

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, March 18, 2026  
**Time:** 9:00 am Mountain Time  
**Location:** Zoom Teleconference  
**Institution:** Associated Retina Consultants, Gilbert, AZ  
**Principal Investigator:** Stephen A.M. De Souza MD  
**Protocol:** Adverum Biotechnologies, ADVM-022-13  
**NCT Number:** N/A  
**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 (AQUARIUS)

### 1. Call to order:

The Meeting was called to order at 9:16 am Mountain 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 one local member 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: 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 5.2.4 be revised to reflect that study staff will begin flushing the affected eye with a prefilled disposable eyewash bottle before being escorted to the plumbed eyewash station.
2. An Institutional Representative confirmed that hand sanitizer is available on the tabletop in the dosing rooms. The Committee recommended that a representative photo of the hand sanitizer on a tabletop be provided to IBC Services.
3. An Institutional Representative confirmed that Lysol Wipes are also available for decontamination.
4. The Committee recommended that Biosafety SOP Sections 3.6 and 5.1.4 be revised to add "Lysol Wipes" since these are also available onsite.
5. The Committee recommended that Site Inspection Checklist Item 19 be revised to add "Lysol Wipes."
6. The Committee recommended the reusable eyelid speculums be decontaminated with a Clorox Healthcare 0.55% Sodium Hypochlorite or a Lysol Wipe, rather than being washed by soap and water.
7. The Committee recommended that Biosafety SOP Section 3.6.2. be revised to indicate the eyelid speculum will be wiped with Clorox Healthcare 0.55% Sodium Hypochlorite Wipes or Lysol Wipes, followed by soaking in 70% alcohol per standard sterilization processes.
8. An Institutional Representative confirmed that staff members use hand sanitizer prior to exiting the dosing room and then wash their hands in the closest available sink, as noted in Site Inspection Checklist Item 21.
9. An Institutional Representative confirmed that the disposable eye wash bottles are checked monthly

### **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: 4

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 9:25 am Mountain Time.

**15. Post-meeting notes:** None.

### **Documents reviewed:**

Agenda

Protocol, Version 0.0, dated 09-19-2025

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

Investigational Medicinal Product Manual, Version 1.0, dated 02-19-2026

Biological Risk Assessment and Summary, updated 02-27-2026

Site Map, Gilbert, dated 05-05-2025

Site Inspection Checklist, Gilbert, expires 05-08-2027, updated 03-05-2026

Photos, Gilbert, dated 05-05-2025

Biohazard Sign, dated 05-07-2025

SOP, Biosafety for ADV-022, dated 03-05-2026

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

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