Meeting Minutes

Institution:	Dignity Health d.b.a. as St. Joseph's Hospital and Medical Center HGT
Meeting Date:	May 13, 2026
Meeting Time	11:00 AM Mountain Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Noriea, Nicholas / Yes / Chair: Biosafety Expert/HGT Expert Campbell, Mark / 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 Goboly, Lindsey / No / Site Contact
Invited Members Not in Attendance:	**Member** **Voting** **Member Type**
Guests:	Stetson, Amanda; Brenner, Adam; Ladha, Shafeeq MD
Staff:	McFarland, Christine

Call to Order: The IBC Chair called the meeting to order at 11:01 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 requests to attend the meeting were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 3-12-26 were approved by the IBC with no changes. There were 0 votes against and 0 abstentions.

New Business:

PI:	Ladha, Shafeeq MD
Sponsor:	Insmed Gene Therapy LLC
Protocol:	INS1202-101: A Phase 1, Multicenter, Open-label, Dose-Finding Study to Investigate the Safety and Pharmacodynamics of a Single Intrathecal Injection of INS1202 in Patients with Amyotrophic Lateral Sclerosis
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: INS1202-101 is a first-in-human, Phase 1, multicenter, open-label, dose-escalation clinical trial sponsored by Insmed Gene Therapy LLC designed to evaluate the safety, tolerability, pharmacodynamics, and recommended Phase 2 dose (RP2D) of a single intrathecal (IT) administration of INS1202 in adult participants aged 18 to <80 years with amyotrophic lateral sclerosis (ALS), including both sporadic ALS (sALS) and familial ALS with confirmed SOD1 mutations. INS1202 is a self-complementary adeno-associated virus serotype 9 (scAAV9) vector encoding a short-hairpin RNA (shRNA) targeting human SOD1 mRNA. The investigational product (IP) is administered via a single intrathecal (IT) bolus injection under fluoroscopic guidance.

Biosafety Containment Level (BSL): INS1202 is classified as a Risk Group 1 agent and is suitable for handling at BSL-1 containment under the NIH Guidelines II-A-3. Administration in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 19101030.)

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 summary of the Site's arrangements and activities presented by the Chair was accurate.
    - In response to a question from the Committee, the Site confirmed that any IBC reviewed study agent prepared in the 4th floor Neuroplex Pharmacy will always be prepared within the Class II Biosafety Cabinet (BSC) in the hazardous gene therapy room shown on the Site Map and never within a laminar flow cabinet. The Committee asked that the Site Map be annotated with that information.
    - In response to a question from the Committee, the Site stated that study agent may be thawed inside a refrigerator located in the adjacent Hazardous Drug Room within the 4th floor Neuroplex Pharmacy. The Committee reminded the Site that the refrigerator used to thaw study agent should be labeled with a biohazard sticker or, alternatively, the Site may use the biohazard sign provided. The Site had no concerns with this request. The Committee asked that the Site Map and Facility details form be administratively updated to capture these additional details.
    - In response to a question from the Committee, the Site confirmed that biohazardous sharps and non-sharps wastes are segregated and collected in separate hard-walled containers.
    - In response to a question from the Committee, the Site confirmed that the blue biohazardous waste and sharps containers shown are brought into the administration rooms on the day of dosing and are not stored in these rooms.

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

New Business:

PI:	Ladha, Shafeeq MD
Sponsor:	VectorY Therapeutics B.V.
Protocol:	VTx-002-01-001: Phase 1/2 Investigation Of Novel Experimental Regimen in Amyotrophic Lateral Sclerosis (PIONEER-ALS): An Open-Label, Uncontrolled, Multicenter Study to Assess the Safety and Tolerability of Two Doses of VTx-002
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: VTx-002-01-001 (PIONEER-ALS) is an open-label, first-in-human Phase I/II trial sponsored by VectorY Therapeutics B.V. and designed to assess the safety and tolerability of VTx-002 in adult participants with Amyotrophic Lateral Sclerosis (ALS). VTx-002 is a recombinant, replication-defective adeno-associated virus (AAV) expressing an antibody binding fragment against TDP-43, a transcriptional repressor whose dysregulation is a hallmark of ALS pathology. The investigational product (IP) is administered via a single suboccipital injection into the cisterna magna (intra-cisterna magna) under CT-fluoroscopy guidance or O-arm (or equivalent) imaging.

Biosafety Containment Level (BSL): The study agent VTx-002 consists of an AAV vector that does not express a hazardous transgene and is produced in the absence of a helper virus and therefore 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 (*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).
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    - 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.
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Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions 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 11:58 PM.

Post-Meeting Pre-Approval Note: None