Meeting Minutes

Institution:	Clinical Research Prime Idaho Falls, LLC
Meeting Date:	November 13, 2025
Meeting Time	9:30 AM Mountain Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Ostrom, Lee	Yes	Local Unaffiliated Member
Andrews, Dalan	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Anderson, Curtis	Yes	Local Unaffiliated Member

Guests:	Cherukuri, Amie Taylor, Nina Waff, Hunter McLaughlin, Bennett
Staff:	Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 9:30 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

Meeting Minutes

Previous Meeting Minutes: Minutes from 6/27/25 were approved by the IBC with no changes.

New Business:

PI:	Baker, Jeffrey MD
Sponsor:	ModernaTX, Inc.
Protocol:	mRNA-1403-P301 A Phase 3, Randomized, Observer-blinded, Placebo-controlled Study to Evaluate the Safety and Efficacy of mRNA-1403, a Multivalent Candidate Vaccine to Prevent Norovirus Acute Gastroenteritis in Adults ≥18 Years of Age
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: mRNA-1403-P301 is a Phase III clinical trial sponsored by ModernaTX, Inc., and designed to evaluate the safety, efficacy, and reactogenicity of mRNA-1403, a multivalent RNA-liposome vaccine, for the prevention of Norovirus (NoV) acute gastroenteritis (AGE) in adults aged ≥18 years. The study agent, mRNA-1403, is an investigational vaccine composed of messenger RNA (mRNA) formulated in lipid nanoparticles (LNPs). The investigational product (IP) is administered by intramuscular (IM) injection.

Biosafety Containment Level (BSL): The study agent mRNA-1403 is a non-infectious synthetic mRNA that is not associated with disease in healthy adults. The mRNA is incapable of replication and does not express known hazardous transgenes. Therefore, BSL-1 containment may be considered as the minimum biocontainment level when 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, splashes, and/or needlestick 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
- 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 the accuracy of the Annual Review Report.
  - The Site confirmed that the IP Storage Room and the Lab are the same room.
  - In response to a question from the Committee, the Site indicated that the silver cylinder seen on the floor in slide 8 of the photos file is a 10kg weight for calibrating the scale.
  - 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.

Motion: A motion of Full Approval for the study at BSL-2 was passed by majority 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 9:54 AM MT.

Post-Meeting Pre-Approval Note: None