Meeting Minutes

Institution:	Dignity Health d.b.a. as St. Joseph's Hospital and Medical Center HGT
Meeting Date:	March 12, 2026
Meeting Time	9:00 AM Mountain Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Bavaret, Tammy / Yes / Chair: Biosafety Expert/HGT Expert Ellis, Robert / Yes / Core Member: Biosafety Expert/HGT Expert Gamble, Rachel / Yes / Local Unaffiliated Member Sefidvash-Hockley, Sepideh / Yes / Local Unaffiliated Member Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Turcotte, Nicole / No / Site Contact
Invited Members Not in Attendance:	**Member** / **Voting** / **Member Type**
Guests:	Burmeister, Jeff
Staff:	McFarland, Christine

Call to Order: The IBC Chair called the meeting to order at 9:00 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: Minutes from 12/2/25 were approved by the IBC with one requested change, i.e. to correct the spelling of one Committee member's name. There were 0 votes against and 0 abstentions.

New Business:

PI:	Ladha, Shafeeq M.D.
Sponsor:	Asklepios BioPharmaceutical, Inc (AskBio)
Protocol:	ASK-POM9-CS101: A single-arm, open-label, dose-escalation study to evaluate the safety, tolerability and efficacy of a single intravenous infusion of AB-1009 in adult participants with late onset Pompe disease (LOPD)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: ASK-POM9-CS101 is an open-label, single-arm, phase I/II study sponsored by AskBio Inc. and designed to assess the safety, tolerability, and preliminary efficacy of AB-1009 in adult participants with late-onset Pompe disease (LOPD). AB-1009 is a recombinant, replication-defective adeno-associated virus (AAV) expressing human acid α-glucosidase, an enzyme deficient in individuals with Pompe disease. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent AB-1009 consists of an AAV vector that does not express a hazardous transgene, is produced in the absence of a helper virus and therefore is considered a Risk Group 1 (RG1) agent defined by the *NIH Guidelines.* As such, Biosafety Level 1 (BSL-1) may be considered as the minimum containment level for handling the study agent. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard

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: 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 overview of the Site's arrangements and activities with the study agent provided by the Chair was accurate.
  - In response to a question from the Committee, the Site confirmed that the blue sharps and blue biohazard waste containers shown in photographs will be used for this study to segregate the collection of used sharps and non-sharps waste, before they are transported to the biohazard waste storage area for vendor pickup. The Committee had no further concerns.
  - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the request of the Site, the Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote. There were 0 votes against and 0 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 9:35 AM Mountain Time.

Post-Meeting Pre-Approval Note: None