

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, March 3, 2026
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Corewell Health, Grand Rapids, MI
Principal Investigator: Conrad Tobert, MD
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 10:10 Eastern 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 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** 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

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 recommended that the Institution confirm if the entrance to the 1B182 biohazardous waste storage area has been labeled with a biohazard symbol.
2. The Committee noted that the plumbed eyewash station in room 1181 of Butterworth Hospital appears to be installed backwards and recommended that the Institution confirm that it swings into the middle of the sink and works properly.
3. The Committee noted that the Shipping Training Certifications will expire in March and May of this year and recommended that newer Certifications be submitted to IBC Services upon completion of retraining.
4. The Institutional Representative confirmed that the plumbed eyewash is flushed weekly. The Committee recommended that a blank plumbed eyewash flush form be submitted to IBC Services and that the Photos document be updated with this form (to be used as an example that the Institution flushes plumbed eyewashes on a regular basis).

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 10:19 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 8.1, dated 12-23-2025

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, Sponsor Note to File, dated 04-04-2025

Research Modification Evaluation, Protocol, Version 8.1

Research Modification Evaluation, Investigator's Brochure, Edition 7.0

Research Modification Evaluation, Pharmacy Manual, Version 11.1

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

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

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

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

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

Biological Risk Assessment and Summary, updated 01-08-2026

Site Map, Blodgett Hospital, 1st Floor, dated 09-20-2024

Site Map, Butterworth Hospital, IDS Pharmacy, dated 11-19-2025

Site Inspection Checklist, expires 01-09-2027, updated 02-17-2026

Photos, Blodgett Hospital, dated 05-27-2025

Photos, BW Hospital, IDS Pharmacy, dated 11-19-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Biohazard Sign, EG-70, dated 04-03-2023

Biological Safety Cabinet Certification, Butterworth ChemoSuite, expires 07-2026

SOP, Biosafety for EG-70, dated 03-05-2025

Training Shipping Certifications, expire 2026

CRRF, dated 12-09-2025

Prior Meeting Minutes, Continuing, dated 03-20-2025