INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, July 13, 2026**
Time:	9:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Baptist Healthcare System, Inc., Lexington, KY
Principal Investigator:	**Firas Badin, MD, MBA-HSM**
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 9:01 am Eastern 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 twelve 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 since 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.

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 discussed the biological safety cabinet (BSC) certification report and noted that the unit is a Class II, Type B2 cabinet designed for 100% total exhaust and that the certification report does not include information regarding the required exhaust system performance verification, blower interlock verification, and alarm function verification.
2. The Committee determined as a **Condition of Approval** that the Institution ensures that the BSC is tested and certified in accordance with NSF/ANSI 49 standards and provides an updated certification report documenting the results of all required annual certification tests, including exhaust system performance verification, blower interlock verification, and alarm function verification.
3. The Committee recommended that the study agent-specific Biohazard Sign be posted on the preparation and dosing room doors during study agent handling activities.
4. An Institutional Representative confirmed that the study agent is placed inside a biohazard bag for transport. The Committee recommended that the bagged study agent be placed inside a leak-proof container labeled with a biohazard symbol and that a photo of this transport container be provided to IBC Services.
5. The Committee recommended that a representative photo of the sharps and biohazardous waste containers in the dosing rooms be provided to IBC Services.
6. The Committee recommended that prefilled disposable eyewash bottles be made available in the preparation and dosing rooms.
7. The Committee recommended that the site's Exposure Control Plan be reviewed and updated annually and that site documents be revised to reflect this.
8. An Institutional Representative confirmed that a sharps container will not be placed inside the BSC during study agent preparation but that it is within arm's reach. The Committee recommended that the comment in the Photos document stating that a sharps container will be inside the BSC be deleted.
9. An Institutional Representative confirmed that only one BSC will be used for study agent preparation.
10. An Institutional Representative confirmed that there is a plumbed eyewash station immediately outside the preparation room.

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:

	APPROVED
X	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

For a vote of CONDITIONALLY APPROVED, the following conditions must be met before the proposed research can proceed:

a. The BSC is tested and certified in accordance with NSF/ANSI 49 standards and an updated certification report documenting the results of all required annual certification tests, including exhaust system performance verification, blower interlock verification, and alarm function verification is provided to IBC Services.

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:29 am Eastern Time.

15. Post-meeting notes: The condition of approval was met on the following date:

Resolution of conditions for Conditional Approval:

Condition No.	Resolution	Date of Resolution	Approved by Chair
a			

Documents reviewed:
Agenda
Protocol, Amendment 04, dated 07-30-2025
Investigator's Brochure, Version 19, dated 09-05-2025
Pharmacy Manual, Version 7.0, dated 03-23-2026
Biological Risk Assessment and Summary, updated 06-12-2026
Site Map, dated 07-01-2026
Site Inspection Checklist, expires 06-18-2028
Photos, dated 06-26-2026
Biohazard Sign, dated 06-12-2026
Biological Safety Cabinet Certification, dated 04-21-2026
SOP, Biosafety for mRNA-based Vaccines, dated 06-19-2026
Training, Shipping Certifications, expire 2027, 2028
CV, Badin, F., signed 5-29-2025