INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:Tuesday, June 17, 2025Time:11:00 am Pacific TimeLocation:Zoom Teleconference

Institution: Southern California Permanente Medical Group, Riverside, CA

Principal Investigator: Vivienne S. Hau, MD, PhD AbbVie, Inc., RGX-314-3101

NCT Number: NCT05407636

Meeting Type: Continuing Review of Protocol and Site

Title: A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate

the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD

1. Call to order:

The Meeting was called to order at 11:01 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 guorum 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 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.

ABSTAIN: 0

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

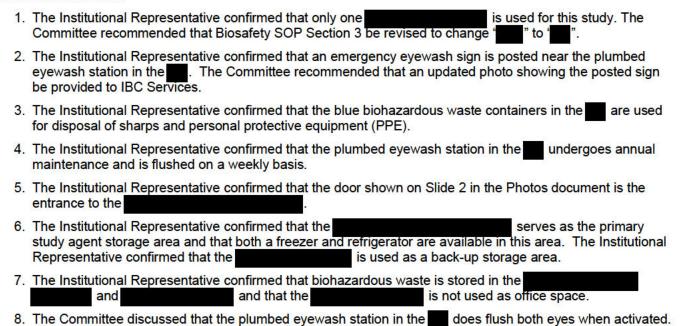
DETERMINATION VOTE - YES: 4 NO: 0

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10. Review of proposed facilities and practices:

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

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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 11:18 am Pacific Time.