

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, July 11, 2025
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Lange Neurology, PC, New York, NY
Principal Investigator: Dale J. Lange, MD
Protocol: Cartesian Therapeutics, Inc., RNAC-MG-002
NCT Number: NCT06799247
Meeting Type: Initial Review of Protocol and Site
Title: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of Descartes-08 in Patients with Generalized Myasthenia Gravis (MG)

1. Call to order:

The Meeting was called to order at 10:02 am Eastern 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 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-2 containment facilities and practices** are required for Descartes-08, since it consists of primary human cells modified via mRNA transfection.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of Descartes-08 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 a biohazard symbol will be placed on the storage freezer when the study agent is onsite and in storage.
2. The Institutional Representative confirmed that the waterbath is not yet onsite yet but that it will be placed in [REDACTED] upon arrival.
3. The Institutional Representative confirmed that Biohazardous Waste is stored in [REDACTED].
The Committee recommended that the Site Map be updated to indicate exactly where this [REDACTED] is located.

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 10:17 am Eastern Time.