

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, October 14, 2026
Time: 11:30 am Arizona Time
Location: Zoom Teleconference
Institution: Retina Macula Institute of Arizona, Scottsdale, AZ
Principal Investigator: Mark Barakat, MD, FASRS
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 11:32 am Arizona 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 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 being administered by injection in a clinical setting. The Committee reaffirmed this determination.

The Committee previously 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. 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: 5 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.

Points of Discussion:

1. The Institutional Representative confirmed that study staff members have current IATA/Shipping training. The Committee recommended that the certifications be provided to IBC Services.
2. The Committee recommended that Biosafety SOP Section 5.1.1 be revised by removing the 10-minute aerosol settling time.
3. The Institutional Representative confirmed that the photo labeled as "Breakroom" is the preparation/dosing room. The Committee recommended that the photo be relabeled to accurately reflect the name of the room.
4. The Institutional Representative could not confirm whether the Sponsor would be providing instructions for or requiring subjects to collect waste generated from tears and nasal secretions at home after dosing. The Committee recommended that the Institution follow up with the Sponsor regarding this and revise site documents as needed.
5. The Committee discussed how the reusable eyelid speculum is handled after use and recommended that the institution follow up with IBC Services on what the speculum is soaked in prior to being placed in the autoclave. An Institutional Representative stated that the autoclave is onsite and is operated by site staff. The Committee recommended that the institution follow up with IBC Services on how the autoclave is validated and the frequency of validation.
6. The Committee recommended that site documents be revised accordingly upon receipt of follow-up information regarding the speculum and autoclave.
7. The Chair noted that the Site Inspection Checklist is valid for two years (expires September 2027).
8. The Committee recommended that a photo of the stabilizing base/stand for the sharps container in the Preparation and Dosing Room be provided to IBC Services.
9. The Committee recommended that the study agent specific biohazard sign be posted at the entrance to the areas where the study agent is handled during study agent handling activities.
10. The Institutional Representative confirmed that there are biohazardous waste containers available in the preparation/dosing room for disposal of used personal protective equipment (PPE) and other non-sharps items. The Committee recommended that a photo of this biohazardous waste container be provided to IBC Services.

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 11:47 am Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 05, dated 07-07-2026

Investigator's Brochure, Edition 02, dated 08-04-2026

Product Management Manual, Version 7.0, Part 1 only, dated 02-02-2026

Product Management Manual, Version 1.0, Part 2 only, dated 08-10-2026

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Research Modification Evaluation, Protocol, Amendment 02
Research Modification Evaluation, Protocol, Amendment 05
Research Modification Evaluation, Investigator's Brochure, Edition 02
Research Modification Evaluation, Product Management Manual, Version 1.0, Part 2 only
Research Modification Evaluation, Product Management Manual, Version 2.0, Part 1 only
Research Modification Evaluation, Product Management Manual, Version 3.0, Part 1 only
Research Modification Evaluation, Product Management Manual, Version 4.0, Part 1 only
Research Modification Evaluation, Product Management Manual, Version 5.0, Part 1 only
Research Modification Evaluation, Product Management Manual, Version 7.0, Part 1 only
Biological Risk Assessment and Summary, updated 08-20-2026
Site Map, dated 09-09-2025
Site Inspection Checklist, expires 09-03-2027, updated 08-26-2026
Photos, dated 08-27-2026
Biohazard Sign, SAR446597, dated 08-27-2026
SOP, Biosafety for SAR446597, dated 08-27-2026
Training, Shipping Certification, expired 09-05-2026
CRRF, dated 07-08-2026
Prior Meeting Minutes, Initial, dated 10-08-2025