

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, June 4, 2025
Time: 2:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Retina-Vitreous Surgeons of CNY, PC, Liverpool, NY
Principal Investigator: Patrick R. Oellers, MD
Protocol: Adverum Biotechnologies, ADVM-022-12
NCT Number: NCT06856577
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 (ARTEMIS)

1. Call to order:

The Meeting was called to order at 2:00 pm 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 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. 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 would 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. The Institutional Representative stated that a plumbed eyewash is not available onsite but that pre-filled disposable eyewash bottles (at least 2) are available in each preparation/dosing room. The Committee recommended that the institution explore purchasing/installing a plumbed eyewash per best biosafety practices.
2. The Institutional Representative stated that a new study agent storage freezer just arrived onsite. The Committee recommended that a biohazard symbol be placed on this freezer and that a photo of the labelled freezer be provided to IBC Services.
3. The Committee discussed how needles will be recapped and recommended that a one-handed technique be used. The Institutional Representative stated that supplies for this protocol have not yet arrived and was not able to confirm the needle type that will be used. The Committee recommended that site documents be revised to indicate the needle type and recapping method once the supplies have arrived and it is known what will be used.
4. The Committee recommended that study staff be trained on the proper use of the disinfecting wipes for work surfaces, noting that the dwell time, in particular, should be adhered to as this varies among different decontaminants.
5. The Committee recommended that biohazardous waste containers be kept lidded when not in use and that new photos showing the lidded biohazardous waste containers be provided to IBC Services.
6. The Institutional Representative confirmed that the 24/7 phone number listed on the Biohazard sign is an on-call number that reaches the person on call at the site.
7. The Institutional Representative stated that Preparation/Dosing Rooms are equipped with sharps containers, which are used for both sharps and non-sharps biohazardous waste disposal. The Committee recommended that separate hard-sided biohazardous waste containers for non-sharps be obtained for these rooms and that the containers be labelled with biohazard symbols. The Committee also recommended that photos of these containers be provided to IBC Services.
8. The Committee discussed the potential spill volumes, and the Institutional Representative stated that potentials spills would be approximately be 1-2 mL in volume.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:22 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 0.0, dated 11-20-2024

Protocol Modification Letter, dated 01-14-2025

Investigator's Brochure, Edition 8.0, dated 11-22-2024

Investigational Medicinal Product Manual, Version 1.0, dated 11-21-2024

Biological Risk Assessment and Summary, updated 02-06-2025

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Site Map, Retina-Vitreous Surgeons of CNY, PC, dated 05-22-2025

Site Inspection Checklist, expires 12-13-2026, updated 05-30-2025

Photos, dated 05-22-2025

Biohazard Sign, dated 05-22-2025

SOP, Biosafety for ADVN-022, dated 05-22-2025

Training Shipping Certifications, expire 06-2026, 01-2027, 03-2027, 04-2027

CV, Oellers, P., signed 03-18-2025

