

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, September 8, 2025
Time: 10:00 am Central Time
Location: Zoom Teleconference
Institution: Retina Consultants of Texas Research Centers, The Woodlands, TX
Principal Investigator: Charles C. Wykoff, MD, PhD, FACS, FASRS
Protocol: Sanofi US Services Inc., DFI18231
NCT Number: N/A
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 10:04 am 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 were 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 was unable to confirm if a public posting was made. The Committee recommended that the Institution confirm that notice of the meeting was publicly posted and to forward any public comments received by the site to IBC Services.

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: 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. As a **Condition of Approval**, the Committee determined that the Institution must submit a photo of the biological safety cabinet (BSC) labeled with a biohazard symbol, and the biohazardous waste containers in the preparation and dosing rooms to IBC Services.
2. As a **Condition of Approval**, the Committee determined that the door to the biohazardous waste storage room must be labeled with a biohazard symbol and an updated photo must be provided to IBC Services.
3. The Committee recommended that the Institution confirm the study agent-specific biohazard signage is posted as required when the study agent is in storage and/or being handled.
4. The Committee noted it appears boxes of soda appear to be stored in the study agent storage room near a staff member's desk. While the study agent is not directly handled in this room, the Committee advised that food and/or drink not be stored in the same room where biological agents are stored.

11. Site requirements:

The Chair did not review 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:

	APPROVED
X	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

For a vote of CONDITIONALLY APPROVED, the following conditions must be met before the proposed research can proceed:

- a. The Institution must submit a photo of the biological safety cabinet (BSC) labeled with a biohazard symbol, and the biohazardous waste containers in the preparation and dosing rooms to IBC Services.
- b. The door to the biohazardous waste storage room must be labeled with a biohazard symbol and an updated photo must be provided to IBC Services.

DETERMINATION VOTE - YES: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:16 am Central Time.