Meeting Minutes

Institution:	The Research Institute of the McGill University Health Centre
Meeting Date:	October 23, 2025
Meeting Time	1:00 PM Eastern 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 Spinato, Joanna / Yes / Core Member: Biosafety Expert/HGT Expert Kunin, Wendy / Yes / Local Unaffiliated Member Nair, Amogh Gopinathan / Yes / Local Unaffiliated Member Vuong, Dac Hien / No / Site Contact
Invited Members Not in Attendance:	None
Guests:	Ndiaye, Mbaye
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 1:00 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

Previous Meeting Minutes: Minutes from 9/8/25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Maryam, Oskoui
Sponsor:	Sarepta Therapeutics, Inc.
Protocol:	SRP-9001-303 A Phase 3, Multinational, Randomized, Double-Blind, Placebo-Controlled Systemic Gene Transfer Therapy Study to Evaluate the Safety and Efficacy of SRP-9001 in Non-Ambulatory and Ambulatory Subjects with Duchenne Muscular Dystrophy (ENVISION)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: SRP-9001-303 is a Phase III clinical trial sponsored by Sarepta Therapeutics, Inc. and designed to assess the efficacy and safety of delandistrogene moxeparvovec (SRP-9001) in male subjects with Duchenne Muscular Dystrophy due to loss-of-function mutations in the DMD gene. SRP-9001 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 produced in the absence of helper virus. BSL-1/CL-1 is the recommended minimum containment level under the NIH Guidelines. The administration of this agent in a clinical setting further requires compliance with OSHA Bloodborne Pathogen 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 Annual Review Report, 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 Site confirmed that the location of the BSCs used for IP preparation is correctly indicated on the Site Map. However, the room number listed in the map key, the Facility Details Form, and the Pharmacy Biohazard Door sign as well as the photo of the BSC are incorrect. The Site Map, Facility Details Form, and Biohazard Door sign will be administratively updated to reflect the correct room number where BSC preparation occurs. The Committee recommended that the Site provide Sabai with an updated photo of the BSCs used for study agent preparation.
    - In response to a question from the Committee, the Site confirmed that the study agent storage room number is correct.

Motion: A motion of Full Approval for the study at CL-1+RP 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 1:35 PM

Post-Meeting Pre-Approval Note: None