

Meeting Minutes



Institution:	Case Western Reserve University		
Meeting Date:	October 07, 2026		
Meeting Time	3:00 PM Eastern 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
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Wilson, LaKetta	Yes	Local Unaffiliated Member
	Yun, Yang	Yes	Local Unaffiliated Member
	Karlo, Colleen	Yes	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Young, Andrew	Yes	Biological Safety Officer
	Tepfenhart, Benjamin	Yes	Site Contact
Guests:	Tokach, Nicholas		
Staff:	Smith, Jennifer; Shields, Justin		

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.

Review of Prior Business: None

Meeting Minutes



Previous Meeting Minutes: Minutes from 7/6/26 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Konczal, Laura
Sponsor:	Beam Therapeutics Inc.
Protocol:	BTX-304-001 A Master Protocol for a Phase 1/2 Study to Evaluate the Safety and Efficacy of BEAM-304 Drug Products in Patients with Phenylketonuria (PKU) Having Specific Homozygous or Compound Heterozygous Mutations
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: BTX-304-001 is a Phase I/II master protocol sponsored by Beam Therapeutics Inc. and designed to evaluate the safety, tolerability, and efficacy of BEAM-304 in participants [REDACTED] [REDACTED] with phenylketonuria (PKU). BEAM-304 is a proprietary gene editing platform consisting of a lipid nanoparticle [REDACTED] [REDACTED]. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent BEAM-304 consists of a synthetic nucleic acid-LNP formulation equivalent in risk to a Risk Group 1 agent (i.e., not associated with disease in healthy adults), thus NIH Guidelines recommends a minimum Biosafety Level 1 containment. Handling of the study agent in the 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 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).

Meeting Minutes

- 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 PI's credentials, 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 reminded the Site that the Exhaust Alarm Verification test had not been completed in the current BSC certification report, though it should be tested in accordance with applicable NSF testing standards. The Committee recommended that the Site ensure that the Exhaust Alarm Verification test is performed during the next BSC certification.
 - The Site confirmed that the windows in the administration rooms cannot be opened.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions 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 3:22 PM.

Post-Meeting Pre-Approval Note: None