INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, June 13, 2025**
Time:	10:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Verum Research, LLC, Eugene, OR
Principal Investigator:	**Albert O. Edwards, MD, PhD**
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 10:00 am Pacific 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.

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 3.4.1 be revised to include absorbent material inside the Ziploc-style bag that the study agent is placed in.
2. An Institutional Representative stated that the dosing rooms have large, hard-sided biohazardous waste containers which are labelled with biohazard symbols and fitted with red biohazard bags. The Committee recommended that photos of these containers in the dosing rooms be provided to IBC Services.
3. The Committee discussed the use of white cardboard biohazardous waste containers in the preparation/dosing room at the surgery center. An Institutional Representative stated that only full, sealed sharps containers are placed inside it, and the Committee found this acceptable.
4. The Committee noted that the study agent storage unit can be labelled with a biohazard symbol; the full study agent specific biohazard sign is not required. The Committee also noted that either is acceptable.
5. The Committee recommended that the door to the biohazardous waste storage room at the surgery center be labelled with a biohazard sign and that an updated photo of this be provided to IBC Services.
6. An Institutional Representative confirmed that the biohazard sign lists 24/7 phone numbers. The Committee recommended that the biohazard sign be revised accordingly to reflect this.
7. The Committee recommended that the institution obtain a transport container for this study agent as the one shown in site photos is for a different agent/protocol. The Committee recommended that the transport container be hard-sided, lidded, and labelled with a biohazard symbol, and that a new photo be provided to IBC Services.
8. An Institutional Representative confirmed that gel ice packs are placed inside the transport container and that dry ice is not used.

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 10:14 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 0.0, dated 11-20-2024
Protocol Modification Letter, dated 01-14-2025
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, updated 02-06-2025
Site Map, Valley River Clinic, dated 06-05-2025
Site Inspection Checklist, expires 12-23-2026, updated 06-05-2025
Photos, dated 06-05-2025
Biohazard Sign, BSL-1 plus, dated 06-05-2025
SOP, Biosafety for ADVM-022, dated 06-05-2025
Training, Shipping Certification, expires 02-20-2026

CV, Edwards, A., signed 06-09-2023