

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, September 17, 2025  
**Time:** 7:00 am Pacific Time  
**Location:** Zoom Teleconference  
**Institution:** Retinal Consultants Medical Group, Sacramento, CA  
**Principal Investigator:** David Telander, MD, PhD  
**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 7:04 am Pacific 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 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 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: 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 discussed the open-topped metal biohazardous waste container in the preparation and dosing rooms and noted that state regulations do allow open-topped biohazardous waste containers provided biohazardous waste bags are removed immediately upon completion of patient care.
2. The Committee recommended that the site confirm with staff at the surgery center that biohazardous waste bags are removed from the metal biohazardous waste containers upon completion of patient care.
3. The Committee recommended that the first comment in the Additional Comments and Observations box on the Site Inspection Checklist be deleted and that the second comment, pending site confirmation as noted above, be revised to indicate that "Hard-sided, labeled biohazardous waste containers without lids are used for biohazardous waste disposal and biohazardous waste bags are removed from these containers upon completion of patient care."
4. The Committee discussed the use of glutaraldehyde as a disinfectant for reusable eye protection and recommended that something less hazardous, with efficacy claims against non-enveloped viruses, be used.
5. The Committee noted that glutaraldehyde can be used as a sterilant for medical equipment, such as the reusable eyelid speculum, when other methods such as steam sterilization are not available. The Committee recommended that the site follow-up with IBC Services to confirm how reusable eyelid speculums are sterilized and to revise site documents as needed.
6. The Committee recommended that Site Inspection Checklist, Item 21 be revised to indicate that a sink is not available inside the preparation room and that staff members will use hand sanitizer prior to exiting rooms when a sink is not available.

### **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 7:21 am Pacific Time.