INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, January 28, 2026**
Time:	10:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Verum Research, LLC, Eugene, OR
Principal Investigator:	**Albert O. Edwards, 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 10:01 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 noted 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 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: 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. The Committee recommended that Biosafety SOP Section 2.3 be revised to indicate that an emergency kit with an EpiPen is available in the event that a study staff member experiences an anaphylactic reaction.
2. The Committee noted that IATA/Shipping training will expire for a study staff member in February 2026.
3. The Committee recommended that a photo of the posted biohazard signage at the entrance to the study agent storage room be provided to IBC Services.
4. The Institutional Representative confirmed that only sealed sharps containers are placed inside cardboard biohazardous waste containers, as shown in site photos. The Committee found this to be acceptable.
5. The Institutional Representative confirmed that the soiled utility room at the Lane Surgery Center is used for storage of full biohazardous waste containers.
6. The Committee recommended that a biohazard symbol be placed on the front of biohazardous waste containers, in addition to the top.
7. The Institutional Representative confirmed that PDI Sani-Cloth Plus Germicidal Disposable Cloth wipes are used to decontaminate work surfaces. The Committee recommended that site documents be revised to reflect this.
8. The Institutional Representative stated that gel packs, not dry ice, are placed inside the study agent transport container. The Committee recommended that the dry ice label on the transport container be removed.

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 10:17 am Pacific 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, Version 10.0
Research Modification Evaluation, Protocol, Version 11.0
Research Modification Evaluation, Investigator's Brochure, Version 14
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Research Modification 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, Valley River Clinic, dated 06-05-2025
Site Map, Lane Surgery Center, dated 11-16-2023

Site Inspection Checklist, expires 12-23-2026, updated 01-13-2026
Photos, dated 01-21-2026
Biohazard Sign, BSL-1 plus, dated 07-09-2025
SOP, Biosafety for RGX-314, dated 01-06-2026
Training, Shipping Certification, expires 02-20-2026
CRRF, dated 10-13-2025
Prior Meeting Minutes, Continuing, dated 01-24-2025