# 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

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**Date:** Thursday, June 5th, 2025
**Time:** 4:00pm – 5:00pm
**Location:** Zoom

**Members Present:**
1. Brian Till, MD - Fred Hutch (Committee Chair)
2. Jacob Appelbaum, MD - University of Washington
3. Marie Bleakley, MD – Fred Hutch
4. Matt Donelan - Local Unaffiliated Member
5. Alex Hirayama, MD – Fred Hutch
6. Brian Hsu, PhD – Local Unaffiliated Member
7. Susan Parazzoli, Fred Hutch (Biosafety Officer)
8. Scott Tykodi, MD – University of Washington
9. Jake White, Fred Hutch

**Members Absent:**
1. Shelly Heimfeld, PhD – Fred Hutch
2. Folashade Otegbeye, MD – Fred Hutch
3. Steve Pergam, MD – University of Washington

**Guests Present:**
1. Ellen Wang (IDS)
2. Cindy Wladyka (EH&S)

I. **Call to Order:** The IBC Chair called the meeting to order at **4:00pm.** 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. None

**V.** **New Business:**

a. Protocol: RG1124123 - A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator- Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer (INTerpath-002).
PI: Lei Deng
Service Areas: IDS, CTU
Overview:
- The goal of the study is to assess the effectiveness of V940 plus pembrolizumab compared to placebo plus pembrolizumab in patients with resected early-stage NSCLC.
- Participants will be randomly assigned to receive either V940 plus pembrolizumab or placebo plus pembrolizumab.
- V940 is administered via intramuscular injection once every 3 weeks, and pembrolizumab is administered intravenously every 6 weeks.

IP/Agent: V940, also known as mRNA-4157, is an investigational mRNA-based personalized neoantigen therapy.
NIH Guidelines Section: Section III-C-1
Biosafety Level Assignment: BSL-1
EH&S - Enhanced Practices/Precautions: None
Major Discussion Points:
- V940 has been used in other IBC approved protocols and there were no differences with the product to address during this review process.

Motion: A motion was made to approve the protocol.
Votes:

Approve: **9**
Disapprove: 0
Abstain: 0
Conflict(s) of Interest: None

## VI. Additional Topics:

a. NIH Announcement - New guidance for IBCs went into effect on June 1st. As a result, the committee roster is accessible to the public and meeting minutes will be posted on the ExtraNet as they become available.
b. Returning IP – The committee discussed IP previously reviewed by the committee but returning for review as part of a new protocol, why these products must be re-evaluated and how to approach the review process if nothing previously captured in the required criteria to address has changed.
c. Upcoming meetings – There is a new submission expected soon and a request for availability will be sent out for the July through September meeting dates.

**VII. Adjournment:** The IBC chair moved to adjourn the meeting at **4:50pm**.