

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, January 5, 2026
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Hackensack Meridian Health, Hackensack, NJ
Principal Investigator: Yukiko Kimura, MD
Protocol: Cartesian Therapeutics, Inc., HELIOS-001
NCT Number: NCT07089121
Meeting Type: Initial Review of Protocol and Site
Title: Descartes-08 for children, adolescents and young adults with childhood-onset systemic lupus erythematosus, ANCA-associated vasculitis, juvenile myasthenia gravis, and juvenile dermatomyositis

1. Call to order:

The Meeting was called to order at 09:59 am Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Biosafety Officer. 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 Biosafety Officer and 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: 6

NO: 0

ABSTAIN: 0

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9. Review of Principal Investigator qualifications:

Points of Discussion:

1. The Committee noted that the Principal Investigator's CV does not indicate that she is currently licensed to practice medicine in the state of New Jersey. The Committee recommended CVs for Principal Investigator's contain this information.
2. The Biosafety Officer and Institutional Representative confirmed that the Principal Investigator is currently licensed to practice medicine in the state of New Jersey.

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

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 [REDACTED] Site Inspection Checklist item 1 be revised to include the following comment: "[REDACTED]".
2. The Committee recommended that [REDACTED] Site Inspection Checklist item 2 be revised to include the following comment: "Study staff members are trained on the Biosafety Guideline(s) following IBC approval and finalization of the document(s) and training will be logged. For all studies, this process is logged and documented after the final Guideline(s) is approved by the IBC."

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 6

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:10 am Eastern Time.