INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, September 5, 2025**
Time:	1:00 pm Atlantic Time
Location:	Zoom Teleconference
Institution:	Nova Scotia Health Authority, Halifax, NS
Principal Investigator:	**Ricardo Rendon, MSc, MD, FRCSC**
Protocol:	EnGene, Inc., **EG-70-101**
NCT Number:	NCT04752722
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 1/2 Study of EG-70 as an Intravesical Administration to Patients with BCG-Unresponsive NMIBC and High-Risk NMIBC Patients who are BCG Naïve or Received Incomplete BCG Treatment

1. Call to order:

The Meeting was called to order at 1:00 pm Atlantic 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. 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-1 containment (Containment Level 1) facilities and practices plus Standard Precautions** are required for EG-70 since it consists of a plasmid complexed with polymers and dosed via intravesical installation. 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 EG-70 locally**, provided that all other criteria for study closure are 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

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 Institutional Representative confirmed that the study agent storage freezer in the preparation/dosing room does not lock but is located in a locked room with limited access.
2. The Institutional Representative confirmed Pharmacy staff will not prepare the study agent in a Biological Safety Cabinet as previously approved and preparation of the study agent occurs on a countertop in the same room where dosing occurs. The Committee found this arrangement acceptable since the study agent is considered to be a lower risk agent.
3. The Institutional Representative confirmed that either a safety needle or closed system transfer device (CSTD) will be used to prepare the study agent. The Committee recommended that Biosafety SOP Section 3.3 be revised to include the option of using a CSTD.
4. The Committee noted there is a possibility that anaphylaxis could occur in the event a study staff member comes into inadvertent contact with the study agent during preparation or dosing. The Institutional Representative confirmed that anaphylaxis treatment is available in the inpatient unit located down the hall from study agent handling area.
5. The Chair explained the IBC oversight closure process and noted that IBC Services will work with the Institution on completing documentation at the conclusion of the 3 month IBC oversight period (3 months after the last subject's last dose at the Institution).

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 1:17 pm Atlantic Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 7.0, Amendment 6, dated 10-16-2024
Investigator's Brochure, Edition 6.0, dated 12-11-2024
Pharmacy Manual, Version 10.0, dated 12-06-2024
Research Modification Evaluation, Protocol, Version 7.0, Amendment 6
Research Modification Evaluation, Investigator's Brochure, Edition 6.0
Research Modification Evaluation, Pharmacy Manual, Version 8.0
Research Modification Evaluation, Pharmacy Manual, Version 9.0
Research Modification Evaluation, Pharmacy Manual, Version 10.0
Biological Risk Assessment and Summary, updated 01-16-2025
Research Modification Evaluation, Site Changes, dated 07-31-2024
Research Modification Evaluation, Additional Dosing Room, dated 08-19-2025
Site Map, 5th floor Victoria, dated 08-15-2025
Site Map, Waste Storage, dated 07-31-2024
Site Inspection Checklist, expires 06-04-2026, updated 08-19-2025
Photos, dated 08-26-2025
Biohazard Sign EG-70, dated 07-18-2024
SOP Biosafety for EG-70, dated 08-18-2025

Training, Shipping Certification, expires 04-30-2026
CRRF, dated 04-02-2025
Prior Meeting Minutes, Initial, dated 07-08-2024