

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, September 12, 2025  
**Time:** 9:00 am Mountain Time  
**Location:** Zoom Teleconference  
**Institution:** Velocity Clinical Research, Inc. - Albuquerque, Albuquerque, NM  
**Principal Investigator:** Sara Friedman, MD  
**Protocol:** ModernaTX, Inc., mRNA-1647-P104  
**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 mRNA-1647 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 9:04 am Mountain 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 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 was unable to confirm if a public posting was made. The Committee recommended that the Institution confirm that notice of the meeting was publicly posted and to forward any public comments received by the site to IBC Services.

### 6. Approval of previous meeting minutes:

Minutes Approved - YES: 5                      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.

### **Point of Discussion:**

1. The Committee noted it appears that a newer Investigator's Brochure is available and recommended that the Institution submit to IBC Services the Investigator's Brochure, dated 03-26-2025.

### 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 mRNA-1647 since it consists of lipid nanoparticle (LNP)-encapsulated mRNA molecules administered 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 mRNA-1647 locally** provided that all biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

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### **9. 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

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

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

#### **Points of Discussion:**

1. The Committee recommended that the photo of the disinfectant be removed from the Photos document since the disinfectants that are available and used at the Institution are noted in other site-specific documents.
2. The Committee recommended that the Institution submit a photo to IBC Services of the pre-filled disposable eyewash bottles that are available in the dosing room and that the Photos document be updated accordingly.

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

The Chair did not review 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: 5

NO: 0

ABSTAIN: 0

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

### **14. Meeting adjourned:** The meeting was adjourned at 9:14 am Mountain 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, dated 01-16-2024

Site Inspection Checklist, expires 12-15-2025, updated 08-28-2025

Photos, dated 01-25-2024

Biohazard Sign, mRNA-based vaccines, dated 01-24-2024

SOP, Biosafety for mRNA-based Vaccines, dated 08-28-2025

Training, Shipping Certification, expires 02-01-2026

CRRF, received 08-12-2025

Prior Meeting Minutes, Continuing, dated 09-05-2024