

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, May 19, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: DM Clinical Research - Brookline, Brookline, MA
Principal Investigator: Basmah A. Jalil, 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 1:01 pm Eastern 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, the Principal Investigator, 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: 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. 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.

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: 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 references to ██████████ be removed from the Biosafety SOP for mRNA-based vaccines.
2. An Institutional Representative confirmed that suites 502/508 and 401/405 are two different suites with different rooms used in each. The Committee recommended that the site map be revised by removing the suite numbers from the site address as they are currently listed separately, making it seem like there are four separate areas.
3. The Committee recommended that the site photos be revised to indicate the specific room, with its corresponding suite number, shown on each slide.
4. The Committee recommended that all biohazardous waste containers be labelled with biohazard symbols and that a photo of the waste containers in the biohazardous waste storage area be provided to IBC Services.
5. An Institutional Representative confirmed that the table the centrifuge is on in the PBMC/Research Lab is bolted to the floor.
6. An Institutional Representative confirmed that prefilled disposable eyewash bottles are labelled with expiration dates.
7. An Institutional Representative confirmed that the institution does not have a plumbed eyewash. The Committee recommended that the institution look into installing a plumbed eyewash per best biosafety practices and to comply with OSHA guidelines (i.e., 15 minutes of continuous eye flushing in the event of an exposure).

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives and the Principal Investigator.

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 1:20 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 3, dated 02-18-2025

Investigator's Brochure, ██████████, Edition 3.0, dated 09-11-2024

Investigator's Brochure, ██████████, Edition 3.0, dated 12-22-2023

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

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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, New Location, dated 09-04-2024
Site Map, Harvard Street, dated 09-04-2024
Site Inspection Checklist, dated 08-23-2024, updated 03-24-2025
Photos, dated 08-19-2024
Biohazard Sign, mRNA-based vaccines, dated 09-03-2024
Biological Safety Cabinet Certification, expires 07-12-2025
SOP, Biosafety for mRNA-based Vaccines, dated 03-24-2025
Training, Shipping Certification, expires 08-07-2025
CRRF, dated 12-05-2024
Prior Meeting Minutes, Continuing, dated 05-24-2024