

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, September 1, 2026
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 9:59 am 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 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: 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 noted 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: 5 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 Institutional Representative confirmed that Soiled Utility Room 140 in the Outpatient Infusion Center is only used for soiled linens and no biohazardous waste is stored in this room. The Committee recommended that site documents be revised to remove Soiled Utility Room 140.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:07 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 05, dated 04-30-2026

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

Pharmacy Manual, dated 01-09-2026

Research Modification Evaluation, Protocol, Version 05

Research Modification Evaluation, Pharmacy Manual, dated 01-09-2026

Research Modification Evaluation, Pharmacy Manual, dated 10-31-2025

Biological Risk Assessment and Summary, updated 08-26-2026

Site Map, Outpatient Infusion Center, dated 04-23-2026

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

Site Inspection Checklist, 3N Investigational Pharmacy & Outpatient IC, expires 08-27-2028

Site Inspection Checklist, Autoclave Addendum, expires 04-20-2028

Photos, Outpatient Infusion Center, dated 04-23-2026

Photos, 3N Investigational Pharmacy, dated 04-23-2026

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

Biological Safety Cabinet Certifications, 3N Investigational Pharmacy, expire 12-2026

SOP, Bioafety for CMV-MVA Triplex, dated 04-20-2026

Training, Shipping Certification, expires 01-2028

CRRF, dated 06-15-2026

Prior Meeting Minutes, Continuing, dated 09-26-2025