

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, May 1, 2026
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Retina Specialists, Towson, MD
Principal Investigator: John T. Thompson, 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 10:03 am Eastern 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 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: 4

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 the door to the ETDRS room be labeled with a biohazard symbol since biohazardous waste is stored inside this room and that an updated photo of the labeled door be provided to IBC Services.
2. The Institutional Representative confirmed that the biohazardous waste on the floor in the ETDRS room is in a leak-proof, sealed container and the red bag is placed around the entire container prior to pick-up by the licensed biohazardous waste hauler.
3. The Institutional Representative confirmed that the study agent is placed inside a small rigid, leak-proof container which is then placed inside the larger gray plastic bin prior to transport.
4. The Institutional Representative confirmed that there is no on-site autoclave but that the eyelid speculum is autoclaved at the nearby hospital, and the hospital ensures the autoclave is properly validated.
5. The Institutional Representative confirmed that the alternate number listed on the Biohazard Sign is monitored 24/7.

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 10:16 am Eastern 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, dated 04-17-2026

Site Inspection Checklist, expires 03-30-2028

Photos, dated 04-20-2026

Biohazard Sign, SAR446597, dated 03-11-2026

SOP, Biosafety for SAR446597, dated 04-28-2026

Training, Shipping Certification, expires 12-16-2026

CV, Thompson, J., signed 12-30-2025