Meeting Minutes

Institution:	Texas Oncology-Sammons CC (Txo-DS)
Meeting Date:	May 21, 2026
Meeting Time	10:00 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 Helm, Allen / Yes / Core Member: Biosafety Expert/HGT Expert Naik, Veena / Yes / Local Unaffiliated Member Scott, Frederick / Yes / Local Unaffiliated Member Koetter, Danielle / No / Site Contact
Invited Members Not in Attendance:	None
Guests:	None
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 9:59 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 3/20/26 were approved by the IBC with no changes**.** There were no votes against and no abstentions.

Meeting Minutes

New Business:

PI:	Cowey, C. Lance
Sponsor:	Replimune, Inc.
Protocol:	RP1-104 A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen [IGNYTE-3]
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: RP1-104 is a Phase III, randomized, open-label study sponsored by Replimune, Inc. and designed to assess the efficacy of Vusolimogene Oderparepvec (VO; also known as RP1), a recombinant, selectively replicating oncolytic Type 1 Herpes Simplex Virus (HSV-1), in combination with nivolumab for the treatment of participants with qualifying advanced melanoma that has progressed on anti-PD-1 and anti-CTLA-4 treatment. The investigational product (IP) is administered by intratumoral injection.

Biosafety Containment Level (BSL): Because the study agent vusolimogene oderparepvec is based on a recombinant Risk-Group 2 herpesvirus containing more than two-thirds of the native genome, BSL2 containment is considered the default biocontainment level under the NIH Guidelines. Agent administration also introduces the potential for exposure to bloodborne pathogens, further requiring 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: Staff who are pregnant or have open skin-lesions should not handle the study agent or materials that come into contact with the study agent. Staff who are immunocompromised or immunosuppressed should consider consulting with the principal investigator, occupational health department, or their primary care physician prior to handling the study agent or materials contaminated with the study agent.
- 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.

Motion: A motion of Full Approval for the study at BSL-2 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 10:23 AM.

Post-Meeting Pre-Approval Note: None