

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, January 9, 2026
Time: 9:00 am Pacific Time
Location: Zoom Teleconference
Institution: California Retina Consultants - Bakersfield, Bakersfield, CA
Principal Investigator: Dante Pieramici, MD, PhD
Protocol: Ray Therapeutics (RayTx), RTx-021-CP-101
NCT Number: NA
Meeting Type: Initial Review of Protocol and Site
Title: Phase 1/2, Open-Label, Dose-Escalation Study to Evaluate Safety of a Single Intravitreal Injection of RTx-021 in Patients with Stargardt Disease

1. Call to order:

The Meeting was called to order at 9:00 am Pacific 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 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 RTx-021 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 RTx-021 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 noted that sponsor documents indicate that a Biological Safety Cabinet (BSC) should be used for study agent preparation. The Chair noted that a BSC is recommended but not required, and the Committee found this to be acceptable.
2. The Committee recommended that an eyewash sign be placed on the wall above the plumbed eyewash station and that a photo of this be provided to IBC Services.
3. An Institutional Representative stated that there is a new biohazardous waste storage area, located on the [REDACTED]. The Committee recommended that photos of this area be provided to IBC Services and that all site documents be updated to reflect the additional biohazardous waste storage area.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:11 am Pacific Time.