosing room does not contain a sink and eyewash inside.

### **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 1:22 pm Central Time.