Meeting Minutes

Institution:	Rocky Mountain Cancer Centers – Englewood
Meeting Date:	June 15, 2026
Meeting Time	3:00 PM Mountain 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 Reed, Craig / Yes / Core Member: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Haltiwanger, Brett / Yes / Local Unaffiliated Member Vance, James / Yes / Local Unaffiliated Member Stensgard, Shelby / No / Site Contact
Invited Members Not in Attendance:	**Member** / **Voting** / **Member Type** Stensgard, Shelby / Yes / Site Contact
Guests:	White, Shana (Affiliated, Non-voting) Beland, Kelly (Affiliated, Non-voting) Ellermann, Jillian (Affiliated, Non-voting)
Staff:	Parrish, Wendy

Call to Order: The IBC Chair called the meeting to order at 3:00 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 6-23-25 were approved by the IBC with no changes.

New Business:

PI:	Burke, John
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 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.
  - The Site confirmed the information in the Annual Review Report.
  - The Committee discussed the Biosafety Cabinet Certification Report. The Site's updated Report was shared with the Committee during the meeting, and the Facility Details xForm will be revised to include the updated Report. The Committee had no concerns.
  - The Site confirmed that the Site's Annual Refresher Training includes Bloodborne Pathogens training, and the updated Certificate was shared with the Committee during the meeting. The Committee had no concerns.
  - The Site indicated the following photos will be submitted to Sabai, and the Site Map+Photos document will be administratively revised to reflect the updates:
    - Study agent storage room showing placement of study agent storage freezers
    - Preparation room showing updated photo of the biosafety cabinet with biohazard sticker and unobstructed vents
    - Photo showing inside of the biohazardous waste storage area
  - The Committee discussed the Site's spill kit, and the Site confirmed they have a biological spill kit on the premises. The Facility Details xForm will be administratively revised to clarify this information. The Committee had no concerns.

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 3:32 PM.

Post-Meeting Pre-Approval Note: None