INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, May 8, 2025**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	DM Clinical Research - Philadelphia, Philadelphia, PA
Principal Investigator:	**David Sherwood Wheeler, 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 11:03 am Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Three 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: 3 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. 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 lipid nanoparticle (LNP)- encapsulated mRNA molecules 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. 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: 3 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 Institutional Representative confirmed that prefilled disposable eye wash bottles are 475 mL in size and that a large supply of bottles is available in the event of an eye exposure.
2. The Institutional Representative stated that the Biological Safety Cabinet (BSC) used for study agent preparation was last certified in October 2024 and that it's recertified annually. The Committee noted that the BSC certification is missing typical tests, including downflow and inflow velocity, airflow smoke pattern, and HEPA filter leak tests.
3. The Committee determined that using the BSC for study agent preparation is acceptable since it was recently certified. The Committee recommended that the institution look into obtaining a more comprehensive BSC certification to be submitted to IBC Services.
4. The Institutional Representative confirmed that all dosing rooms have large biohazardous waste containers. The Committee recommended that a photo of the biohazardous waste container in a dosing room be provided to IBC Services.

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: 3 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:14 am 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 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
Site Map, dated 03-25-2025

[redacted]

Site Inspection Checklist, dated 03-25-2025
Photos, DM Clinical Research, Philadelphia, dated 03-27-2025
Biohazard Sign, DM Clinical-Philadelphia, dated 03-25-2025
Work Order Report, dated 10-01-2024
SOP, Biosafety for mRNA-based Vaccines, dated 03-25-2025
Training, Shipping Certification, expires 03-03-2026
CRRF, dated 12-10-2024
Research Modification Evaluation, Change in Principal Investigator, dated 08-16-2024
CV, Wheeler, D., signed 05-13-2024
Prior Meeting Minutes, Continuing, dated 03-26-2024