

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, May 27, 2026  
**Time:** 8:00 am Arizona Time  
**Location:** Zoom Teleconference  
**Institution:** Center for Neurosciences, Tucson, AZ  
**Principal Investigator:** Michael Badruddoja, MD  
**Protocol:** Cartesian Therapeutics, Inc., RNAC-MG-002  
**NCT Number:** NCT06799247  
**Meeting Type:** Continuing 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 8:00 am Arizona 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5                      NO: 0                      ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

### 8. 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.

### 9. 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

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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 Biosafety SOP Section 3.3 be revised to state that both a heat block and a water bath may be used for thawing.
2. The Committee discussed that the sharps containers mounted on the wall in the dosing rooms appear to be too high for many individuals to clearly see the disposal opening and recommended that the Institution consider mounting them at a height of approximately 52-56 inches.

### **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 8:14 am Arizona Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Version 1.2, dated 03-13-2026

Investigator Brochure, Edition 6, dated 12-19-2025

Handling, Storage, and Administration Instructions, Edition 11, dated 12-05-2024

Research Modification Evaluation, Protocol, Version 1.2

Research Modification Evaluation, Investigator Brochure, Edition 6

Biological Risk Assessment and Summary, updated 03-17-2026

Site Maps, dated 06-23-2025

Site Inspection Checklist, expires 06-03-2027, updated 02-24-2026

Photos, dated 04-03-2026

Biohazard Sign, dated 06-04-2025

SOP, Biosafety for Descartes-08, dated 02-05-2026

Training, Shipping Certification, expires 11-12-2026

CRRF, dated 03-13-2026

Prior Meeting Minutes, Initial, dated 06-23-2025