Meeting Minutes

Institution:	Urological Specialists of Oklahoma - Tulsa
Meeting Date:	October 8, 2026
Meeting Time	10:30 AM Central Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Fakhr, Mohamed	Yes	Local Unaffiliated Member
Hood, Amber	Yes	Local Unaffiliated Member

Invited Members Not in Attendance:

Member	Voting	Member Type
Puckett, Ciara	No	Site Contact

Guests:	Bowers, Donna (Site Representative) Long, DeeAnn Sommers, Felicia Williams, Liliokalani
Staff:	Payne, Kaylie

Call to Order: The IBC Chair called the meeting to order at 10:30 AM. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Meeting Minutes

Review of Prior Business: None

Previous Meeting Minutes: None

New Business:

PI:	Forrest, John MD
Sponsor:	CG Oncology, Inc
Protocol:	CRETO-EAP An Expanded Access Program of Cretostimogene Grenadenorepvec in Participants with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: CRETO-EAP is an open-label, expanded access trial (EAP) sponsored by CG Oncology, Inc. and designed to provide access to cretostimogene grenadenorepvec, a recombinant, conditionally replicating oncolytic adenovirus, in patients with non-muscle invasive bladder cancer (NMIBC) unresponsive to BCG. The investigational product (IP) is administered by intravesical instillation.

Biosafety Containment Level (BSL): The study agent cretostimogene is based on a recombinant Risk Group 2 virus containing more than two-thirds of the native genome, requiring the use of BSL-2 containment under the *NIH Guidelines.*

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).
    - The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
    - The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
    - The Site confirmed that staff members receive Bloodborne Pathogens training.
    - Occupational Health Recommendations: The Sponsor notes that individuals who are at a potentially higher risk from working with or handling the study agent, such as pregnant or breastfeeding women and immunosuppressed or immunocompromised individuals, should not prepare, administer, or otherwise handle the study agent or materials contaminated with the study agent or provide direct care for treated participants presenting with any symptoms of illness attributed to cretostimogene for at least 1 week after treatment or until complete resolution of symptoms.
    - The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site noted that the Site Map provided may be outdated and they will update as needed. The Site indicated that there is only 1 plumbed eyewash at each Nurse's station. The Site Map will be administratively updated.

- The Site indicated that they would like to use different administration rooms and waiting rooms than what was reviewed at this IBC meeting. The Site described the rooms, and the Chair reminded the Site that the administration rooms being reviewed at the meeting today are what will be approved for Administration and new locations will need to be submitted as a Change in Research for review by the IBC before they can be used.
- The Site confirmed that the participant will void in a nearby restroom. The restroom will be disinfected prior to opening back up to the public.
- The Site confirmed that they will prepare the study agent as needed and will not require refrigerated storage.
- The Committee recommended that the Site either laminate the biohazard sign on the IP storage freezer or place it in a plastic sleeve so that it is waterproof and easily cleanable.
- The Committee recommended moving the eyewash placard to a more visible location.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 11:10 AM

Post-Meeting Pre-Approval Note: None