# Meeting Minutes

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| **Meeting Date:** | June 20, 2025 at 1:30 PM Eastern Time |
| **Meeting Place:** | Teleconference (Remote)<br>Meeting is open to the public |
| **Members in Attendance:** | Noriea, Nicholas<br>Ellis, Robert<br>Rastein, Daniel<br>Singh, Christopher<br>Sullivan, Marcy (Joined at 1:40PM) |
| **Members Not in Attendance:** | Browne, Angela |
| **Guests**: | Cochrane, Monica |
| **Staff:** | Hemmelgarn, Marian |
| **Institution:** | VA Cancer Specialists HGT |

**Call to Order:** The meeting was called to order at 1:33 PM. A quorum was present.

**Conflicts of Interest:** None declared by voting members of the IBC.

**Meeting Minutes**: Previous meeting minutes were reviewed and approved with no requested changes.

**New Business:**

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| **PI:** | Gandhi, Mitul MD |
| **Sponsor:** | Allogene Therapeutics, Inc. |
| **Protocol:** | ALLO-501A-202<br>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:** | III-C |

**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.

Biosafety Containment Level per Risk Assessment: BSL-2

**Comments:**

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, 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 accuracy of the Annual Review Report.
    - The Committee discussed the Biological Safety Cabinet (BSC) certification report noting there was an issue identified with a hood motor in a BSC in the non-chemo room. The Site confirmed this room and BSC are not used for agent preparation.

**Motion:** A motion of Full Approval for the study at BSL-2 was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

**Reminder of IBC Approval Requirements.**

**Adjournment:** 2:02PM ET

**Post-Meeting Pre-Approval Note:** None