

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, July 24, 2025
Time: 12:00 pm Pacific Time
Location: Zoom Teleconference
Institution: Verum Research, LLC, Eugene, OR
Principal Investigator: Albert O. Edwards, MD, PhD
Protocol: Sanofi US Services Inc., DFI18231
NCT Number: NA
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 1/2, study to evaluate the safety, tolerability, and efficacy of one-time intravitreal dose of SAR446597 in participants with geographic atrophy secondary to age-related macular degeneration

1. Call to order:

The Meeting was called to order at 12:00 pm 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 was one Institutional Representative 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:

The 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 SAR446597**, 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 SAR446597 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 absorbent material be placed on the countertop during study agent preparation and that section 3.3 of the Biosafety SOP be revised to reflect this.
2. The Committee recommended that absorbent material be placed inside the Ziploc-style bag during study agent transport and that section 3.4.1 of the Biosafety SOP be revised to reflect this.
3. The Institutional Representative confirmed that an orange, hard-sided biohazardous waste container, with a lid and labelled with a biohazard symbol, is brought into the dosing room at the time of dosing. The Committee found this to be acceptable.
4. The Committee recommended that the sponsor label be removed from the study agent transport container as it doesn't apply to this protocol.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

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 12:09 pm Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1, dated 02-25-2025

Investigator's Brochure, Edition 1, dated 03-11-2025

Product Management Manual, draft, dated 03-11-2025

Biological Risk Assessment and Summary, dated 06-12-2025

Site Map, Valley River Clinic, dated 06-05-2025

Site Inspection Checklist, expires 12-23-2026, updated 07-14-2025

Photos, dated 07-11-2025

Biohazard Sign, dated 07-09-2025

SOP, Biosafety for SAR446597, dated 07-09-2025

Training, Shipping Certification, expires 02-20-2026

CV, Edwards, A., signed 09-25-2024