

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, May 11, 2026
Time: 2:00 pm Central Time
Location: Zoom Teleconference
Institution: University Retina and Macula Associates, PC, Lemont, IL
Principal Investigator: Veeral Sheth, MD, MBA, FACS
Protocol: Adverum Biotechnologies, ADVM-022-14
NCT Number: N/A
Meeting Type: Initial Review of Protocol and Site
Title: Evaluation of the safety and tolerability of Ixoberogene soroparvovec (Ixo-vec) intravitreal gene therapy in the second (contralateral) eye of participants with bilateral neovascular age-related macular degeneration

1. Call to order:

The Meeting was called to order at 2:00 pm Central 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 two 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.

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10. Review of proposed facilities and practices:

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

Points of Discussion:

1. An Institutional Representative confirmed that there is no plumbed eyewash station onsite. The Committee noted that this is acceptable from a biosafety standpoint but does not meet OSHA requirements and recommended that the Institution consider purchasing and installing a sink-mounted plumbed eyewash station.
2. The Committee recommended that biohazardous waste containers for the disposal of used PPE and other non-sharps items are placed in the dosing rooms during subject dosing and that a photo of the biohazardous waste container in the room be provided to IBC Services.
3. An Institutional Representative confirmed that windows in the pharmacy open to the exterior and that they are fitted with screens. The Committee recommended that Site Inspection Checklist, Item 20 be revised accordingly.
4. An Institutional Representative confirmed that the door to the biohazardous waste storage area is locked and not accessible to the public.
5. An Institutional Representative confirmed that safety needles are used for study agent preparation.
6. An Institutional Representative confirmed that the preparation and dosing rooms have numerous small prefilled disposable eyewash bottles available and that larger prefilled disposable eyewash bottles are available at the Nurses Station, which is within 10-15 seconds of all rooms.
7. An Institutional Representative confirmed that Room 4 (Pharmacy) will be used for study agent storage and preparation and Rooms 1, 2, 3 and 5 will be used for subject dosing.
8. An Institutional Representative confirmed that the internal transportation cooler, as shown in the Photos document, is used to transport the study agent from the preparation room to the dosing rooms.

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 2:19 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 0.0, dated 02-19-2026

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

Investigational Medicinal Product Manual, Draft, dated 04-20-2026

Biological Risk Assessment and Summary, dated 04-24-2026

Site Map, Lemont Location, dated 06-11-2025

Site Inspection Checklist, expires 09-17-2026, updated 05-04-2026

Photos, Lemont, dated 06-12-2025

Biohazard Sign, ADVM-022-14, dated 05-04-2026

SOP, Biosafety for ADVM-022-14, dated 05-04-2026

Training, Shipping, Certification, expires 05-12-2027

CV, Sheth, V., signed 07-15-2024