

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, April 14, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: DM Clinical Research - Southfield, Southfield, MI
Principal Investigator: Rana Sami Balboul, 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 1:00 pm Eastern 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 were five 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. 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 dosing status.

The Chair provided an overview of the protocol.

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

Point of Discussion:

1. An Institutional Representative confirmed that screening for Part B of the study has started.

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] and [REDACTED] since they consist 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 [REDACTED] and [REDACTED] locally**, provided that all biosafety criteria for study closure are also met. The Committee reaffirmed this determination

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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

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 biological safety cabinet (BSC) be labeled with a biohazard symbol.
2. The Committee recommended that the lids of the biohazardous waste containers be labeled with a biohazard symbol.
3. The Committee discussed that the study agent requires storage at -60 to -90°C but the study agent storage unit shown in the Photos document is a refrigerator. The Committee recommended that a photo of the study agent storage freezer, labeled with a biohazard symbol, be provided to IBC Services.
4. An Institutional Representative confirmed that the prefilled disposable eyewash bottles have been replaced and have an expiration date of May 2028.
5. An Institutional Representative confirmed that biohazardous waste containers are available in the IP 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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:13 pm Eastern 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 3

Research Modification Evaluation, Protocol, Amendment 2

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

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

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

Research Modification Evaluation, Pharmacy Manual, Version 4.0

Research Modification Evaluation, Pharmacy Manual, Version 3.0

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

Site Map, dated 03-31-2025

Site Inspection Checklist, DM Clinical Research - Southfield, dated 05-08-2024, updated 03-30-2025

Photos, DM Clinical Research- Southfield, dated 03-30-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Biohazard Sign, DM Clinical Research - Southfield, dated 03-30-2025

SOP, Biosafety for mRNA-based Vaccines, DM Clinical Research - Southfield, dated 03-25-2025

Biological Safety Cabinet Certification, dated 03-19-2025

Training, Shipping Certification, expires 10-28-2025

CRRF, dated 02-04-2025

Prior Meeting Minutes, Continuing, dated 05-24-2024