

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, December 23, 2025
Time: 12:00 pm Central Time
Location: Zoom Teleconference
Institution: Austin Clinical Research, LLC, Austin, TX
Principal Investigator: Fuad Makkouk, MD
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 12:00 pm 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 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 the 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: 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 Institutional Representative confirmed that only sharps containers are available in the dosing rooms. The Committee recommended that the institution explore obtaining non-sharps biohazardous waste containers for these rooms for the disposal of soiled gloves and other non-sharps.
2. The Institutional Representative stated that full sharps containers are placed inside red bags inside the cardboard biohazardous waste containers, which are located in the [REDACTED]. The Institutional Representative stated that the waste hauler retrieves these containers from their storage area inside the [REDACTED].
3. The Committee noted that biohazard signage at the entrance to the [REDACTED] is visible in site photos but recommended that any photos of the [REDACTED] be re-labelled to indicate that this is also the storage location for biohazardous waste.
4. The Committee recommended that plastic trays be placed under cardboard biohazardous waste containers in the event of a spill.
5. The Institutional Representative confirmed that at least twenty eye wash bottles are available in each dosing room and that an even larger supply is available in the [REDACTED]. The Committee found this to be acceptable.
6. The Institutional Representative confirmed that Caviwipes¹ are used to decontaminate work surfaces. The Committee recommended that a photo of these wipes 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 12:21 pm Central Time.