

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

**Meeting Date:** Friday, October 10, 2025  
**Time:** 9:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** DM Clinical Research - Tomball, Tomball, TX  
**Principal Investigator:** Muhammad Irfan, MD, BS  
**Protocol:** [REDACTED]  
**NCT Number:** NCT05575492  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 1/2a Open-Label Dose-Ranging and Observer-Blind Placebo-Controlled, Safety and Immunogenicity Study of [REDACTED] Cytomegalovirus Vaccine in Female and Male Participants 9 to 15 Years of Age and Participants 16 to 25 years of Age

**1. Call to order:**

The Meeting was called to order at 9:01 am Central Time.

**2. Introductions and orientation:**

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

**3. Declaration of quorum:**

Four voting members were present, including one local member unaffiliated with the institution. Also present was one Institutional Representative 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:**

The 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. Approval of previous meeting minutes:**

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

**7. Review of proposed research:**

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

**8. Determination for biosafety level and period of IBC oversight:**

The Committee previously determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for [REDACTED] since it consists of an LNP-encapsulated mRNA administered by injection in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of [REDACTED] locally**, provided that all biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

**9. Vote on the Protocol:**

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

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### **10. Review of proposed facilities and practices:**

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

#### **Point of Discussion:**

1. The Institutional Representative confirmed that gloves are removed and disposed of in the sharps container in the dosing room and that a biohazardous waste container for disposal of other personal protective equipment (PPE) is located immediately outside of the dosing room.

### **11. Site requirements:**

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

### **12. Vote on the Site:**

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 9:09 am Central Time.

**15. Post-meeting notes:** None.

### **Documents reviewed:**

Agenda

Protocol, Amendment 4, dated 02-27-2025

Investigator's Brochure, Edition 12.0, dated 12-11-2024

Pharmacy Manual, Version 4.0, dated 01-10-2025

Research Modification Evaluation, Protocol, Amendment 3

Research Modification Evaluation, Protocol, Amendment 4

Research Modification Evaluation, Investigator's Brochure, Edition 12.0

Research Modification Evaluation, Pharmacy Manual, Version 3.0

Research Modification Evaluation, Pharmacy Manual, Version 4.0

Biological Risk Assessment and Summary, updated 04-22-2025

Site Map, Medical Complex Dr., dated 09-21-2023

Site Inspection Checklist, Medical Complex, expires 09-16-2026, updated 09-26-2025

Photos, Medical Complex Drive, dated 06-25-2025

Biohazard Sign, mRNA-based vaccines, Medical Complex, dated 06-26-2025

Biosafety Cabinet Certification, Medical Complex, expires 02-10-2026

SOP, Biosafety for mRNA-based vaccines, DM Clinical, Texas locations, dated 06-26-2025

Training, Shipping Certification, expires 05-27-2026

CRRF, dated 06-04-2025

Prior Meeting Minutes, Continuing, dated 09-30-2024