INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, March 19, 2025**
Time:	11:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Saint John's Cancer Institute, Santa Monica, CA
Principal Investigator:	**Kim Margolin, MD**
Protocol:	[redacted] **RPL-EAP-001**
Meeting Type:	Initial Review of Protocol and Site
Title:	An Expanded Access Program – Real-world Data Collection for VO in Combination with Nivolumab in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 Containing Treatment Regimen

1. Call to order:

The Meeting was called to order at 11:01 am Pacific Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were five Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for RP1 since it is based on a recombinant herpes simplex virus-1 administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of RP1 locally,** provided that other biosafety criteria for study closure are also met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee recommended that Biosafety SOP Section 3.5 be revised to briefly describe the process by which subjects dispose of used injection site dressings at home and return them to the Institution within closed biohazard containers.
2. The Institutional Representative noted that plumbed eyewash stations are flushed weekly.
3. The Committee recommended that the sharps container in the Preparation Room be labeled with a larger biohazard symbol and a photo to be sent to IBC Services.
4. The Committee recommended that Biosafety SOP Section 3.6.2 be revised to remove the reference to goggles/face shields.
5. The Committee recommended that an alternate phone number be added for the secondary contact listed on the Biohazard Sign.
6. The Committee noted that instructions for the disposal and return of used dressings within the Patient Information Sheet do not stipulate that biohazard containers be closed prior to return to the Institution. The Committee recommended that these containers be closed prior to return, and that a photo of the containers provided to subjects be sent to IBC Services.
7. The Institutional Representative confirmed that the biological safety cabinet (BSC) was recertified in January 2025, and that the certification report has been provided to IBC Services.
8. The Institutional Representative confirmed that the study agent will be stored in the -80°C freezer and that biohazardous materials are not stored in the refrigerator.
9. The Institutional Representative confirmed that a sharps container will be placed within the BSC during study agent preparation.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:23 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 1.1, dated 07-15-2024
Investigator's Brochure, Edition 10.0, dated 02-19-2025
Pharmacy and Administration Manual, Version 1.0, dated 10-23-2024
Intratumoral Injection Manual, Version 1.0, dated 03-26-2024
Patient Information for Post VO Injection, Version 1.0, dated 10-09-2024
Biological Risk Assessment and Summary, dated 03-17-2025
Site Map, Saint John's Cancer Institute, Radiology, Endoscopy, dated 11-18-2022
Site Map, Pharmacy, Waste, Basement, dated 08-12-2024
Site Map, Cancer Center Clinic, Infusion Center, basement, dated 03-12-2025
Site Inspection Checklist, dated 08-06-2024, updated 03-06-2025

Photos, dated 03-12-2025
Biohazard Sign, RP1, dated 03-12-2025
Biological Safety Cabinet Certification, dated 01-30-2025
SOP, Biosafety for RP1, dated 03-12-2025
Training, Shipping Certification, dated 11-06-2023, 04-16-2024
CV, Margolin, K., signed 03-07-2024