

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, April 17, 2026
Time: 11:30 am Eastern Time
Location: Zoom Teleconference
Institution: Retina Associates of Western NY, PC, Rochester, NY
Principal Investigator: Edward Hall, MD
Protocol: Adverum Biotechnologies, **ADVM-022-13**
NCT Number: NCT07482176
Meeting Type: Initial Review of Protocol and Site
Title: A Multi-Center, Randomized, Double-Masked, Active-Comparator-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of ixoberogene soroparvovec (Ixo-vec) in Participants with Neovascular Age-Related Macular Degeneration (AQUARIUS)

1. Call to order:

The Meeting was called to order at 11:29 am 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 were three 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:

An 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for ADVM-022, since it consists of an AAV vector administered by injection in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of ADVM-022 locally**, provided that other biosafety criteria for study closure are also met.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 the Biosafety SOP be revised to include the appropriate biosafety level required for handling the study agent.
2. The Committee recommended that Biosafety SOP Section 5.2 be revised to add a section that includes the Principal Investigator's name and contact information.
3. The Committee recommended that a photo of the biohazardous waste storage area be provided to IBC Services.
4. The Committee recommended that larger (16 ounce or 32 ounce) prefilled disposable eyewash bottles, designed to specifically flush eyes in the event of eye exposure, be purchased.
5. The Committee recommended that the plumbed eyewash station be flushed weekly and that a log of this action be maintained and posted near the eyewash.
6. The Committee recommended that biohazardous waste containers be kept covered when not in use.
7. An Institutional Representative confirmed that the location of the plumbed eyewash station is accurately depicted on the Site Map. The Committee recommended that the legend be revised to remove the yellow circle denoting the plumbed eyewash station.
8. The Committee discussed that non-safety needles are used as the Sponsor specifically requires the use of a filter needle.
9. An Institutional Representative confirmed that biohazardous waste containers are brought to the dosing room during subject dosing and returned to the Storage/Server Room upon completion of dosing activities.
10. An Institutional Representative confirmed that individuals are referred to an occupational medicine physician in the event of overt exposure.

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:

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 11:57 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 0.0, dated 09-19-2025

Investigator's Brochure, Edition 9.0, dated 02-25-2026

Investigational Medicinal Product Manual, Version 1.0, dated 02-19-2026

Biological Risk Assessment and Summary, updated 02-27-2026

Site Map, dated 04-14-2026

Site Inspection Checklist, expires 04-14-2028

Photos, dated 04-02-2026

Biohazard Sign, ADVM-022, dated 04-14-2026

SOP, Biosafety for ADVM-022, dated 04-14-2026

Training, Shipping Certifications, expire 10-2026, 12-2026

CV, Hall, E., signed 02-26-2026