

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, July 21, 2026
Time: 1:00 pm Pacific Time
Location: Zoom Teleconference
Institution: Verum Research, LLC, Eugene, OR
Principal Investigator: Albert Edwards, MD, PhD
Protocol: Sanofi US Services Inc., DFI18231
NCT Number: NCT07215234
Meeting Type: Continuing 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 1:00 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 were 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. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair noted changes since the last review.

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 SAR446597, 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 SAR446597 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: 4 NO: 0 ABSTAIN: 0

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices. The Committee had no questions or comments regarding these.

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 1:06 pm Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 02, dated 12-17-2025

Investigator's Brochure, Edition 01, dated 05-27-2025

Product Management Manual, Version 7.0, dated 02-02-2026

Research Modification Evaluation, Protocol, Amendment 01

Research Modification Evaluation, Protocol, Amendment 02

Research Modification Evaluation, Product Management Manual, Version 2.0

Research Modification Evaluation, Product Management Manual, Version 3.0

Research Modification Evaluation, Product Management Manual, Version 4.0

Research Modification Evaluation, Product Management Manual, Version 5.0

Research Modification Evaluation, Product Management Manual, Version 7.0

Biological Risk Assessment and Summary, updated 02-13-2026

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

Site Inspection Checklist, expires 12-23-2026, updated 01-13-2026

Photos, dated 07-21-2026

Biohazard Sign, dated 07-09-2025

SOP, Biosafety for SAR446597, dated 07-14-2026

Training, Shipping Certification, expires 01-22-2028

CRRF, dated 04-14-2026

Prior Meeting Minutes, Initial, dated 07-24-2025