Meeting Minutes

Institution:	Texas Oncology - Tyler (Txo-T)
Meeting Date:	March 23, 2026
Meeting Time	11:30 AM Central Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Noriea, Nicholas / Yes / Chair: Biosafety Expert/HGT Expert Helm, Allen / Yes / Core Member: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Filla, Beth / Yes / Local Unaffiliated Member Frydenlund, Chris / Yes / Local Unaffiliated Member Maxfield, Shelly / No / Site Contact
Invited Members Not in Attendance:	None
Guests:	None
Staff:	Payne, Kaylie

Call to Order: The IBC Chair called the meeting to order at 11:29 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 11-4-2025 were approved by the IBC with no changes. There were no votes against and no abstentions.

Meeting Minutes

New Business:

PI:	Yimer, Habte MD
Sponsor:	Allogene Therapeutics, Inc.
Protocol:	ALLO-501A-202 A Randomized, Open-Label Study Evaluating the Efficacy and Safety of Cemacabtagene Ansegedleucel in Participants with Minimal Residual Disease After Response to First Line Therapy for Large B-Cell Lymphoma.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: ALLO-501A-202 (ALPHA3 Study) is a Phase II randomized, open-label study sponsored by Allogene Therapeutics, Inc. designed to assess the safety and efficacy of cemacabtagene ansegedleucel (cema-cel; formerly known as ALLO-501A) for the treatment of large B-cell lymphoma (LBCL) in adult subjects with minimal residual disease (MRD) after completion of first line (1L) therapy. Cema-cel is a genetically engineered allogeneic chimeric antigen receptor (CAR)-T cell product that targets CD19, a tumor antigen highly expressed on the surface of certain B cell malignancies. In addition to expression of the anti-CD19 CAR, cema-cel cells have also been engineered to knock out expression of the native T cell receptor (TCR) that may cause graft-versus-host disease (GvHD), and to knock out expression of native CD52, a target for ALLO-647 antibody-mediated lymphodepletion. The investigational product (IP) is administered by intravenous (IV) infusion.

Biosafety Containment Level (BSL): Cema-cel consists of primary human cells stably transfected with a recombinant, replication-defective lentiviral vector derived from a Risk-Group 3 (RG3) virus. BSL2 containment is recommended under the NIH Guidelines. This study also requires compliance with the OSHA Bloodborne Pathogens 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.
  - In response to a question from the Committee, the Site confirmed that the Pharmacy Staff do use chairs at the BSC's when preparing the study agent.
  - In response to a question from the Committee, the Site confirmed that they leave the study agent inside the shipping container until they are retrieved for preparation and administration. The Site Map & Photos will be administratively updated.

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 11:53 AM

Post-Meeting Pre-Approval Note: None