

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, September 4, 2025
Time: 11:00 am Pacific Time
Location: Zoom Teleconference
Institution: Saint John's Cancer Institute, Santa Monica, CA
Principal Investigator: Naveed Wagle, MD
Protocol: [REDACTED], 1456-0001
NCT Number: NCT05155332
Meeting Type: Continuing Review of Protocol and Site
Title: Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 antibody in patients with advanced or metastatic solid tumors.

1. Call to order:

The Meeting was called to order at 11:20 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 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:

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. 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 and status of the study.

The Chair provided an overview of changes since the last review.

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for BI 1831169, since it is a replication-competent oncolytic virus derived from the VSV Indiana serotype. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of BI 1831169 locally**, provided that all biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. 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

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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 include an additional section (3.5.3) that indicates how subjects are to handle the extra gloves, dressings, and biohazard-labeled bag provided for home use.
2. The Committee recommended that Biosafety SOP Sections 3.6.1, 3.6.2 and 5.1.4.i be revised with a wet contact of 3 minutes for Peridox RTU.
3. The Committee recommended that Biosafety SOP Section 5.1.4.i be revised to remove "overlay the spill with one of the following".
4. The Committee noted that the Instructions for Use for Peridox RTU indicate that wipes should be used and recommended that the site contacts the manufacturer to confirm that paper towels are acceptable.
5. An Institutional Representative confirmed that the dosing room in the Infusion Center is a private room and that the bedding is changed between subjects.
6. An Institutional Representative confirmed that the yellow sharps container in the preparation room is used for disposal of used personal protective equipment (PPE) and sharps, and the black hazardous waste container is used for bulk waste. The Committee recommended that the Photos document be updated to reflect this.
7. The Committee noted that IATA/DOT Shipping Training Certification will expire for one individual in November 2025 and recommended that the training be renewed prior to the expiration date and an updated certificate be provided to IBC Services.
8. An Institutional Representative confirmed that disposable eye protection is primarily used but that reusable eye protection is available as a back-up.

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 11:28 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 9.0, dated 02-28-2025

Investigator's Brochure, Version 7, dated 06-04-2025

Preparation and Administration Manual, Version 4.0, dated 05-15-2025

Pathogen Safety Data Sheet, Version 02, dated 08-09-2017

Research Modification Evaluation, Protocol, Version 9.0

Research Modification Evaluation, Investigator's Brochure, Version 7

Research Modification Evaluation, Investigator's Brochure, Version 6

Research Modification Evaluation, Preparation and Administration Manual, Version 4.0

Research Modification Evaluation, Preparation and Administration Manual, Version 3.0

Research Modification Evaluation, Preparation and Administration Manual, Version 2.0

Biological Risk Assessment and Summary, updated 08-18-2025

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Site Map, Saint John's Cancer Institute, Radiology, Endoscopy, dated 08-26-2025
Site Map, Saint John's Cancer Institute, 4th Floor Inpatient, dated 08-24-2025
Site Map, Pharmacy, Waste, Basement, dated 08-12-2024
Site Map, Cancer Center Clinic, Infusion Center, basement, dated 03-26-2025
Site Inspection Checklist, expires 08-06-2026, updated 08-13-2025
Photos, dated 08-25-2025
Biohazard Sign, BI 1831169, dated 08-25-2025
Biological Safety Cabinet Certification, dated 07-24-2025
SOP Biosafety for, BI 1831169, dated 08-25-2025
Training, Shipping Certification, dated 11-06-2023, 04-16-2024
CRRF, dated 07-30-2025
Prior Meeting Minutes, Continuing, dated 08-23-2024