

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, August 25, 2025
Time: 2:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Marietta Eye Clinic, Marietta, GA
Principal Investigator: Annal D. Meleth, MD, MS
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 2:05 pm Eastern 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 Committee recommended that the Institution confirm if a public posting was made prior to the meeting and if any public comments were received.

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. The Committee recommended that first question in Site Inspection Checklist Item 14 be revised to check "No" since reusable sharps are not used in this study.
2. The Committee recommended that a more rugged/waterproof biohazard symbol or label be placed on the outside of the transport container.
3. The Committee determined as **Conditions of Approval** the following:
 - a. The Institution must confirm which freezer will be used to store the study agent (as shown in the Photos) and this freezer must be labeled with a biohazard symbol/sign.
 - b. The Institution must confirm that non-sharps biohazardous waste generated in the Preparation/Dosing Room is discarded into its own separate container (e.g., sharps and non-sharps biohazardous waste is segregated), and a photo of this biohazardous waste container must be submitted to IBC Services.

11. 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 confirm which freezer will be used to store the study agent (as shown in the Photos) and this freezer must be labeled with a biohazard symbol/sign.
- b. The Institution must confirm that non-sharps biohazardous waste generated in the Preparation/Dosing Room is discarded into its own separate container (e.g., sharps and non-sharps biohazardous waste is segregated), and a photo of this biohazardous waste container must be submitted to IBC Services.

DETERMINATION VOTE - YES: 5

NO: 0

ABSTAIN: 0

12. Advice to the Institution: None.

13. Meeting adjourned: The meeting was adjourned at 2:25 pm Eastern Time.