

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, July 14, 2025  
**Time:** 2:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Vitreo Retinal Associates, P.A., Gainesville, FL  
**Principal Investigator:** Christine N. Kay, MD  
**Protocol:** Sanofi US Services Inc., DF118231  
**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 2:23 pm Eastern 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 two local members unaffiliated with the institution. Also present were two 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.

## INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

### **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 discussed the carpeted room where full containers of biohazardous waste are stored and noted that the Florida Department of Health Regulations require these areas to be easily cleanable and impervious to liquids. The Committee found the Institution's plan for decontamination of carpet in the event of a spill acceptable, but also recommended that a lipped tray be placed under the biohazardous waste containers.
2. An Institutional Representative confirmed that the study agent preparation/dosing room is carpeted. The Committee advised the Institution that flooring in areas where biological agents are handled and where biohazardous waste is stored should be easily cleanable and impervious to liquids.
3. The Committee recommended that the cloth chair in the preparation/dosing room be replaced with one that is easily cleanable and impervious to liquids.
4. The Committee recommended that a biohazard sticker be placed on top of the internal transportation container.
5. An Institutional Representative confirmed the study agent storage freezer is labeled with a biohazard symbol.
6. An Institutional Representative confirmed that the silver tray countertop that will be used to prepare the study agent is secure and does not have wheels.
7. An Institutional Representative confirmed that expiration dates of prefilled disposable eyewash bottles are checked on a monthly basis per institutional policy.

### **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 2:29 pm Eastern Time.

**15. Post-meeting notes:** None.

### **Documents reviewed:**

Name

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, VitreoRetinal Associates (VRA), dated 11-10-2023

Site Inspection Checklist, expires 04-22-2027, updated 06-30-2025

Photos, dated 06-25-2025

Biohazard Sign, SAR446597, dated 06-30-2025

SOP, Biosafety, for SAR446597, dated 06-30-2025

Training, Shipping Certification, dated 10-25-2023

CV, Kay, C., signed 06-05-2025