

# 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, Phoenix, AZ  
**Principal Investigator:** Benjamin B.A. Bakall, MD, PhD  
**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 9:01 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. The Institutional Representative confirmed that the dosing rooms do not have handwashing sinks. The Committee recommended that the sink icon on the map be removed or it is noted that this is just a tabletop.
3. The Institutional Representative confirmed that Clorox Healthcare 0.55% Sodium Hypochlorite Wipes and Lysol Wipes, are available for decontamination and spill clean-up.
4. The Institutional Representative confirmed that Cavicide wipes are not used.
5. The Committee recommended that Biosafety SOP Sections 3.6 and 5.1.4 be revised to replace “Cavide” with “Clorox Healthcare 0.55% Sodium Hypochlorite”.
6. The Committee recommended that Site Inspection Checklist Item 19 be revised to remove the reference to Cavicide Wipes since an Institutional Representative confirmed that these are no longer purchased by the Institution.
7. An Institutional Representative confirmed that the disposable eye wash bottles are checked monthly and the plumbed eyewash station is flushed weekly
8. The Institutional Representative confirmed there are three sinks in the Laboratory, one of which is equipped with a plumbed eyewash station.

### **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 9:16 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, Phoenix, 03-04-2026

Site Inspection Checklist, Phoenix expires 01-03-2027, updated 03-04-2026

Photos, Phoenix, dated 07-31-2025

Biohazard Sign, ADVN-022, dated 03-04-2026

SOP, Biosafety for ADVN-022, dated 03-04-2026

Training, Shipping Certification, Phoenix, expires 11-05-2026

CV, Bakall, B., signed 08-20-2024