INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, October 29, 2025**
Time:	12:00 pm Central Time
Location:	Zoom Teleconference
Institution:	Retina Foundation of the Southwest, Dallas, TX
Principal Investigator:	**Karl Csaky, MD, PhD**
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 12:02 pm Central Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures. The Chair noted that this Committee previously met on October 24, 2025 for the initial review of this protocol. However, quorum requirements were not met, and the initial review is being re-held.

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. 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.

Point of Discussion:

1. The Chair noted that the IBC had previously requested that an updated CV, or an addendum to the CV, that lists the PI's clinical research experience be provided to IBC Services. An Institutional Representative stated that this will be provided.

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 biohazardous waste bag in the preparation room be placed inside a rigid, leak-proof container and that an updated photo be provided to IBC Services.
2. An Institutional Representative confirmed that there are no plumbed eyewash stations at [redacted] and that only prefilled disposable eyewash bottles are available. The Committee recommended that the Institution consider installing a faucet mounted eyewash station on a sink located in or near the dosing rooms.

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 12:09 pm Central Time.