

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, April 7, 2026
Time: 1:00 pm Central Time
Location: Zoom Teleconference
Institution: Retina Center of Texas, Southlake, TX
Principal Investigator: Jawad A. Qureshi, MD
Protocol: Sanofi US Services Inc., DF118231
NCT Number: NCT07215234
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 12:59 pm Central 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 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 being administered by injection in a clinical setting.

The Committee determined that IBC oversight will 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: 5

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 Biosafety SOP Section 3.4.1 be revised to reflect that absorbent material will be added to the Ziploc bag.
2. The Committee recommended that Slide 12 of the Photos document be annotated to indicate that the commercial biohazardous waste vendor transfers the bag of biohazardous waste from the hard-sided biohazardous waste container to a cardboard box that they then remove from the facility.
3. The Institutional Representative confirmed that preparation of the study agent will not occur in the VA Room 1/Research Exam 5A. The Committee recommended that the Site Map, Biosafety SOP, Site Inspection Checklist, and Photos documents be updated to reflect that preparation will only occur in the Research Storage Room.
4. The Institutional Representative confirmed that the internal transport container has a red biohazardous symbol on it. The Committee recommended that a photo be submitted to IBC Services.
5. The Institutional Representative confirmed that large spills will be treated with a freshly-prepared 10% bleach solution. The Committee recommended that Site Inspection Checklist Item 19 be revised to add that a freshly prepared 10% bleach solution is also available.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:13 pm Central Time.

15. Post-meeting notes: Immediately following the meeting, the Institutional Representative submitted to IBC Services a new photo of the internal transport container labeled with a colored biohazard symbol.

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
Biological Risk Assessment and Summary, updated 02-13-2026
Site Maps, dated 03-19-2026
Site Inspection Checklist, expires 04-18-2026, updated 03-12-2026
Photos, dated 03-19-2026
Biohazard Sign, dated 03-12-2026
SOP, Biosafety for SAR446597, dated 03-12-2026
Training, Shipping Certification, expires 08-26-2027
CV, Qureshi, J., signed 01-24-2025