INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, June 25, 2025**
Time:	1:00 pm Arizona Time
Location:	Zoom Teleconference
Institution:	Associated Retina Consultants, Phoenix, AZ
Principal Investigator:	**Benjamin B.A. Bakall, MD, PhD**
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 1:01 pm Arizona Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were three Institutional Representatives 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 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.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative confirmed that a biohazard sign is available and posted at the entrance to areas where the study agent is handled. The Committee recommended that the Site Inspection Checklist (#4) be revised to reflect this information.
2. An Institutional Representative confirmed that there are no sinks present inside the dosing rooms. The Committee recommended that the Site Inspection Checklist (#21) be revised to reflect this information, and to note that staff members use hand sanitizer prior to exiting, then proceed to the closest sink to wash with soap and water.
3. An Institutional Representative confirmed that prefilled eyewash bottles are present in both dosing rooms. The Committee recommended that the Site Inspection Checklist (#22) be revised to reflect this information.
4. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to specify what "…according to institutional policy…" entails (e.g. a 15-minute flush).
5. The Committee recommended that the small bottles shown near a sink/plumbed eyewash in site photos be moved to prevent splash contamination.
6. The Committee recommended that the study agent storage freezer be labeled with a biohazard symbol and that a new photo be provided to IBC Services.
7. An Institutional Representative confirmed that safety needles are not used for study agent preparation.
8. An Institutional Representative confirmed that emergency eyewash signage is posted on the wall near the eyewash.
9. An Institutional Representative stated that plumbed eyewash stations are flushed monthly. The Committee recommended that the plumbed eyewash be flushed on a weekly basis.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

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 1:22 pm Arizona pm 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, Phoenix, dated 01-06-2025
Site Inspection Checklist, Phoenix expires 01-03-2027, updated 06-09-2025
Site Photos, dated 06-06-2025
Biohazard Sign, dated 06-12-2025
SOP, Biosafety for SAR446597, dated 06-18-2025
Training, Shipping Certification, Phoenix, expires 11-05-2026
CV, Bakall, B., signed 08-20-2024