Meeting Minutes

Institution:	Neurology Rare Disease Center, PLLC		
Meeting Date:	February 27, 2026		
Meeting Time	9:30 AM Pacific Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	**Member**	**Voting**	**Member Type**
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Hauke, Caitlyn A.	Yes	Chair: Biosafety Expert/HGT Expert
	Naik, Veena	Yes	Local Unaffiliated Member
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Scott, Frederick	Yes	Local Unaffiliated Member
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Avelar, Jennifer	No	Site Contact - Rostered
Guests:	Gomez, Natalie		
Staff:	Mahrt, Elena		

Call to Order: The IBC Chair called the meeting to order at 9:32 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 11-03-23 were approved by the IBC with no changes.

New Business:

PI:	Castro, Diana MD
Sponsor:	Sarepta Therapeutics, Inc.
Protocol:	SRP-9001-103: An Open-Label, Systemic Gene Delivery Study Using Commercial Process Material to Evaluate the Safety of and Expression From SRP-9001 in Subjects With Duchenne Muscular Dystrophy (ENDEAVOR)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: SRP-9001-103 is a Phase Ib clinical trial study sponsored by Sarepta Therapeutics, Inc. and designed to assess the efficacy and safety of delandistrogene moxeparvovec (SRP-9001) in patients with Duchenne Muscular Dystrophy (DMD) due to loss-of-function mutations in the DMD gene. Delandistrogene moxeparvovec is a recombinant, replication-defective adeno-associated virus (AAV) vector designed to express a miniaturized version of the human DMD gene.The investigational product (IP) is administered by intravenous infusion

Biosafety Containment Level (BSL): The study agent SRP-9001 is based on a recombinant Risk Group 1 AAV virus, requiring the use of BSL-1 containment at a minimum under the *NIH Guidelines*. The administration of this agent in a clinical setting further requires compliance with OSHA Bloodborne Pathogen Standards 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/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 information provided by the Chair was accurate.
    - The Committee noted that the BBP training certificate was out of date and stipulated that an updated BBP training certificate be provided.
    - The Committee discussed the outdoor biohazard waste storage unit. The Site confirmed that access is restricted via a lock on the lid, the unit is made immovable via bolts to the ground, and a biohazard sticker had been recently applied. The Committee stipulated that an updated photo of the outdoor biohazard waste storage unit labeled with a biohazard sticker be provided.
    - During review of the Biosafety Cabinet (BSC) in the preparation room, the Committee noted a split AC unit on the wall adjacent to the BSC. The Committee discussed the biosafety best practice of minimizing air flow around BSCs and stipulated that the Site either adjust the fins on the unit to point away from the BSC or adopt the practice of turning the unit off during BSC use. The Site Checklist will be revised to reflect the practice adopted by the Site.
    - The Committee discussed the Site's current practice of disposing of sharps waste in a sharps container outside the BSC during agent preparation. The Site was encouraged by the Committee to adopt biosafety best practice of disposing of sharps in a sharps container inside the BSC. The Site confirmed they would discuss a change in their practices to follow biosafety best practice.
    - The Site confirmed that the internal transport container can be labeled with a biohazard sticker. The Committee stipulated that an updated photo of the internal transport container labeled with a biohazard sticker be provided.
    - The Site confirmed that the chair depicted in the dosing room is made of cleanable material. The Committee had no further concerns.
    - The Site confirmed that there are biohazard stickers on the red biohazard waste bins in the Pharmacy. The Committee stipulated that updated photos of the red biohazard waste bins labeled with biohazard stickers in the Procedure Room 1 and Second Floor Pharmacy be provided.
    - The Committee discussed the Site Map + Photos document and noted that a sink is depicted in photos of the second-floor infusion rooms. The Site Map + Photos document and Facility Details Form will be administratively revised to correct this clerical error. The Committee had no concerns.

Motion: A motion of Approval with Stipulations 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:
    - The Committee noted that the BBP training certificate was out of date and stipulated that an updated BBP training certificate be provided by 3/27/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee stipulated that an updated photo of the outdoor biohazard waste storage unit labeled with a biohazard sticker be provided by 3/27/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee discussed the biosafety best practice of minimizing air flow around BSCs and stipulated that the Site either adjust the fins on the unit to point away from the BSC or adopt the practice of turning the unit off during BSC use. The Site Checklist will be revised to reflect the practice adopted by the Site by 3/27/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee stipulated that an updated photo of the internal transport container labeled with a biohazard sticker be provided by 3/27/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee stipulated that updated photos of the red biohazard waste bins labeled with biohazard stickers in the Procedure Room 1 and Second Floor Pharmacy be provided by 3/27/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 10:02 AM

Post-Meeting Pre-Approval Note: During the post meeting discussion, the Chair identified that the biohazard waste bin in Procedure Room 1 did not have a biohazard sticker. The Chair requested a stipulation be made to ensure biohazard labels are on all biohazard bins and updated photos are sent from the Site.