

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, June 3, 2025
Time: 9:00 am Mountain Time
Location: Zoom Teleconference
Institution: Banner MD Anderson Cancer Center at North Colorado Medical Center, Greeley, CO
Principal Investigator: Lin Hao, MD, PharmD, MS
Protocol: Merck Sharp & Dohme LLC, V940-009
NCT Number: NCT06623422
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INTerpath-009)

1. Call to order:

The Meeting was called to order at 9:00 am Mountain Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were five 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-1 containment facilities and practices plus Standard Precautions** are required for V940 because the study agent consists of synthetic mRNA administered via intramuscular injection.

The Committee 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.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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 Biosafety SOP Section 3.6.2 and Site Inspection Checklist (#19) be revised by removing Isopropyl alcohol as a decontaminant as it's not effective on its own.
2. The Committee recommended that the 10-minute aerosol settling time be removed from Biosafety SOP Section 5.1.1.
3. The Committee noted that the NCMC and BMDACC locations have different addresses. An Institutional Representative stated that the buildings are connected via a tunnel system.
4. The Committee recommended that the study agent storage unit and Biological Safety Cabinet (BSC) be labelled with biohazard symbols. The Committee recommended that new photos of the labelled storage unit and BSC be provided to IBC Services.
5. The Committee recommended that the study agent specific biohazard sign be posted at the entrance to all areas where the study agent is handled and that photos of the posted signage be provided to IBC Services.
6. An Institutional Representative confirmed that plumbed eyewashes are flushed on a weekly basis and that a flush log is kept.
7. An Institutional Representative confirmed that all plumbed eyewashes have posted eyewash signs.
8. An Institutional Representative stated that preparation of the study agent occurs in the clean room suite, which has several doors inside but only one entrance/exit door. An Institutional Representative stated that the BSC is located in Room B1-405.3.

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:18 am Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 03, dated 03-10-2025

Investigator's Brochure, Version 18, dated 12-17-2024

Pharmacy Manual, Version 2.0, dated 09-24-2024

Biological Risk Assessment and Summary, updated 04-08-2025

Site Map, BMDACC, dated 04-03-2025

Site Map, NCMC, dated 04-03-2025

Site Inspection Checklist, expires 04-28-2027

Photos, dated 04-14-2025

Biohazard Sign, mRNA-based vaccines, dated 04-03-2025

Biological Safety Cabinet Certification, dated 03-12-2025

SOP, Biosafety for mRNA-based Vaccines, dated 04-03-2025

Training, Shipping Certifications, expire 06-2026, 03-2029

CV, Hao, L., signed 01-31-2024