Meeting Minutes

Institution:	Case Western Reserve University
Meeting Date:	November 04, 2025
Meeting Time	9:30 AM 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
Reed, Craig	Yes	Core Member: Biosafety Expert/HGT Expert
Wilson, LaKetta	Yes	Local Unaffiliated Member
Yun, Yang	Yes	Local Unaffiliated Member
Karlo, Colleen	Yes	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Young, Andrew	Yes	Biological Safety Officer
Tepfenhart, Benjamin	Yes	Site Contact

Guests:	None
Staff:	Smith, Jennifer

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 8/11/25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Wu, Chen-Han Wilfred MD to Konczal, Laura MD
Sponsor:	ModernaTX, Inc.
Protocol:	mRNA-3705-P101 A Global, Phase 1/2 Study to Evaluate the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of mRNA-3705 in Participants with Isolated Methylmalonic Acidemia Due to Methylmalonyl-CoA Mutase Deficiency
Review Type:	Annual Review, Change in Research (PI Change from Dr. Wu to Dr. Konczal)
NIH Guidelines Section:	III-C-1

Trial Summary: mRNA-3705-P101 is a first-in-human, 3-part, global, multicenter Phase I/II study sponsored by ModernaTX, Inc. and designed to assess the safety, tolerability, and efficacy of mRNA-3705, an mRNA-liposome complex encoding human methylmalonyl-coenzyme A mutase enzyme (MUT), in participants with methylmalonic acidemia (MMA) due to MUT deficiency. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent mRNA-3705 consist of synthetic mRNA incapable of replication, BSL1 containment is considered the minimum biocontainment level. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens (BBP) 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 splash or spray 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, 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 stipulated that the Site complete BBP training and send Sabai an updated certificate by 12/4/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee noted the shipping training will expire this month and reminded the Site to send Sabai the updated certificate when it is available. The Site had no concerns.
    - The Committee recommended that the Site affix a biohazard sticker to the BSC when the study agent is being prepared.
    - The Committee stipulated that the Site send Sabai a photo of the crib/bed/chair where participants will be placed during administration by 12/4/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

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 stipulated that the Site complete BBP training and send Sabai an updated certificate by 12/4/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee stipulated that the Site send Sabai a photo of the crib/bed/chair where participants will be placed during administration by 12/4/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

Meeting Minutes

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 10:08 AM

Post-Meeting Pre-Approval Note: None