

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, January 16, 2025
Time: 1:00 pm Arizona Time
Location: Zoom Teleconference
Institution: Associated Retina Consultants, Phoenix, AZ
Principal Investigator: Benjamin B.A. Bakall, MD, PhD
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 1:02 pm Arizona 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 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: 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. An Institutional Representative confirmed that the countertop in the Laboratory, where the study agent will be prepared, will be decontaminated before and after with one of the available disinfecting wipes, and that a sterile drape will be placed on the countertop prior to study agent preparation. The Committee recommended that Biosafety SOP Section 3.3 be revised to reflect this.
2. An Institutional Representative confirmed that there are two handwashing sinks and prefilled disposable eyewash bottles located in the Laboratory, where the study agent will be stored and prepared. The Committee recommended that site documents be revised to reflect this.
3. An Institutional Representative confirmed that currently there are no sinks or prefilled disposable eyewash bottles in the dosing rooms but hand sanitizer is available. The Committee recommended that site documents be revised to indicate that the dosing rooms have hand sanitizer, not handwashing sinks.
4. The Committee recommended that prefilled disposable eyewash bottles be made available in the dosing rooms and that site documents be revised to reflect this.
5. An Institutional Representative stated that the plumbed eyewash station is located in the Tech Station, which is located down the hallway from the dosing rooms. The Committee recommended that a new site map, which shows the Tech Station and plumbed eyewash, be provided to IBC Services.
6. The Committee recommended that Site Inspection Checklist (#22) and Site Photos be revised to indicate that the plumbed eyewash station is located in the Tech Station.
7. An Institutional Representative confirmed that the expiration dates of prefilled disposable eyewash bottles are checked regularly and that new bottles are purchased prior to their expiration date.
8. The Committee recommended that the institution confirm with IBC Services how often the plumbed eyewash is flushed and if a flush log is maintained. The Committee recommended that it be flushed at least once weekly.
9. The Committee recommended that an eyewash sign be posted on the wall behind the plumbed eyewash station. The Committee recommended that a new photo, showing the eyewash sign on the wall, be provided to IBC Services.
10. An Institutional Representative confirmed that the expiration dates of the wipes used to decontaminate work surfaces are checked regularly. The Committee recommended that a photo of the wipes, showing the expiration date(s), be provided to IBC Services.
11. The Committee recommended that the Biohazard Sign be revised to add an alternate phone number.
12. An Institutional Representative confirmed that hard-sided biohazardous waste containers are fitted with red biohazardous waste bags, prior to anything being placed in them.

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 1:24 pm Arizona Time.

15. Post-meeting notes: None.

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Documents reviewed:

Agenda

Protocol, Version 0.0, dated 11-20-2024

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, dated 12-02-2024

Site Map, dated 01-06-2025

Site Inspection Checklist, dated 01-03-2025

Photos, dated 01-16-2024

Biohazard Sign, dated 01-06-2025

SOP, Biosafety for ADVN-022, dated 01-13-2025

Training, Shipping Certification, expires 11-05-2026

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