

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, May 2, 2025  
**Time:** 1:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** DM Clinical Research - Tomball, Sugarland, TX  
**Principal Investigator:** Kecia Leigh, MD  
**Protocol:** [REDACTED]  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 1, Randomized, Observer-Blind, Placebo-Controlled, 2-Part, Dose-Ranging Study of an EBV Candidate Vaccine, [REDACTED], in Healthy Participants 18 through 55 Years of Age

### 1. Call to order:

The Meeting was called to order at 1:06 pm Central 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:

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: 5                      NO: 0                      ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the dosing status.

The Chair provided an overview of the protocol.

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

### **Points of Discussion:**

1. An Institutional Representative stated that the study recently re-opened for subject enrollment.
2. After discussion, the Committee determined that only [REDACTED] will be referenced for the biosafety level since this is the only agent being tested in the current Protocol.

### 8. 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 [REDACTED] since it consists of a lipid nanoparticle (LNP)- encapsulated mRNA molecule administered in a clinical setting.

The Committee 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.

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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 lids be placed on biohazardous waste containers when not in use.
2. An Institutional Representative confirmed that sharps containers are available in all dosing rooms.

### **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 1:18 pm Central Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Amendment 3, dated 02-18-2025

Investigator's Brochure, [REDACTED], Edition 3.0, dated 09-11-2024

Investigator's Brochure, [REDACTED], Edition 3.0, dated 12-22-2023

Pharmacy Manual, Version 4.0, dated 02-20-2025

Research Modification Evaluation, Protocol, Amendment 2

Research Modification Evaluation, Protocol, Amendment 3

Research Modification Evaluation, [REDACTED], Investigator's Brochure, Edition 2.0

Research Modification Evaluation, [REDACTED], Investigator's Brochure, Edition 3.0

Research Modification Evaluation, [REDACTED], Investigator's Brochure, Edition 3.0

Research Modification Evaluation, Pharmacy Manual, Version 3.0

Research Modification Evaluation, Pharmacy Manual, Version 4.0

Biological Risk Assessment and Summary, updated 02-27-2025

Research Modification Evaluation, Additional Dosing Room, dated 04-08-2025

Research Modification Evaluation, Change in Principal Investigator, dated 05-01-2024

CV, Leigh K., signed 09-29-2023

Site Map, Sugarland, dated 04-07-2025

Site Inspection Checklist, Sugarland, dated 03-25-2025, updated 04-03-2025

Photos, Sugarland, dated 04-04-2025

Biohazard Sign, mRNA vaccines, Sugarland, dated 05-01-2025

Biosafety Cabinet Certification, dated 03-21-2025

SOP, Biosafety for mRNA-based vaccines, DM Clinical, Texas locations, dated 04-06-2025

Training, Shipping Certification, expires 07-31-2025

CRRF, dated 12-03-2024

Prior Meeting Minutes, Continuing, dated 03-14-2024