

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, October 21, 2025
Time: 8:00 am Central Time
Location: Zoom Teleconference
Institution: Prairie Education and Research Cooperative, O'Fallon, IL
Principal Investigator: Raghav Govindarajan, 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 8:01 am Central 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-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: 4

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 any non-sharps disposable items subject to potential contamination be discarded into a durable, leak-proof, red-bagged biohazardous waste container. An Institutional Representative confirmed that they will purchase or obtain this type of container and that it will be available in the preparation room.
2. The Committee recommended that a photo depicting the setup of how the study agent vials will be thawed in a water bath be provided to IBC Services.
3. The Committee recommended that sharps containers be securely mounted on walls or stabilized on a countertop to prevent spillage of the contents.
4. The Committee recommended that the Training and Shipping Certification should indicate the specific regulations the training covers for clarity and auditing purposes (e.g., 49 CFR 172.704, IATA 1.5) and that a memo or note to file be provided to IBC Services with this information.
5. An Institutional Representative confirmed that the pre-filled eyewash bottles have been ordered and will be available in rooms where the study agent is handled.
6. An Institutional Representative confirmed that the storage unit is provided by the Sponsor and is not yet onsite. The Committee recommended that the storage unit be properly labeled with a biohazard symbol sticker/magnet when the study agent is onsite in storage and that a photo of this unit be provided to IBC Services.
7. An Institutional Representative confirmed that the alternate phone number listed on the Biohazard Sign is a "24/7" number. The Committee recommended that the "Biohazard Sign" be updated to reflect this information.

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 8:23 am Central Time.