

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, June 23, 2025  
**Time:** 10:00 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:** 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 9:59 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. There were some general questions from the public received and answered by the site 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 Committee recommended that Biosafety SOP Section 5.2.4 be revised to note that individuals will be escorted to the nearest plumbed eyewash station after using the prefilled disposable eyewash bottles in the event of an eye exposure.
2. The Committee recommended that Site Inspection Checklist, item 4 be revised to indicate that there are no special provisions or restrictions for entry into areas where the study agent is handled.
3. The Institutional Representative confirmed that hand sanitizer is available in the preparation room. The Committee recommended that the Site Map be revised accordingly.
4. The Institutional Representative could not confirm how frequently the plumbed eyewash station is flushed. The Committee recommended that the eyewash station be flushed weekly and that the Institution confirm with IBC Services whether this is being done.
5. The Institutional Representative confirmed that the plumbed eyewash station is located approximately 15 feet from the preparation room.
6. The Institutional Representative confirmed that the door to the storage and preparation room and the study agent storage freezer will be labeled with a biohazard symbol once the study agent is on-site. The Committee recommended that updated photos showing the labeled door and freezer be provided to IBC Services.
7. The Committee recommended that the sharps container located in the storage/preparation room be moved away from the air vent so as not to impede proper airflow in the room.
8. The Committee recommended that larger biohazard symbols be posted on the door to the biohazardous waste storage room.
9. The Institutional Representative confirmed that biohazardous waste containers with a step-on lid, as shown in the dosing room photos, will be available inside all preparation and dosing rooms during study agent handling activities for disposal of PPE and other non-sharp items.
10. The Institutional Representative confirmed that the preparation room is accessed through the [REDACTED] and that there is a door separating the [REDACTED] from the [REDACTED].
11. The Institutional Representative confirmed that the study agent is transported from the preparation room to the dosing rooms at room temperature using the internal transport container shown in the Photos document.

### **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 10:26 am Arizona Time.