Meeting Minutes

Institution:	University of Missouri
Meeting Date:	December 10, 2025
Meeting Time	11:00 AM Central Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Bavaret, Tammy / Yes / Chair: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Wang, Anthony / Yes / Core Member: Biosafety Expert/HGT Expert Hoffman, Dusty (joined at 11:14 AM CT) / Yes / Local Unaffiliated Member Popa, Kyle (joined at 11:12 AM CT) / Yes / Local Unaffiliated Member Rehard, David / Yes / Biological Safety Officer
Invited Members Not in Attendance:	None
Guests:	Little, Hannah; Bryant, Karissa; Nanney, Heather; Roehrs, Emily; Wakefield, Mark
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 11:05 AM. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 6/5/2025 were approved by the IBC with no changes.

Meeting Minutes

New Business:

PI:	Wakefield, Mark
Sponsor:	Merck Sharp & Dohme LLC
Protocol:	V940-011 A Phase 2 Open-label Randomized Study of V940 in Combination with BCG Versus BCG Monotherapy in Participants with High-risk Non-muscle Invasive Bladder Cancer (INTerpath-011)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: V940-011 is a Phase II randomized, active-controlled, open-label study sponsored by Merck Sharp & Dohme LLC designed to evaluate the efficacy and safety of the study agent V940 (also known as mRNA-4157) in combination with Bacillus Calmette Guerin (BCG) compared to BCG monotherapy in adult participants with high-risk non-muscle invasive bladder cancer (NIMBC) and have undergone transurethral resection of bladder tumor (TURBT). V940 is a novel mRNA-based individualized neoantigen therapy (INT) consisting of a single lipid encapsulated mRNA encoding up to 34 participant-specific neoantigens. The investigational product (IP) is administered by intramuscular injection (IM).

Biosafety Containment Level (BSL): The study agent V940 (mRNA-4157) is a non-infectious synthetic mRNA that is not associated with disease in healthy adults. It is incapable of replication and does not express known hazardous transgenes. Therefore, BSL-1 containment may be considered as the minimum biocontainment level when handling the study agent. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills, splashes, and/or needlestick exposures of the IP during preparation and/or administration procedures These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report, and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Committee noted that the Site has already completed their BSC recertifications and Sabai recently received the updated reports.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 11:40 AM

Post-Meeting Pre-Approval Note: None