INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

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| **Meeting Date:** | **Tuesday, June 17, 2025** |
| **Time:** | 12:00 pm Eastern Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | John-Kenyon American Eye Institute, New Albany, IN |
| **Principal Investigator:** | **Howard Lazarus, 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 12:00 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 two local members 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:**

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 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:

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|---|---|
| X | APPROVED |
| | CONDITIONALLY APPROVED |
| | TABLED |
| | DISAPPROVED |

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

**10. Review of proposed facilities and practices:**

The Chair provided an overview of the arrangement for the facilities and practices.

**Points of Discussion:**

1. An Institutional Representative confirmed that RGX-314, for this study, is only provided frozen. The Committee recommended that Biosafety SOP Section 3.3 be revised to add "If received frozen, the study agent is thawed and then drawn from a …"
2. An Institutional Representative confirmed that CaviWipes1 are used to decontaminate reusable eye protection. The Committee noted that Biosafety SOP Section 3.6.1 indicates a 10% bleach solution or CaviWipes1 may be used to decontaminate reusable eye protection, and found either of these disinfectants acceptable to use.
3. The Committee noted that a photo shows an expired bottle of saline solution used to flush eyes. The Chair noted expiration dates of prefilled disposable eyewash bottles are now captured in the Site Inspection Checklist.

**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:

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|---|---|
| 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 12:14 pm Eastern Time.