Meeting Minutes

Institution:	Texas Oncology-Sammons CC (Txo-DS)
Meeting Date:	August 08, 2025
Meeting Time	1:00 PM 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 Helm, Allen — Yes — Core Member: Biosafety Expert/HGT Expert Koetter, Danielle — No — Site Contact Naik, Veena — Yes — Local Unaffiliated Member Rastein, Daniel — Yes — Core Member: Biosafety Expert/HGT Expert Scott, Frederick — Yes — Local Unaffiliated Member
Invited Members Not in Attendance:	**Member** — **Voting** — **Member Type** None
Guests:	Lopez, Rita
Staff:	Mahrt, Elena

Call to Order: The IBC Chair called the meeting to order at 12:59 PM. 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 6/24/2025 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

Meeting Minutes

PI:	Paulson, Andrew Scott MD
Sponsor:	BioNTech SE
Protocol:	BNT122-01: A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: BNT122-01 is a Phase II clinical trial sponsored by BioNTech SE designed to assess the safety and potential efficacy of a recombinant personalized cancer vaccine for the treatment of participants with advanced colorectal cancer following surgical resection. The study agent RO7198457 (autogene cevumeran) consists of messenger RNA (mRNA) expressing personalized tumor antigens formulated as a liposome complex. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent RO7198457 consists of synthetic mRNA incapable of replication and does not encode for known hazardous transgenes (e.g., toxins or oncogenes), BSL1 containment is considered the minimum biocontainment level. The administration of this agent by intravenous infusion in a clinical setting requires compliance with the OSHA Bloodborne Pathogen Standard.

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 or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. 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 suggested that the agent descriptions on the Biohazard Sign be simplified so that all agents of the same type have the same description. The Site had no concerns.
  - The Committee discussed the biohazard waste container next to the Biosafety Cabinet (BSC) in the Pharmacy and noted that it appeared overfull. The Committee reminded the Site that biohazard waste containers should be closed and removed before they become overfull. The Committee had no further concerns.
  - The Committee discussed the BSC certification reports and noted that they were due for recertification this month. The Site will confirm if recertification was scheduled for this month. The Committee also noted that some of the NSF/ANSI 49 testing results appeared to be missing from the report. The Site will obtain and provide the remaining portions of the report. The Committee had no further concerns.

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 1:30 PM

Post-Meeting Pre-Approval Note: None