

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, June 13, 2025  
**Time:** 12:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** Retina Consultants of Texas - San Antonio, Schertz, TX  
**Principal Investigator:** Jeremiah Brown, Jr., MS, 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 12:00 pm Central 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 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 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.

#### **Point of Discussion:**

1. An Institutional Representative confirmed that the floor in the biohazardous storage waste area is not carpeted.

### **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 12:09 pm Central Time.