

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, October 6, 2025
Time: 2:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Neurology Associates, P.A., Maitland, FL
Principal Investigator: Adam D. Slansky, 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 2:00 pm 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 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: 5

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

Point of Discussion:

1. The Committee recommended that the institution provide IBC services with more detailed clinical research experience for the Principal Investigator.

The Committee reviewed and accepted the qualifications of the Principal Investigator.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 absorbent material be placed on the countertop for study agent preparation and that Biosafety SOP, Section 3.3 be revised to indicate this.
2. An Institutional Representative stated that biohazardous waste containers are available in the dosing rooms. The Committee recommended that photos of the biohazardous waste containers, labelled with biohazard symbols, be provided to IBC services.
3. The Committee recommended that a photo of the biohazard sign at the entrance to the Lab/Medication Room be provided to IBC services.
4. An Institutional Representative stated that the study agent storage freezer is labelled with a biohazard symbol. The Committee recommended that an updated photo of this freezer in the Lab/Medication Room be provided to IBC services.
5. An Institutional Representative stated that the water bath and heat block will be provided by the sponsor. The Committee recommended that the water bath be labelled with a biohazard symbol and that photos of the water bath and heat block be provided to IBC services once available.
6. The Committee recommended that photos of the decontaminants be provided to IBC Services.
7. An Institutional Representative stated that pillow covers in the dosing rooms are disposable.
8. The Committee discussed a photo of Exam Room 2, noting that the disposable eyewash station is located near a microwave and handwashing sink. An Institutional Representative stated that this is actually a photo of the kitchenette, not the exam room. The Committee recommended that the handwashing sink in the kitchenette not be used by study staff after study agent handling as food and drink may be prepared in that room and that this photo be removed from the site photos.
9. The Committee discussed the locations of the disposable eyewash bottle stations noting that site documents indicate that both dosing rooms are equipped with these. An Institutional Representative stated these stations are currently in the kitchenette and the Lab/Medication Room. The Committee recommended that the disposable eyewash bottles be moved from the kitchenette to the Infusion Room and that disposable eyewash bottles be obtained for Exam Room 2.
10. The Committee recommended that photos of the disposable eyewash bottle stations in the dosing rooms be provided to IBC Services once installed.
11. An Institutional Representative stated there are both wall-mounted and tabletop sharps containers in the Lab/Medication Room. The Committee recommended that the institution obtain devices which prevent tipping for the tabletop sharps containers.

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 2:30 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Protocol, Version 1.1, dated 01-20-2025

Investigator Brochure, Edition 5, dated 11-22-2024

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

Biological Risk Assessment and Summary, dated 02-12-2025

Site Map, dated 09-19-2025

Site Inspection Checklist, expires 09-19-2027

Photos, dated 09-19-2025

Biohazard Sign, Descartes-08, dated 09-22-2025

SOP, Biosafety for Descartes-08, dated 09-08-2025

Training, Shipping Certification, dated 06-25-2025

CV, Slansky, A., signed 12-05-2023