

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, June 9, 2025  
**Time:** 12:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** Ochsner Clinic Foundation, New Orleans, LA  
**Principal Investigator:** Sidharth Puri, MD  
**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 12:32 pm Central 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 were thirteen 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 AAV vector administered 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 all 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

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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 address listed in the Site Inspection Checklist for the [REDACTED] be updated to [REDACTED].
2. An Institutional Representative confirmed that an autoclave is only used to sterilize reusable surgical instruments, such as the reusable eyelid speculum which is first soaked in a PRE-Klenz solution.
3. An Institutional Representative noted that the Institution's [REDACTED] collects full containers of biohazardous waste and transports them to a central location where they are picked up by the commercial biohazardous waste hauler. An Institutional Representative noted that they do not have access to this area and are unable to obtain photos.
4. An Institutional Representative confirmed that a hard-sided sealable container will be used to transport the study agent from the storage location to the preparation/dosing location, but could not confirm if the study agent vials will remain in their original sponsor packaging.
5. An Institutional Representative confirmed that hand sanitizer is available in the dosing room.

### **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 12:46 pm Central Time.