

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, April 20, 2026  
**Time:** 3:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Ochsner Clinic Foundation, New Orleans, LA  
**Principal Investigator:** Kyle M. Rose, MD, MS  
**Protocol:** CG Oncology, Inc., CORE-008  
**NCT Number:** NCT06567743  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A phase 2, multi-arm, multi-cohort, open-label study to evaluate the safety and efficacy of Cretostimogene Grenadenorepvec in participants with high-risk Non-Muscle-Invasive Bladder Cancer (NMIBC)

### 1. Call to order:

The Meeting was called to order at 2:01 pm Eastern 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 four 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 noted changes since the last review.

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for CG0070, since it consists of a replication-competent oncolytic adenovirus administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **6 months after the last subject's last dose of CG0070 locally**, provided that other biosafety criteria for study closure are also 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

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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 Committee noted the Continuing Review Report Form (CRRF) was marked as “Yes” to a deviation/RRI. An Institutional Representative confirmed that there have been no deviations or research related incidents.
2. The Committee noted that an eyewash sign is posted on the door to the urology clinic and recommended that a sign also be posted on the wall above the plumbed eyewash station, and that a new photo be provided to IBC Services.
3. An Institutional Representative confirmed that the urology clinic soiled utility room is exclusively used for biohazardous waste storage. The Committee recommended that a red biohazard symbol be placed on the entrance door to this room and that a new photo be provided to IBC Services.
4. The Committee noted that the Biological Safety Cabinet (BSC) is due for recertification by June 2026.

### **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 2:25 pm Eastern Time.

### **15. Post-meeting notes:** None.

#### **Documents reviewed:**

Agenda

Protocol, Amendment 1, dated 01-23-2025

Investigator's Brochure, Version 8, dated 03-06-2025

Pharmacy Manual, Version 2.0, dated 04-02-2025

Instillation Manual, Version 8.0, dated 10-08-2025

Intravesical Instillation Preparation Worksheet, Version 8, dated 08-05-2024

Research Modification Evaluation, Protocol, Amendment 1

Research Modification Evaluation, Investigator's Brochure, Version 8

Research Modification Evaluation, Pharmacy Manual, Version 2.0

Research Modification Evaluation, Instillation Manual, Version 8.0

Research Modification Evaluation, Instillation Manual, Version 7

Biological Risk Assessment and Summary, updated 12-19-2025

Site Map, 2nd floor, BCC, Urology Clinic, dated 03-20-2025

Site Map, 5th floor, BCC, Pharmacy, dated 05-27-2025

Site Inspection Checklist, expires 01-09-2027, updated 02-26-2026

Photos, 2nd floor, BCC, Urology Clinic, dated 03-27-2026

Photos, 5th floor, BCC, Pharmacy, dated 05-27-2025

Biohazard Sign, Cretostimogene, dated 03-10-2026

Biological Safety Cabinet Certification, Vector room, dated 12-20-2025

SOP Biosafety for Cretostimogene, dated 03-10-2026

Training, Shipping Certification, expires 01-15-2027

CRRF, dated 12-18-2025

Prior Meeting Minutes, Initial, dated 03-14-2025