INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, November 7, 2025**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Altanta, GA
Principal Investigator:	**Hong Li, MD, PhD**
Protocol:	ModernaTX, Inc., **mRNA-3705-P101**
NCT Number:	NCT04899310
Meeting Type:	Initial Review of Protocol and Site
Title:	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

1. Call to order:

The Meeting was called to order at 1:00 pm Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were two Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for mRNA-3705 since it consists of lipid nanoparticle (LNP)-encapsulated mRNA administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of mRNA-3705 locally** provided that all biosafety criteria for study closure are also met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative stated that the Biological Safety Cabinet (BSC) used for study agent preparation was recently re-certified. The Committee recommended that the institution submit the latest BSC Certification to IBC Services.
2. The Committee recommended that a small sharps container be placed inside the BSC and that site documents be revised to reflect this.
3. An Institutional Representative stated that a -80°C freezer will be available for study agent storage for this protocol. The Committee recommended that the freezer be labelled with a biohazard symbol and that a photo be submitted to IBC Services.
4. An Institutional Representative stated that pre-filled disposable eyewash bottles are available in all dosing rooms and there is a large supply onsite. The Committee recommended that site documents be revised to reflect this.
5. An Institutional Representative stated that dosing rooms will be used per their availability.
6. An Institutional Representative stated that the Arthur M. Blank Hospital (AMBH) and the Center for Advanced Pediatrics-Pediatric Research Unit (PRU) are two different buildings.
7. The Committee recommended that the biohazard sign be posted at the entrance to the areas where the study agent is handled.
8. An Institutional Representative stated that PDI Super Sani-Cloth wipes are used to decontaminate work surfaces in the dosing rooms. The Committee recommended that site documents be revised to reflect this.
9. An Institutional Representative confirmed that the study agent transport container is hard-sided. The Committee recommended that a biohazard symbol be placed on the transport container and that a new photo be submitted to IBC Services.
10. An Institutional Representative confirmed that a biohazardous waste container for disposal of PPE is available in the PRU Exam Rooms and will follow up with IBC Services on whether these are available in the dosing rooms on the 14th floor of the AMBH.
11. An Institutional Representative stated that there are handwashing sinks in the pharmacy and ante room.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:23 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 10, dated 04-03-2025
Investigator's Brochure, Edition 5.0, dated 06-11-2024
Pharmacy Manual, Version 14.0, dated 04-25-2025
Dose Preparation and Administration Packet, Version 1.0, dated 04-15-2025
Biological Risk Assessment and Summary, dated 09-24-2025
Site Map, PRU, 5th Floor IDS Pharmacy, Dosing, dated 10-23-2025

Site Map, AMBH, 14th Floor, Dosing, dated 10-02-2025
Site Inspection Checklist, PRU, IDS Pharmacy, Dosing, expires 07-18-2027, updated 10-14-2025
Photos, PRU, 5th Floor, IDS Pharmacy, dated 10-29-2025
Photos, PRU, 5th Floor, Dosing Rooms, dated 10-29-2025
Photos, AMBH, 14th Floor Dosing, dated 09-15-2025
Biohazard Sign, dated 10-23-2025
Biological Safety Cabinet Certification, expires 09-2025
SOP, Biosafety for mRNA-3705-P101, dated 10-14-2025
Training, Shipping Certification, expires 07-02-2026
CV, Li, H., signed 05-14-2025