

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, April 10, 2025
Time: 12:00 pm 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: Modification Review; Change in Dosing Location
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 12:01 pm 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 four 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:

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

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol.

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

The Chair restated the previously determined biosafety level and period of IBC oversight; both will be redetermined at the next convened meeting.

9. Review of proposed facilities and practices

The Chair provided an overview of the proposed site change.

Point of Discussion:

1. The Committee recommended that the areas where study activities take place be decontaminated appropriately after use.
2. An Institutional Representative confirmed that there will be spill cleaning materials available in each dosing room.
3. The Committee recommended that all discussion points from the previous meeting be carried over and listed below:
 - a. 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.
 - b. The Institutional Representative noted that plumbed eyewash stations are flushed weekly.

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- c. 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.
- d. The Committee recommended that Biosafety SOP Section 3.6.2 be revised to remove the reference to goggles/face shields.
- e. The Committee recommended that an alternate phone number be added for the secondary contact listed on the Biohazard Sign.
- f. 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.
- g. 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.
- h. 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.
- i. The Institutional Representative confirmed that a sharps container will be placed within the BSC during study agent preparation.

10. Site responsibilities:

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

11. 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

12. Advice to the Institution: None.

13. Meeting adjourned: The meeting was adjourned at 12:08 pm Pacific Time.

14. 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

Research Modification Evaluation, Additional Preparation Rooms, dated 03-26-2025

Site Map, Saint John's Cancer Institute, Radiology, Endoscopy, dated 03-26-2025

Site Map, Cancer Center Clinic, Infusion Center, basement, dated 03-26-2025

Site Inspection Checklist, dated 08-06-2024, updated 04-02-2025

Photos, dated 03-26-2025

SOP Biosafety for RP1 dated 04-03-2025

Prior Meeting Minutes, Initial, dated 03-19-2025