

Meeting Minutes



Institution:	Arkansas Children’s Research Institute		
Meeting Date:	March 12, 2026		
Meeting Time	3:30 PM Central 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
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Steiner, Lindsey	Yes	Local Unaffiliated Member
	Hernandez, Jill	Yes	Local Unaffiliated Member
	Ono-Moore, Kikumi	No	Site Contact
Invited Members Not in Attendance:	None		
Guests:	Giompoletti, Steven; Gassaway, Jill		
Staff:	Smith, Jennifer; Parrish, Wendy		

Call to Order: The IBC Chair called the meeting to order at 3:30 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: None

New Business:

PI:	Veerapandiyan, Aravindhan
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 SRP-9001 (Delandistrogene moxeparvec), a recombinant, replication-defective adeno-associated virus (AAV) vector designed to express a miniaturized version of the human DMD gene in patients with Duchenne Muscular Dystrophy due to loss-of-function mutations in the 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, splashes, needlestick, and aerosols of the IP during preparation and/or administration procedures. 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

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- 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 discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific 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.
 - The Site confirmed that biohazardous waste containers would be brought into the room during administration and all PPE used will be disposed of in biohazardous waste.
 - The Site confirmed that they will post signage above the plumbed eyewash station in the preparation location.
 - The Site confirmed that all waste, including sharps, apart from PPE, is disposed of into the yellow chemo container inside the preparation room. The Site confirmed institutional practice is to not place a sharps container inside the BSC. The Site further clarified that PPE waste is disposed of into non-sharps red biohazardous waste bin in the ante room directly outside of the room. The Site confirmed there is hands-free access between the preparation room and ante room. The Committee recommended the Site place a sharps container in the BSC as a matter of best practice and to ensure their BSC is certified in the same configuration and equipment setup that would be used during normal operation.
 - The Site confirmed there is no carpeting and all the floors are easily cleanable.
 - The Site confirmed the room numbers on the map were accurate. The Chair noted the FDF would be revised to include the storage and preparation area room numbers.

Motion: A motion of Full Approval for the study at BSL-2 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.

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Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 4:45 PM.

Post-Meeting Pre-Approval Note: None