

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, September 26, 2025
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Northside Hospital, Atlanta, GA
Principal Investigator: Scott R. Solomon, MD
Protocol: City of Hope, 23008
NCT Number: NCT06059391
Meeting Type: Continuing Review of Protocol and Site
Title: Placebo-controlled and randomized phase 2 trial of CMV-MVA Triplex vaccination in HLA-matched related stem cell donors to enhance CMV-specific immunity and prevent CMV viremia in recipients after hematopoietic stem cell transplant

1. Call to order:

The Meeting was called to order at 10:09 am 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 two local members unaffiliated with the institution. Also present were four 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 protocol and status of the study.

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

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 CMV-MVA-Triplex since it consists of a recombinant Modified Vaccinia Ankara vaccine 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 CMV-MVA-Triplex locally**, provided that other 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: 4 NO: 0 ABSTAIN: 0

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10. Review of proposed facilities and practices:

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

Point of Discussion:

1. The Committee recommended that the third sentence in Biosafety SOP Section 3.3 be revised to read as “using a non-safety needle”.

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 10:16 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 04, dated 11-12-2024

Investigator's Brochure, Edition 18, dated 10-29-2024

Pharmacy Manual, dated 10-29-2024

Research Modification Evaluation, Protocol, Version 03

Research Modification Evaluation, Protocol, Version 04

Research Modification Evaluation, Investigator's Brochure, Edition 18

Research Modification Evaluation, Pharmacy Manual, dated 10-29-2024

Biological Risk Assessment and Summary, updated 06-10-2025

Site Map, 3N Investigational Pharmacy, dated 09-12-2024

Site Map, Outpatient Infusion Center, dated 08-12-2024

Site Inspection Checklist, 3N Investigational Pharmacy & Outpatient IC, expires 07-22-2026, updated 09-05-2025

Site Inspection Checklist, Autoclave Addendum, dated 02-11-2025, updated 02-24-2025

Photos, Outpatient Infusion Center, dated 09-08-2025

Photos, 3N Investigational Pharmacy, dated 09-08-2025

Biohazard Sign, CMV-MVA Triplex, dated 09-13-2024

Biological Safety Cabinet Certifications, 3N Investigational Pharmacy, expire 12-2025

SOP, Biosafety for CMV-MVA Triplex, dated 09-16-2025

Training, Shipping Certification, expire 03-10-2026, 04-30-2026

CRRF, dated 06-02-2025

Prior Meeting Minutes, Initial, dated 09-20-2024