

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, August 4, 2025
Time: 3:00 pm Central Time
Location: Zoom Teleconference
Institution: The West Clinic, Germantown, TN
Principal Investigator: Bradley G. Somer, MD, MBA
Protocol: ImmunityBio, Inc., 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 3:00 pm Central 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 was one Institutional Representative 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 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.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 discussed the removal of bladder contents after subject dosing. The Committee noted that sponsor documents indicate that “voided urine should be disinfected for 15 minutes with an equal volume of household bleach before flushing.” The Committee noted that it would be difficult to calculate the volume of urine in order to determine how much bleach to add.
2. The Committee found the institution’s plan for draining contents of the subject’s bladder via catheter into a container containing 8 mL of household bleach to be acceptable. The Committee recommended that Biosafety SOP, Section 3.5.1 be revised by removing “Alternatively, the subject will void into a toilet ...”.
3. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to indicate that in the event of an eye exposure, an exposed person will be escorted to the closest plumbed eyewash and that the affected eye should be rinsed for up to 15 minutes.
4. The Institutional Representative confirmed that the study agent will be stored in a refrigerator, as shown in site photos. The Committee recommended that the site photos (slide 3) be revised to indicate that what is shown is a storage refrigerator, not freezer.
5. The Committee noted that IATA/Shipping training for a staff member expires on August 9, 2025 and recommended that the training be completed prior to the expiration date and that the new certification be provided to IBC Services.
6. The Institutional Representative confirmed that the Biological Safety Cabinets (BSCs) used for study agent preparation are recertified semi-annually and were recently re-certified in June 2025. The Committee recommended that the BSC certifications be provided to IBC Services when available.
7. The Committee recommended that prefilled disposable eyewash bottles be made available in the preparation room and that Site Inspection Checklist (#22) be revised to indicate this.

11. Site requirements:

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

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 3:18 pm Central 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, dated 07-31-2025

Site Inspection Checklist, expires 10-04-2026, updated 07-30-2025

Photos, dated 07-31-2025

Biohazard Sign, rMBCG, dated 07-29-2025

Biological Safety Cabinet Certifications, dated 12-06-2024

SOP, Biosafety for rMBCG, dated 07-31-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Training, Shipping Certification, expires 08-09-2025
CV, Somer, B, signed 05-20-2025