INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, November 24, 2025**
Time:	2:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Cincinnati Eye Institute, Cincinnati, OH
Principal Investigator:	**Robert Sisk, 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 2:04 pm Eastern 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 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: 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-2 containment facilities and practices** are required for ABBV-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 ABBV-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

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 the Biological Safety Cabinet (BSC) used to prepare the study agent is due for recertification this month. The Institutional Representative noted that the BSC was recently recertified and agreed to provide the report to IBC Services following the meeting.
2. The Committee recommended photos of the biohazardous waste containers for disposal of personal protective equipment (PPE) and other non-sharps waste in the Preparation and Dosing Rooms be provided to IBC Services.

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 2:18 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 11.0, dated 10-14-2025
Investigator's Brochure, Version 14, dated 03-24-2025
Pharmacy Manual, Version 8.0, dated 10-27-2025
Subretinal Administration Manual, Version 7.0, dated 10-30-2025
Research Modification Evaluation, Protocol Administrative Change 3 Letter, dated 07-23-2025
Research Modification Evaluation, Protocol, Version 10.0
Research Modification Evaluation, Protocol, Version 11.0
Research Modification Evaluation, Investigator's Brochure, Version 13
Research Modification Evaluation, Investigator's Brochure, Version 14
Research Modification Evaluation, Pharmacy Manual, Version 6.0
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Research Modfication Evaluation, Pharmacy Manual, Version 8.0
Research Modification Evaluation, Subretinal Administration Manual, Version 6.0
Research Modification Evaluation, Subretinal Administration Manual, Version 7.0
Biological Risk Assessment and Summary, updated 11-10-2025
Site Map, updated 10-29-2024
Site Inspection Checklist, expires 10-29-2026, updated 10-10-2025
Photos, dated 10-24-2025
Biohazard Sign, all studies, dated 09-15-2025
Biological Safety Cabinet Certification, dated 05-05-2025
SOP, Main, Biosafety for Ophthalmic AAV Study Agents, dated 08-04-2025
SOP, Addendum Biosafety for ABBV-RGX-314, dated 09-09-2024
Training, Shipping Certification, expires 10-21-2026
CRRF, dated 08-01-2025
Prior Meeting Minutes, Continuing, dated 11-15-2024