# Meeting Minutes

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| **Institution:** | Children's Hospital of Orange County (CHOC) |
| **Meeting Date:** | June 10, 2026 |
| **Meeting Time** | 10:30 AM Pacific Time |
| **Meeting Type:** | Virtual Platform Teleconference (Remote)<br>Open to the Public |

**Members in Attendance:**

| Member | Voting | Member Type |
|---|---|---|
| Bavaret, Tammy | Yes | Chair: Biosafety Expert/HGT Expert |
| Rastein, Daniel | Yes | Core Member: Biosafety Expert/HGT Expert |
| Wang, Anthony | Yes | Core Member: Biosafety Expert/HGT Expert |
| De Zoysa, Prashan | Yes | Local Unaffiliated Member |
| Lally, Rebecca | Yes | Local Unaffiliated Member |
| Larson, Krista | No | Site Contact |
| Stover, Alexander | Yes | Biological Safety Officer |

**Invited Members Not in Attendance:**

| Member | Voting | Member Type |
|---|---|---|
| None | | |

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| **Guests**: | Movsesyan, Nina<br>Stockton, Winnie<br>Becerra, Julia |
| **Staff:** | Hemmelgarn, Marian |

**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.

**Review of Prior Business:** None

**Previous Meeting Minutes**: Minutes from 1/15/26 were approved by the IBC with no changes**.**

**New Business:**

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| **PI:** | Al-Hertani, Walla MD, MSc, FRCPC, FCCMG, FACMG |
| **Sponsor:** | Beam Therapeutics Inc. |
| **Protocol:** | BTX-301-001<br>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 |
| **Review Type:** | Annual Review |
| **NIH Guidelines Section:** | III-C-1 |

**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, a lipid nanoparticle encapsulating a messenger RNA encoding an adenine base editor and guide RNA targeting a pathogenic allele variant of G6PC1, in participants with Glycogen storage disease type Ia (GSDIa) homozygous or compound heterozygous for the p.R83C variant. The investigational product (IP) is administered by intravenous infusion.

**Biosafety Containment Level (BSL):** Because the study agent consists of synthetic mRNA incapable of replication and does not encode for known hazardous transgenes, BSL-1 containment may be considered as the minimum biocontainment level. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

**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, splashes, and needlestick of the IP during preparation and/or administration procedures. 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: None
- 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 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 Site confirmed the accuracy of the Annual Review Report.
  - In response to a question from the Site regarding removal of Personal Protective Equipment (PPE), the Committee indicated that once agent administration is complete, staff can remove any agent specific required PPE that is additional to the clinic specific PPE.
  - The Committee reminded the Site to ensure that biohazard waste containers have red liners, and waste goes completely inside the receptacle. The Site confirmed they follow this practice.
  - The Committee reminded the Site that bloodborne pathogens (BBP) training will be due for recertification in the coming month.
  - The Committee discussed a photo of a biohazard waste storage room included on both the 4$^{th}$ floor and 6$^{th}$ floor slides and recommended the correct location of the photo be confirmed and the duplicate removed.
  - In response to a question from the Site regarding PPE between different studies, the Committee noted that required PPE is based on the biosafety level of the study agent and is listed on the Biohazard Sign.

**Motion:** A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by majority vote.

- 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 11:07 AM

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