

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, March 9, 2026
Time: 7:00 am Pacific Time
Location: Zoom Teleconference
Institution: Saint John's Cancer Institute, Santa Monica, CA
Principal Investigator: Jennifer Linehan, MD
Protocol: ██████████ ResQ132EX-NMIBC
NCT Number: NCT06810141
Meeting Type: Initial Review of Protocol and Site
Title: Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Non-muscle Invasive Bladder Cancer

1. Call to order:

The Meeting was called to order at 7:01 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 the Principal Investigator, seven 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 rMBCG since it consists of an attenuated mycobacterium administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of rMBCG 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.

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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 Virex TB Ready-to-Use or bleach be used to decontaminate the toilet with a 15-minute dwell time and that Biosafety SOP Section 3.5.1 be revised accordingly.
2. The Committee recommended that subjects remain in the clinic for the recommended 2-hour retention time and not be discharged prior to removal of the study agent from the bladder, and that Biosafety SOP Section 3.5.1 be revised accordingly. The Principal Investigator confirmed that this is acceptable.
3. The Committee recommended that a photo of the interior of the biohazardous waste storage area be provided to IBC Services.
4. The Committee recommended that the Institution confirm that reusable eye protection can be disinfected with the disinfectants listed in the site documents.
5. The Committee noted that Shipping Training Certification will expire in April 2026 and recommended that an updated certificate be provided to IBC Services once the training is renewed.
6. An Institutional Representative confirmed that the storage unit will be labeled with a biohazard symbol once the study agent is on-site.

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 7:18 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 3.0, dated 02-12-2025

Investigator's Brochure, Version 1.0, dated 02-19-2025

Pharmacy Manual, Version 1, dated 02-11-2025

TICE BCG Package Insert, dated 08-2022

Biological Risk Assessment and Summary, dated 07-21-2025

Site Map, Cancer Center Clinic, Infusion Center, Basement, dated 02-25-2026

Site Map, Main Pharmacy, Vaccine Rm, BHW, Basement, dated 02-25-2026

Site Map, Satellite Pharmacy, 3rd Floor, dated 02-13-2026

Site Inspection Checklist, expires 08-06-2026, updated 02-24-2026

Photos, dated 02-16-2026

Biohazard Sign, rMBCG, dated 02-24-2026

Biological Safety Cabinet Certification, dated 12-02-2025

SOP, Biosafety for rMBCG, dated 02-24-2026

Training, Shipping Certification, expires 04-16-2026

CV, Linehan, J., signed 05-14-2024