

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, October 27, 2025
Time: 10:00 am Central Time
Location: Zoom Teleconference
Institution: Houston Metro Urology, Houston, TX
Principal Investigator: Francisco Gelpi-Hammerschmidt, MD, MPH
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 10:05 am 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 two local members 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 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 EG70 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.

Points of Discussion:

1. The Institutional Representative confirmed that either a safety needle or a venting needle may be used for study agent preparation depending on availability of needles. The Committee recommended that Biosafety SOP Section 3.3 be revised to state that "An appropriate volume of water will be added to the study agent vial using either a safety needle or a venting needle."
2. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to indicate that the affected eye will be rinsed for up to 15 minutes in the event of an exposure.
3. The Institutional Representative confirmed that both main phone numbers listed on the Biohazard Sign are monitored 24/7. The Committee recommended that the sign be revised to reflect this.
4. The Committee recommended that the Biohazard Sign be revised to indicate that booties are required to be worn during spill clean-up.
5. The Committee recommended that the Site Map be updated to reflect the location of the bathroom that will be used for post-dosing voiding.

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 10:17 am Central Time.