INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, October 16, 2025**
Time:	3:00 pm Eastern (12:00 pm Pacific, 1:00 pm Mountain, 2:00 pm Central)
Location:	Zoom Teleconference
Institution:	NJ Retina, Teaneck, NJ
Principal Investigator:	**Michael M. Park, MD**
Protocol:	Adverum Biotechnologies, **ADVM-022-12**
NCT Number:	NCT06856577
Meeting Type:	Continuing 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 3:05 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members 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. However, some of the Institution's staff members inquired about the meeting and an Institutional Representative answered their questions.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

Points of Discussion:

1. The Committee noted that the Sponsor revised some of the preparation step photos and removed a reference to recapping the needle using the one-handed scoop method in the Investigational Medicinal Product Manual, Version 2.0, dated 03-18-2025.
2. The Committee noted that the Institution has been advised to continue to use their approved Biosafety SOP which detail safe needle handling practices. An Institutional Representative confirmed that they continue to use the one-handed scoop method to recap the preparation needle.
3. The Committee discussed the changes to the Investigational Medicinal Product Manual, Version 2.0, dated 03-18-2025, that adversely affect biosafety and determined to send a Letter of Advice to the Sponsor.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously 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 reaffirmed this determination.

The Committee previously 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. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

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 5.2.3 be revised to reflect that in the event of a needle stick, the exposed staff member will be referred to an appropriate healthcare professional or their personal primary healthcare physician.
2. The Committee discussed the "Humane Choice Disinfecting & Cleaning Wet Wipes" and was unable to determine if was registered with the Environmental Protection Agency (EPA).
3. The Committee noted that although it contains the following active ingredients: Didecyldimethylammonium Chloride 0.2%, Ethanol <5%, Benzalkonium Chloride 0.3%, publicly available product information does not demonstrate effectiveness against non-enveloped viruses.
4. The Committee recommended that the Institution use a different EPA-approved disinfecting agent, one that has proven efficacy against non-enveloped viruses such as adenovirus, AAV, and/or poliovirus.
5. The Committee recommended that the Site Inspection Checklist and Biosafety SOP be updated accordingly once a new disinfectant is identified that is effective against non-enveloped viruses.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Sponsor:

1. The Committee advises that the Investigational Medicinal Product Manual be amended to follow Occupational Safety and Health Administration (OSHA) Standards regarding safe needle-handling practices in accordance with the Bloodborne Pathogens Standard (1910.1030).
2. The Committee noted that recent revisions to the ADVM-022-12 Investigational Medicinal Product Manual (Version 2.0, dated 03-18-2025) adversely affect biosafety with respect to needle handling. Specifically, the removal of the one-handed scoop method for recapping filter needles and the inclusion of a photo (item 17, page 27) depicting an uncapped needle held in a gloved hand are of concern. The Committee recommends removing the photo in item 17 on page 27, which depicts an uncapped needle held in a gloved hand, and reinstating the one-handed scoop method for recapping filter needles in the study agent preparation instructions.

14. Meeting adjourned: The meeting was adjourned at 3:32 pm Eastern Time.