

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, June 27, 2025
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Retina Consultants of Southern California, Redlands, CA
Principal Investigator: Eric Chin, 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 8:11 am Pacific Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Three voting members were present, including one local member 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:

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 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: 3

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

10. Review of proposed facilities and practices:

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

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Points of Discussion:

1. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to reflect that in the event of an eye exposure, the staff member will be escorted to the plumbed eyewash, where the affected eye will be flushed continuously for 15 minutes.
2. The Committee noted that per the California Medical Waste Management Act (CA MWMA), specific signage is required to be posted on doors to biohazardous waste storage rooms. The Committee recommended the institution consult their waste collection vendor and Section 118310 of the CA MWMA for clarification, and update signage on waste storage room doors accordingly.
3. The Committee also noted that per CA MWMA Section 118280 (c), all sides of biohazardous waste containers must be labeled with a biohazard symbol, and recommended this be addressed. In the event that the waste container is round, the front, back and top of the container should be labeled.
4. The Committee recommended that a phone number that is monitored 24/7 be added to the Biohazard Sign.
5. The Institutional Representative confirmed that a sign alerting staff to the location of the plumbed eyewash is posted over the sink.
6. The Institutional Representative confirmed that plumbed eyewashes are flushed weekly, and that this flushing is logged.
7. The Institutional Representative confirmed that expiration dates on disposable eyewash bottles are checked weekly.
8. The Institutional Representative confirmed that the study agent is not opened or removed from its packaging in the storage room, only in the preparation area.

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: 3

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:35 am Pacific Time.