

Institutional Biosafety Committee (IBC) - Clinical

Commonly Used Abbreviations

BSL: Biosafety Level

CTL: Cell Therapy Lab

CTU: Clinical Trials Unit

EH&S: Employee Health & Safety

IDS: Investigational Drug Services

IMTX: Immunotherapy

IP: Investigational Product

PI: Principal Investigator

NIH: National Institutes of Health

SOP: Standard Operating Procedure

Date: Thursday, October 2nd, 2025

Time: 4:00pm – 5:00pm

Location: Zoom

Members

Present:

1. Brian Till, MD - Fred Hutch (Committee Chair)
2. Marie Bleakley, MD – Fred Hutch
3. Alex Hirayama, MD – Fred Hutch
4. Brian Hsu, PhD – Local Unaffiliated Member
5. Susan Parazzoli, Fred Hutch (Biosafety Officer)
6. Steve Pergam, MD – University of Washington (Infection Prevention)
7. Scott Tykodi, MD – University of Washington
8. Jake White, Fred Hutch

Members 1. Jacob Appelbaum, MD – University of Washington

Absent:

2. Matt Donelan – Local Unaffiliated Member
3. Shelly Heimfeld, PhD – Fred Hutch
4. Folashade Otegbeye, MD – Fred Hutch

Guests 1. Soyoung Park (IMTX Clinic)

Present: 2. Cindy Wladyka (EH&S)

- I. **Call to Order:** The IBC Chair called the meeting to order at **4:02pm**. The IBC has **12** voting members, and **6** (including a Local Unaffiliated member) are required to conduct business. A quorum was **confirmed**.
- II. **Conflicts of Interest:** The IBC Chair reminded all members that no member of an IBC may be involved (except to provide information requested by the IBC) with the approval

of a protocol in which he/she has been or expects to be engaged or has a direct financial interest. Committee members with a conflict of interest must self-identify and abstain during the voting process.

III. Confidentiality: The IBC Chair reminded all members that the materials distributed in preparation for the meeting and the details of the summary prepared for the committee are considered confidential.

IV. Prior Business:

- a. Acknowledgement of August 21st, 2025, Meeting Minutes

V. New Business:

- a. Protocol: RG1125684 -The CAROLYN Trial: Lisocabtagene Maraleucel as First-Line Therapy for Primary Central Nervous System Lymphoma (PCNSL) in Transplant-Ineligible Patients.

PI: Vyshak Venur

Service Areas: CTL, IMTX Clinic

Overview:

- Primary central nervous system lymphoma (PCNSL) is a rare and aggressive form of non-Hodgkin lymphoma (NHL) comprising approximately 3% of all neoplasms and 4% to 6% of all extra nodal lymphomas.
- Cellular therapy, such as the targeting of CD19 with CAR T cells, has already demonstrated deep and durable responses in the treatment of various B-cell lymphomas, including PCNSL and secondary CNS lymphoma (SCNSL).
- Currently, there are no CAR T-cell therapy treatments approved for PCNSL in the front-line or relapsed/refractory setting; however, published experiences evaluating its use in the relapsed/refractory setting have been reported, confirming its safety and feasibility, including lisocabtagene maraleucel (liso-cel).
- This is a Phase 2, single arm, open-label, multicenter study to evaluate the efficacy and safety of liso-cel in adults with newly diagnosed PCNSL deemed transplant-ineligible.

IP/Agent: Lisocabtagene maraleucel (Breyanzi, BMS-986387, further referred to as liso-cel) is composed of autologous CD8+ and CD4+ T cells that express a CD19-specific chimeric antigen receptor (CAR). The CD19-specific CAR is introduced into autologous CD8+ and CD4+ T cells ex vivo using a replication-incompetent, self-inactivating lentiviral vector.

NIH Guidelines Section: Section III-C-1

Biosafety Level Assignment: BSL-2

EH&S - Enhanced Practices/Precautions: None

Major Discussion Points: None

Motion: A motion was made to approve the protocol.

Votes:

Approve: **7**

Disapprove: 0

Abstain: 1

Conflict(s) of Interest: 1

VI. Additional Topics:

- a. An announcement regarding the retirement of the Clinical IBC following today's meeting was circulated to members on October 1st; going forward all new oncology clinical trial submissions will be reviewed by the historical Fred Hutch Lab based IBC (new Fred Hutch IBC); study teams will be redirected to ehs@fredhutch.org for assistance.*

VII. Adjournment: The IBC chair moved to adjourn the meeting at **4:16pm**.

**These minutes could not be formally acknowledged by this committee during a meeting.*