

## Meeting Minutes

<b>Meeting Date:</b>	July 29, 2025 at 9:30 AM Pacific Time	
<b>Meeting Place:</b>	Teleconference (Remote) Open to the public	
<b>Members in Attendance:</b>	Hauke, Caitlyn	
	Reed, Craig	
	Rastein, Daniel	
	Lally, Rebecca	
	De Zoysa, Prashan	
	Larson, Krista	
<b>Members Not in Attendance:</b>	Stover, Alexander (BSO)	
<b>Guests:</b>	Fernandez, Nubia (joined at 9:51AM)	
<b>Staff:</b>	Hemmelgarn, Marian	
<b>Institution:</b>	Children's Hospital of Orange County (CHOC)	

**Call to Order:** The meeting was called to order at 9:32 AM PT. A quorum was present.

**Conflicts of Interest:** None declared by voting members of the IBC.

**Meeting Minutes:** Previous meeting minutes were reviewed and approved with no requested changes.

### New Business:

<b>PI:</b>	Al-Hertani, Walla MD, MSc, FRCPC, FCCMG, FACMG
<b>Sponsor:</b>	Beam Therapeutics Inc.
<b>Protocol:</b>	BTX-301-001
	A Phase 1/2, Dose-Exploration Study to Evaluate the Safety and Efficacy of BEAM-301 in Patients with Glycogen Storage Disease Type Ia (GSDIa) Homozygous or Compound Heterozygous for the G6PC1 c.247C>T (p.R83C) Variant
<b>Review Type:</b>	Annual Review
<b>NIH Guidelines:</b>	III-C

**Trial Summary:** BTX-301-001 is an open-label, single-ascending-dose, Phase I/II study sponsored by Beam Therapeutics Inc. and designed to evaluate the safety and efficacy of BEAM-301, REDACTED.

Biosafety Containment Level per Risk Assessment: BSL-1 plus Standard Precautions

### Comments:

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- The Committee reviewed the Sponsor’s study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules (“investigational product [IP]”) and the proposed clinical research involving the IP.
  - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.
  
- The Committee reviewed the Site’s facility details, study-specific procedures and practices, training records, Annual Review Report, 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 Committee recommended that the Site add a Biohazard label to the BSCs and provide an updated photo.
  - In response to a question from the Committee, the Site confirmed that all sinks have paper towels available.
  - In response to a question from the Committee, the Site confirmed that eyewash signs are present above eyewashes in the 4th floor Inpatient Unit and the preparation area, and the Site will provide updated photos with eyewash signage in view. The Committee stipulated that the Site provide updated photos of the plumbed eyewashes in the 4th floor Inpatient Unit and the preparation area with eyewash signage by October 31.
  - The Committee noted that, for the BSC Certifications, the Field Certifier noted "N/T-not tested" for exhaust because a port was not readily available for the sampling probe. This test is important to ensure appropriate HEPA filtration of air exhausted into the environment via the hard ducting through the roof. The Field Certifier could drill a hole in the hard duct downstream of the exhaust HEPA filter for sampling access, which would be sealable after testing the exhaust HEPA. The exhaust HEPA testing is required by NSF49 and manufacturer’s standards. The appropriate means for installing a sampling port and testing/challenging of the exhaust HEPA filters was provided on the 3rd page of each II/B2 report under subsection labeled "Exhaust Filter". The Committee stipulated that the Site communicate with the Certifier to ensure the HEPA exhaust filter is certified to NSF49 and manufacturer’s standards and provide an updated report with this information for the next testing period by October 31.

**Motion:** A motion of Approval with Stipulations for the study at BSL-1 plus Standard Precautions was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None
  
- Stipulations stated by the Committee:
  - The Committee stipulated that the Site provide updated photos of the plumbed eyewashes in the 4th floor Inpatient Unit and the preparation area with eyewash signage

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- by 10/31/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
- The Committee stipulated that the Site communicate with the BSC Certifier to ensure the HEPA exhaust filter is certified to NSF49 and manufacturer's standards and provide an updated report with this information for the next testing period by 10/31/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

### **Reminder of IBC Approval Requirements.**

**Adjournment:** 10:03AM PT

**Post-Meeting Pre-Approval Note:** None