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, August 21st, 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 (*call-in*)
5. Alex Hirayama, MD – Fred Hutch
6. Folashade Otegbeye, MD – Fred Hutch
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. Brian Hsu, PhD – Local Unaffiliated Member
3. Steve Pergam, MD – University of Washington (Infection Prevention)

Guests Present:
1. Hanahlyn Park (CTU)

I. **Call to Order:** The IBC Chair called the meeting to order at **4:03pm.** 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 June 5, 2025, Meeting Minutes

V. **New Business:**

a. Protocol: RG1125649 - A Randomized, Phase 2/3, Open-Label Study to Investigate the Efficacy and Safety of RP2 in Combination with Nivolumab versus Ipilimumab in Combination with Nivolumab in Immune Checkpoint Inhibitor-Naïve Adult Patients with Metastatic Uveal Melanoma
PI: Natalie Miller
Service Areas: IDS, 3rd Floor Treatment Room, Interventional Radiology
Overview:
   - Historically, in metastatic uveal melanoma (mUM), median progression-free survival (mPFS) is generally less than 5 months and median overall survival (mOS) is less than 12 months.
   - Favorable preliminary efficacy and safety data was observed in patients with mUM treated with RP2 in combination with nivolumab in Study RP2-001-18.
   - A randomized phase 2/3 trial will now be performed to compare RP2 in combination with nivolumab versus ipilimumb with nivolumab.
   - RP2 will be administered by intratumoral injection performed by a qualified Investigator or under computed tomography (CT) or ultrasound guidance by a qualified interventional radiologist.

   IP/Agent: RP2 (rHSV-1 hGM-CSF/ahCTLA-4/GALV), is an oncolytic virus, specifically an attenuated selectively replication competent HSV-1 Type 1 virus. (The first FDA approved oncolytic virus (Talimogene laherparepvec, Imilytic) is also an HSV-1 virus.)
   NIH Guidelines Section: Section III-C-1
   Biosafety Level Assignment: BSL-2
   EH&S - Enhanced Practices/Precautions: See Medical Management Plan (MMP)
   Major Discussion Points:
   - The PI's involvement with the submission process.
   - Similarities between the investigational products RP-1, RP-3 used in protocols open at this site and RP-2.
   - Shedding data and interaction between participants and other patients.
   - Whether bedside preparation of syringes was appropriate for this product.
   - Locations of RP-2 administration and clinic staff involved with swab collection.

Motion: A motion was made to approve the protocol contingent on a response to the follow-up items identified during the discussion.
Votes:

Approve: **7**
Disapprove: 0
Abstain: *2
Conflict(s) of Interest: None
**Did not vote*

VI. Additional Topics:

a. Reminder: Respond to availability requests so that quorums can be confirmed.
b. Returning IP/agent: The group discussed how to manage the primary reviewer assignments, and it was determined to keep the current review assignment rotation but leverage an abbreviated template.

VII. Adjournment: The IBC chair moved to adjourn the meeting at **4:37pm**.