

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, June 3, 2025
Time: 1:00 pm Pacific Time
Location: Zoom Teleconference
Institution: Macula Retina Vitreous Research Institute, Torrance, CA
Principal Investigator: Mehran Taban, 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 1:00 pm 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 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. 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: 4

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 Committee recommended that Biosafety SOP Section 5.1.1 be revised to remove the 10 minute aerosol settling time.
2. The Committee recommended that Biosafety SOP Section 5.1.4a be revised to remove "a."
3. The Institutional Representative confirmed that prefilled disposable eyewash bottles are available in the preparation and dosing rooms. The Committee recommended that a photo of the prefilled eyewash bottles be provided to IBC Services.
4. The Institutional Representative confirmed that biohazard signage is posted at the entrance to the areas where the study agent is handled. The Committee recommended that photos of the posted signage be provided to IBC Services.
5. The Committee recommended that the study agent be transported inside a rigid, leak-proof container, labelled with a biohazard symbol. The Committee recommended that a photo of the container be provided to IBC Services.
6. The Institutional Representative confirmed that the preparation and dosing rooms are equipped with both sharps containers and larger biohazardous waste containers, which are used for the disposal of PPE.
7. The Institutional Representative stated that the bleach solution used to decontaminate work surfaces is not freshly prepared as it is purchased from the manufacturer as a 10% bleach solution.

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 1:12 pm Pacific Time.