Meeting Minutes

Institution:	Texas Oncology-Sammons CC (Txo-DS)
Meeting Date:	August 18, 2025
Meeting Time	9:00 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 Ellis, Robert / Yes / Core Member: Biosafety Expert/HGT Expert Scott, Frederick / Yes / Local Unaffiliated Member Naik, Veena / Yes / Local Unaffiliated Member Koetter, Danielle / No / Site Contact
Invited Members Not in Attendance:	None
Guests:	Lopez, Rita
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 8:58 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: None

New Business:

PI:	Cowey, C. Lance
Sponsor:	Merck Sharp & Dohme Corp
Protocol:	V940-001 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 High-Risk Stage II-IV Melanoma (INTerpath-001)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: V940-001 is a Phase III randomized, double-blind study sponsored by Merck Sharp & Dohme LLC and designed to evaluate the safety and efficacy of the study agent V940 (also known as mRNA-4157) plus pembrolizumab, and to compare the effects of the combination of V940 and pembrolizumab to placebo plus pembrolizumab in participants with completely resected high-risk cutaneous melanoma. V940 is a novel personalized mRNA- directed against patient-specific neoantigens referred to as an individualized neoantigen therapy (INT). The investigational product (IP) is administered by intramuscular injection.

Biosafety Containment Level (BSL): The study agent V940 (mRNA-4157) is a non-infectious synthetic mRNA incapable of replication and does not encode for known hazardous transgenes. For these reasons, BSL-1 containment may be considered as the minimum biocontainment level. The administration of this agent in a clinical setting requires compliance with 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, needlesticks, or aerosols 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.
  - In response to a question from the Committee, the Site confirmed that the BSC will be recertified this week and the Committee reminded the Site to send Sabai the full updated report when it is available.

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 9:19 AM

Post-Meeting Pre-Approval Note: Minutes from 8/8/25 were approved by the IBC after this IBC meeting convened with no changes. There were no votes against and no abstentions.