

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, October 17, 2025
Time: 12:00 pm Central Time
Location: Zoom Teleconference
Institution: Urology Austin, PLLC, Austin, TX
Principal Investigator: Brian Mazzearella, 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 12:23 pm Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members 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: 5 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 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: 5 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 Biosafety SOP Section 5.2.4 be revised to indicate that the affected eye is rinsed thoroughly (e.g. 15 minutes).
2. An Institutional Representative confirmed that plumbed eyewash stations are available at both locations (one not shown on a Site Map as it is located in another clinical area on the same floor).
3. An Institutional Representative confirmed that the four large prefilled disposable eyewash bottles available at both locations for immediate flushing contain enough fluid to get the affected individual to the closest plumbed eyewash station.
4. An Institutional Representative confirmed that bladder contents are drained into a leak-proof plastic urine bag, which is double-bagged in biohazard waste bags and placed inside a hard-sided container. This double-bagged urine bag is then placed into a third biohazard bag within a cardboard container for pickup by a commercial biohazard waste hauler.
5. An Institutional Representative confirmed that the study agent-specific Biohazard Sign is posted as required during study agent handling.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:28 pm Central Time.