INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, August 28, 2026**
Time:	9:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Hackensack Meridian Health, Hackensack, NJ
Principal Investigator:	**Miguel Gonzalez-Velez, MD**
Protocol:	Merck Sharp & Dohme LLC, **V940-002**
NCT Number:	NCT05933577
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer

1. Call to order:

The Meeting was called to order at 9:18 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 were two 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:

The Biosafety Officer 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: 6 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 previously determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for V940 since the study agent consists of synthetic mRNA administered via intramuscular injection. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of V940 locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. 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

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 noted that the biological safety cabinet (BSC) certifications are due for recertification next month (September 2026).
2. The Committee discussed the recent changes to the Continuing Review Report Form (CRRF).

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 6 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:24 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 7, dated 02-12-2026
Investigator's Brochure, Version 19, dated 09-05-2025
Pharmacy Manual, Version 9.0, dated 03-20-2026
Research Evaluation Modification, Protocol, Amendment 5
Research Evaluation Modification, Protocol, Amendment 7
Research Evaluation Modification, Pharmacy Manual, Version 7.0
Research Evaluation Modification, Pharmacy Manual, Version 8.0
Research Evaluation Modification, Pharmacy Manual, Version 9.0
Biological Risk Assessment and Summary, updated 06-10-2026
Research Modification Evaluation, Change in Principal Investigator, dated 03-27-2026
Site Map, Outpatient, 4th Floor JTCC, updated 10-01-2025
Site Map, Outpatient, 3rd Floor JTCC, updated 10-01-2025
Site Map, Cancer Center Pharmacy, dated 04-16-2025
Site Map, Cancer Center Loading Dock, dated 01-19-2022
Site Inspection Checklist, JTCC Cancer Center, expires 04-15-2027, updated 08-19-2026
Biohazard Sign, mRNA-based study agents, dated 03-27-2026
Biological Safety Cabinet Certifications, JTCC Pharmacy, expire 09-2026
Biosafety Guidelines for mRNA-based Vaccines, dated 01-30-2026
Training, Shipping Certifications, expire 10-2026, 11-2026, 12-2026, 2027
CRRF, dated 06-03-2026
CV, Gonzalez-Velez, M., signed 04-01-2025
Prior Meeting Minutes, Continuing, dated 09-30-2025