Meeting Minutes

Institution:	Urological Specialists of Oklahoma - Tulsa
Meeting Date:	October 27, 2026
Meeting Time	3:00 PM 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
Reed, Craig	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Fakhr, Mohammed	Yes	Local Unaffiliated Member
Hood, Amber	Yes	Local Unaffiliated Member

Invited Members Not in Attendance:

Member	Voting	Member Type
Sommers, Felicia	No	Site Contact

Guests:	Bowers, Donna Long, DeeAnn Puckett, Ciara
Staff:	Payne, Kaylie Haller, Isaiah

Call to Order: The IBC Chair called the meeting to order at 3:00 PM. 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: Minutes from 10-8-26 were approved by the IBC with no changes. There were no votes against and no abstentions.

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:	Change in Research 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, and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information provided by the Chair was accurate.

- The Chair discussed the Change in Research to update the preparation, administration and waiting rooms.
- The Site confirmed that the two waiting rooms will not be used as administration rooms. The Site also confirmed that if there are no other participants scheduled to come in, the participant may stay in the Administration Room for the dwell period and would not need to be moved to the waiting room.
- The Site confirmed that the grey chairs in the dwell waiting rooms are made of vinyl.

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 3:25 PM

Post-Meeting Pre-Approval Note: None