

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, May 14, 2025
Time: 1:00 pm Arizona Time
Location: Zoom Teleconference
Institution: Associated Retina Consultants, Gilbert, AZ
Principal Investigator: Stephen A.M. De Souza, MD
Protocol: Adverum Biotechnologies, **ADVM-022-12**
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 Arizona 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 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 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.

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 noted that the Institution does not have a plumbed eyewash station onsite. An Institutional Representative stated that there is a large supply of prefilled eyewash bottles available in each room that the study agent is handled in. The Committee found this to be acceptable.
2. An Institutional Representative stated that a new study agent storage unit just arrived. The Committee recommended that the storage unit be labelled with a biohazard symbol and that a photo of the labelled storage unit be provided to IBC Services.
3. The Committee noted that the exam rooms (used for dosing) do not have large biohazardous waste containers. An Institutional Representative stated that biohazardous waste is placed into a biohazard bag and brought to a biohazard waste container in the storage room. The Committee recommended that the institution obtain large, leakproof biohazardous waste containers for the exam 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: 3

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:13 pm Arizona 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

Site Map, Gilbert, dated 05-05-2025

Site Inspection Checklist, Gilbert, expires 05-08-2027

Photos, Gilbert, dated 05-05-2025

Biohazard Sign, dated 05-05-2025

SOP, Biosafety for ADV-022, dated 05-08-2025

Training, Shipping Certification, Gilbert, expires 06-05-2026

CV, De Souza, S., signed 03-01-2024