

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, June 2, 2026
Time: 9:00 am Pacific Time
Location: Zoom Teleconference
Institution: Sierra Eye Associates, Reno, NV
Principal Investigator: Arshad Khanani, MD, BA, MA
Protocol: Sanofi US Services Inc., DFI18231
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 9:01 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 two local members 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 SAR446597 since it consists of an AAV vector 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: 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 internal transport container contains a visible biohazard symbol. The Committee recommended that the Institution submit an updated photo of the internal transportation container displaying the biohazard symbol to IBC Services.
2. An Institutional Representative confirmed that the plumbed eyewash station is flushed on a monthly basis for at least 30 seconds and that these flushes are logged. The Committee recommended that the Institution submit a photo of the plumbed eyewash station.
3. An Institutional Representative confirmed that two -80°C freezers are available to store the study agent (one in a preparation/dosing room and one in the basement). The Committee recommended that the Institution submit a photo of basement room with the freezer and that this freezer should also be labeled with a biohazard symbol when the study agent is in storage.
4. An Institutional Representative confirmed that red biohazardous waste containers for non-sharps waste are available in the Preparation and Dosing Rooms.
5. An Institutional Representative confirmed that sharps containers are replaced when they reach three-quarters full or the fill line.
6. An Institutional Representative confirmed that expiration dates of 16 ounce prefilled disposable eyewash bottles are checked monthly.
7. An Institutional Representative confirmed that sinks for washing hands are available near rooms (within approximately 10 feet) where the study agent is handled.
8. An Institutional Representative confirmed that one refrigerator and multiple freezers are used for various study agents, with each agent stored in a separate bin or box.

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 9:17 am 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

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

Site Map, Sierra Eye Associates, dated 05-20-2026

Site Inspection Checklist, expires 02-17-2028, updated 05-12-2026

Photos, DF118231, dated 05-20-2026

Biohazard Sign, SAR446597, dated 05-20-2026

SOP, Biosafety for SAR446597, dated 05-18-2026

Training, Shipping Certifications, expire 2028

CV, Khanani, A., signed 03-04-2024