INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, November 21, 2025**
Time:	12:00 pm Central (10:00 am Pacific, 11:00 am Mountain, 1:00 pm Eastern)
Location:	Zoom Teleconference
Institution:	Austin Clinical Research, LLC, Round Rock, TX
Principal Investigator:	**Fuad Makkouk, 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 Central 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 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 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 "RGX-314" be replaced with "ABBV-RGX-314" in the Biosafety SOP and the Biohazard Sign.
2. The Institutional Representative confirmed that disposable eyewash bottles and plumbed eyewashes stations are available at the [redacted] The Committee recommended that photos of the disposable eyewash bottles be provided to IBC Services.
3. The Institutional Representative confirmed that sharps and non-sharps biohazardous waste is separated and that waste containers for both are available in the [redacted] used for preparation and dosing. The Committee recommended that site photos be revised to indicate which biohazardous waste containers are used for sharps and which are used for non-sharps.
4. The Institutional Representative confirmed that full biohazardous waste containers are stored for pickup by the waste hauler in both the [redacted] The Committee found this to be acceptable.
5. The Institutional Representative confirmed that the study agent is transported between locations in a sponsor-provided cooler, which is hard-sided and labelled with a biohazard symbol. The Committee recommended that a photo of this transport container be provided to IBC Services.
6. The Committee recommended that the biohazard sign be posted at the entrance to the areas where the study agent is handled. The Institutional Representative stated that study staff can bring the Biohazard Sign to the [redacted] so that it is posted during preparation and dosing. The Committee found this to be acceptable.

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 12:15 pm Central Time.