Meeting Minutes

Institution:	**Dignity Health d.b.a. as St. Joseph's Hospital and Medical Center HGT**
Meeting Date:	December 2, 2025
Meeting Time	12:00 PM 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 Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Sefidvash-Hockley, Sepideh / Yes / Local Unaffiliated Member Stevenson, Karen / Yes / Local Unaffiliated Member Turcotte, Nicole / No / Site Contact Goboly, Lindsay / No / Site Contact
Invited Members Not in Attendance:	**Member** / **Voting** / **Member Type** Wang, Anthony / Yes / Core Member: Biosafety Expert/HGT Expert
Guests:	Burmeister, Jeff and Brenner, Adam
Staff:	McFarland, Christine

Call to Order: The IBC Chair called the meeting to order at 12:03 PM MT. 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.

Meeting Minutes

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 12/19/24 were approved by the IBC with no changes.

New Business:

PI:	Ladha, Shafeeq, M.D.
Sponsor:	uniQure biopharma B.V.
Protocol:	AMT-162-001: A Phase 1/2, Multi-Center, Single Ascending Dose Study to Evaluate the Safety, Tolerability, and Exploratory Efficacy of Intrathecally Administered Gene Therapy AMT-162 in Adult Participants with *SOD1* Amyotrophic Lateral Sclerosis (*SOD1*-ALS).
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: AMT-162-001 (EPISOD1) is a Phase 1/2 clinical trial sponsored by uniQure biopharma B.V. designed to assess the safety, tolerability, and efficacy of AMT-162, a recombinant adeno-associated virus (AAVrh10) genetically modified to express a silencing artificial micro-RNA targeting superoxide dismutase 1 (*SOD1*), in participants with amyotrophic lateral sclerosis (ALS) with *SOD1* pathogenic variations. The investigational product (IP) is administered along the spinal cord as a single intrathecal infusion.

Biosafety Containment Level (BSL): The study agent is based on a replication-defective, recombinant Risk Group 1 AAV virus. Therefore, Biosafety Level 1 containment is recommended under NIH Guidelines II-A-3. The administration of this agent in a clinical setting further requires compliance with OSHA Bloodborne Pathogens Standard precautions.

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/IP) 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 Annual Review Report, and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information they provided in the Annual Review Report form remains accurate.
    - The Site confirmed the arrangements and activities at the Site, as described by the Chair, are accurate.
    - The Committee noted the black and white biohazard sticker placed on the biosafety cabinet and recommended that a red/orange sticker be used instead, in keeping with OSHA BBP Standard requirements. The Site stated that they can replace the sticker with a colored one and send an updated photo. The Committee had no additional concerns.
    - During the initial review of this study, the Committee discussed the transmission risks associated with study agent preparation activities and the comprehensive mitigation strategies in place relating to the Site's work practices and engineering controls and noted that these practices cumulatively aligned more closely with a containment level of BSL-2, rather than BSL-1. The Site previously stated and reaffirmed today that their institutional practices, including the use of a BSC, additional PPE, and a negatively pressurized room for preparation, align with BSL-2 practices, so setting containment at BSL-2 would not present any issues or concerns. Therefore, the Committee agreed to continue setting containment for the Site at BSL-2 to align with Site arrangements and practices.

Motion: A motion of Full Approval for the Site 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 12:38 PM MT.

Post-Meeting Pre-Approval Note: None