

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, July 14, 2025
Time: 2:00 pm Central Time
Location: Zoom Teleconference
Institution: University Retina and Macula Associates, PC, Lemont, IL
Principal Investigator: Veeral Sheth, MD, MBA, FACS
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 2:02 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 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:

An 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 administered by injection in a clinical setting.

The Committee determined that IBC oversight would 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 “a” be removed from Section 5.1.4 of the Biosafety SOP.
2. The Institutional Representative confirmed that the study agent is prepared in Room 4 of the Pharmacy, then placed inside a transport container and brought to the nurses’ station temporarily before it is transported to one of the dosing rooms. The Institutional Representative confirmed that each dosing room is equipped with personal protective equipment (PPE), disinfecting agents, sharps containers, and prefilled disposable eyewash bottles.
3. The Institutional Representative stated that larger biohazardous waste containers (for disposal of PPE, etc.) are not typically kept in the dosing rooms but they can be brought in if needed. The Committee recommended that hard-sided biohazardous waste containers with lids be placed in the dosing room at the time of subject dosing.
4. The Institutional Representative confirmed that the study agent specific biohazard sign will be posted at the entrance to the areas where the study agent is handled.
5. The Institutional Representative stated that windows in the Pharmacy do open but are kept locked and closed. The Institutional Representative also stated that the Pharmacy exit door is kept locked and has a “Do Not Open” sign.
6. The Committee recommended that Site Inspection Checklist (#21) be revised to replace “Lamont” with “Lemont.”
7. The Committee noted the laminar flow hood (LFH) in the Pharmacy and recommended that it not be used for study agent preparation for this protocol as it can expose the user to potentially harmful aerosols. The Institutional Representative confirmed that the study agent will be prepared on the countertop in the Pharmacy, not the LFH.
8. The Institutional Representative confirmed that the sharps container in the pharmacy is normally kept on the counter and not on the cart as shown in site photos.
9. The Institutional Representative confirmed that the Lemont location used for this protocol does not have a plumbed eyewash station onsite. The Committee noted that this is acceptable from a biosafety standpoint but does not meet OSHA requirements.
10. The Institutional Representative confirmed that sharps and non-sharps biohazardous waste are disposed of into separate containers.
11. The Committee recommended that both sharps and biohazardous waste containers not be overfilled.
12. The Committee recommended that a plastic container/tray be placed under any cardboard biohazardous waste containers to limit any potential leakage or water damage.
13. The Institutional Representative confirmed that the door to the biohazardous waste storage room is kept locked and is only accessible by study staff.
14. The Committee noted that the transport container has a sponsor sticker that does not apply to this protocol and recommended that it be removed from the container.

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

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13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:30 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1, dated 02-25-2025

Investigator's Brochure, Edition 1, dated 03-11-2025

Product Management Manual, draft, dated 03-11-2025

Biological Risk Assessment and Summary, dated 06-12-2025

Site Map, Lemont Location, dated 06-11-2025

Site Inspection Checklist, expires 09-17-2026, updated 06-11-2025

Photos, Lemont, dated 06-12-2025

Biohazard Sign, SAR446597, dated 06-11-2025

SOP, Biosafety for SAR446597, dated 06-12-2025

Training, Shipping, Certification, expires 05-12-2027

CV, Sheth, V., signed 07-15-2024