INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, July 28, 2025**
Time:	10:00 am Central Time
Location:	Zoom Teleconference
Institution:	Northwestern University, Chicago, IL
Principal Investigator:	**Michael Angarone, DO, FIDSA**
Protocol:	National Institute of Allergy and Infectious Diseases (NIAID), **CTOT-44**
NCT Number:	NCT06075745
Meeting Type:	Continuing Review of Protocol and Site
Title:	Cytomegalovirus (CMV) Vaccine in Orthotopic Liver Transplant Candidates

1. Call to order:

The Meeting was called to order at 10:23 am Central 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 one local member unaffiliated with the institution and the Institution's Biosafety Officer. Also present were six 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:

The Biosafety Officer confirmed that the notice of the meeting was not publicly posted. The Committee recommended that the notice of the meeting be publicly posted for one week from today and that any questions or comments received be forwarded to IBC Services.

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.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for CMV-MVA Triplex, since it consists of a recombinant vaccinia virus-based 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 all 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

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 Chair confirmed that the Sponsor had not revised the Pharmacy Manual in response to the Letter of Advice that was sent following the initial review meeting.
2. An Institutional Representative confirmed that three subjects have been dosed to date and that there have been no issues related to dispersion of the study agent when opening the vial nor have there been any problems withdrawing the required dosing volume from the vial.
3. An Institutional Representative could not confirm whether a vortex and centrifuge is available in the [redacted]. The Committee recommended that if a vortex and centrifuge are available, the study agent vial be vortexed and spun per the Pharmacy Manual as opposed to flicking the vial and that site documents be revised accordingly.
4. The Committee recommended that Site Inspection Checklist Item 10 be revised to reflect that the study agent will be mixed by repeated flicking of the vial for 30 seconds if no vortex or centrifuge is available.
5. The Committee recommended that the description of the study agent on the [redacted] Biohazard Sign be revised to read "Recombinant, replication-defective vaccinia virus vector."
6. The Committee noted that the study agent may be temporarily stored at 2-8°C after thawing and prior to administration. The Committee recommended that a photo of the refrigerator, labeled with a biohazard symbol, be provided to IBC Services if the study agent will be stored at 2-8°C.
7. The Committee discussed previous concerns regarding the duration of flushes for plumbed eyewash stations and noted that longer flush times can help identify issues that may not occur during short flushes, such as sudden decreases in water pressure or sudden increases in water temperature.
8. The Biosafety Officer confirmed that all plumbed eyewash stations are tested annually with longer flush times to ensure mixing valves are functioning properly and water pressure is maintained.
9. The Committee determined that the Compounding Aseptic Containment Isolator (CACI) Certification report and HEPA Filter Integrity Testing report contain all required information.
10. The Committee noted that an emergency eyewash sign is posted above the plumbed eyewash station in the dosing area.
11. The Committee noted that reusable face shields are used and that site documents accurately reflect this.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:41 am Central Time.