

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, August 11, 2026
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: McGill University Health Centre, Montreal, Quebec
Principal Investigator: Wassim Kassouf, MD, CM, 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 Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four members were present, including one local member unaffiliated with the institution. Also present were two 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 noted changes since the last review.

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

The Committee previously determined that **BSL-1 containment facilities and practices plus Standard Precautions (Containment Level 1 with Routine Practices)** 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

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices. The Committee had no questions or concerns regarding these.

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 1:06 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 8.2, dated 03-27-2026

Protocol Clarification Letter, dated 03-04-2026

Investigator's Brochure, Edition 7.0, dated 12-22-2025

Pharmacy Manual, Version 11.1, dated 10-31-2025

Research Modification Evaluation, Protocol, Version 8.0

Research Modification Evaluation, Protocol, Version 8.1

Research Modification Evaluation, Protocol, Version 8.2

Research Modification Evaluation, Protocol Clarification Letter, dated 03-04-2026

Research Modification Evaluation, Protocol Clarification Letter, dated 05-09-2025

Research Modification Evaluation, Protocol Clarification Letter, dated 03-27-2025

Research Modification Evaluation, Protocol Clarification Letter, dated 12-23-2024

Research Modification Evaluation, Investigator's Brochure, Edition 7.0

Research Modification Evaluation, Pharmacy Manual, Version 11.1

Research Modification Evaluation, Sponsor Letter to Investigators, dated 12-26-2024

Research Modification Evaluation, Sponsor Letter to Investigators, dated 12-12-2024

Research Modification Evaluation, Sponsor Note to File, dated 04-04-2025

Biological Risk Assessment and Summary, updated 05-05-2026

Site Map, 4th floor C04.35, dated 03-16-2026

Site Map, Central Pharmacy, dated 05-05-2026

Site Map, Onc. Pharm., Clean Rm, D01.6335.2, dated 04-29-2026

Site Map, Biohazardous Waste Storage, dated 03-16-2026

Site Inspection Checklist, McGill University Health Centre, expires 07-24-2028

Photos, 4th floor C04.35 and Waste, dated 05-05-2026

Photos, Central Pharmacy, B01.8004.1, dated 05-04-2026

Photos, Oncology Pharmacy, D01.6335.1 & 2, Clean, dated 05-01-2026

Biohazard Sign, Administration CIM, dated 07-28-2026

Biohazard Sign, Prep. Pharmacy, dated 07-28-2026

Biological Safety Cabinet Certifications (4) Room 6335.2, dated 02-26-2026

SOP, Biosafety for EG-70, dated 07-09-2026

Training, Shipping Certifications, EG-70, expires 09-24-2027, 07-14-2027

CRRF, dated 05-12-2026

Prior Meeting Minutes, Continuing, dated 08-29-2025