INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, July 20, 2026**
Time:	9:00 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 9:01 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 two local members unaffiliated with the institution. Also present were the Principal Investigator, 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: 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-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 Committee noted that the Bioquell Compounding Aseptic Containment Isolator was due for recertification at the end of June 2026, and acknowledged that IBC Services had previously asked Institutional staff members to submit the newer certification to IBC Services, with no response to this request.
2. The Committee determined the following as a Condition of Approval:
    a. The Institution must submit a current Bioquell CACI Certification (including the HEPA filter certification results) to IBC Services, and this new Certification must indicate that the Bioquell CACI and HEPA filter passed all required tests.
3. The Committee determined that the Bioquell CACI must not be used for study agent preparation until the designated member of the IBC (IBC Chair) confirms that this piece of equipment is working properly.
4. The Committee noted that the Biological Safety Cabinets in the IDS Pharmacy, which were most recently certified in November 2025 are acceptable to use for study agent preparation.
5. The Committee discussed that if the study agent vial will be flicked and not centrifuged, some of the study agent will be trapped in the vial's cap so the full dose may not be able to be withdrawn into the dosing syringe and there is also a risk of the study agent dispersing onto work surfaces when the vial is opened. The Committee determined to send a Letter of Advice to the Sponsor requesting that additional information regarding study agent preparation for sites that do not have a centrifuge is included in the Pharmacy Manual (see Section 13 "Advice to the Sponsor" for the details of this Letter).
6. The Chair confirmed that the Sponsor had not revised the Pharmacy Manual in response to the Letter of Advice that was sent following the previous IBC meeting. The Committee recommended that a second Letter of Advice be sent to the sponsor.
7. The Committee had the following advice for the Sponsor:
    a. The Pharmacy Manual states that the study agent should be vortexed for 30 seconds and then centrifuged to maximize the extractable volume. However, the Pharmacy Manual also indicates that if a vortex and a centrifuge are not available, the vial can be repeatedly flicked for 30 seconds to mix the study agent.
    b. The Committee noted that if the study agent vial will be flicked and not centrifuged, some of the study agent will be trapped in the vial's cap so the full dose may not be able to be withdrawn into the dosing syringe and there is also a risk of the study agent dispersing onto work surfaces when the vial is opened.
    c. Additional information regarding study agent preparation for sites that do not have a centrifuge should be included in the Pharmacy Manual. This information should include how to account for loss of study agent in the vial's cap, in addition to risks related to dispersion of the study agent when opening the vial.
8. 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.
9. The Committee recommended that Site Inspection Checklist Item 13 be updated to include the type of needle used at the Arkes dosing location, including how the needle is recapped.
10. The Committee recommended that Biosafety SOP Section 5.4 be revised to add that the study agent is diluted in PBS during study agent preparation activities.
11. The Committee noted that the Biohazard Sign for the Galtier location and recommended that the Institution confirm how this sign is posted, and that if possible a photo of it posted be submitted to IBC Services.
12. The Committee previously 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 (or alternatively a cooling block), labeled with a biohazard symbol, be provided to IBC Services if the study agent will be stored at 2-8°C.

13. The Principal Investigator confirmed that the Galter and Arkes buildings just across the street from each other and are connected by a walkway bridge.
14. The Committee recommended that the Institution confirm that the Institution's Environmental Health and Services staff move biohazardous waste from the Arkes dosing floor to the Feinberg and Olson Loading Docks where it is ultimately picked up by the commercial biohazardous waste hauler.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

	APPROVED
X	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

For a vote of CONDITIONALLY APPROVED, the following condition must be met no later than August 20, 2026, in order to maintain IBC approval:

a. A current Bioquell CACI Certification (including the HEPA filter certification results) must be submitted to IBC Services, and this new Certification must indicate that the Bioquell CACI and HEPA filter passed all required tests.

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Sponsor:

The Committee had the following advice for the Sponsor:

a. The Pharmacy Manual states that the study agent should be vortexed for 30 seconds and then centrifuged to maximize the extractable volume. However, the Pharmacy Manual also indicates that if a vortex and a centrifuge are not available, the vial can be repeatedly flicked for 30 seconds to mix the study agent.

b. The Committee noted that if the study agent vial will be flicked and not centrifuged, some of the study agent will be trapped in the vial's cap so the full dose may not be able to be withdrawn into the dosing syringe and there is also a risk of the study agent dispersing onto work surfaces when the vial is opened.

c. Additional information regarding study agent preparation for sites that do not have a centrifuge should be included in the Pharmacy Manual. This information should include how to account for loss of study agent in the vial's cap, in addition to risks related to dispersion of the study agent when opening the vial.

14. Meeting adjourned: The meeting was adjourned at 9:24 am Central Time.

15. Post-meeting notes:

1. The Committee noted that the BSCs in the Galter IDS Pharmacy, most recently certified in November 2025, were due for recertification in May 2026 and recommended that updated Certifications be submitted to IBC Services.
2. The condition of approval was met on the following date:

Resolution of condition for Conditional Approval:

Condition No.	Resolution	Date of Resolution	Approved by Chair
a			

Documents reviewed:

Agenda
Protocol, Version 4.0, dated 06-16-2025
Investigator's Brochure, Edition 18, dated 10-29-2024
Pharmacy Manual, dated 01-09-2026
Research Modification Evaluation, Protocol, Version 4.0
Research Modification Evaluation, Pharmacy Manual, dated 10-31-2025
Research Modification Evaluation, Pharmacy Manual, dated 01-09-2026
Biological Risk Assessment and Summary, updated 04-09-2026
Site Map, Arkes Building, 9th floor, dated 06-20-2024
Site Map, Galter, 17th Floor, IDS Pharmacy, updated 11-20-2025
Site Map, Feinberg and Olson Loading Docks, received 10-16-2018
Site Inspection Checklist, Non-Cell Therapies, expires 03-05-2027, updated 06-12-2026
Photos, Arkes 9th Floor, dated 08-28-2024
Photos, Galter, 17th Floor, IDS Pharmacy, dated 04-07-2026
Photos, Feinberg and Olson Loading Dock, dated 03-25-2026
Biohazard Sign, CMV-MVA Triplex, dated 07-12-2026
Biohazard Sign, Galter IDS Pharmacy, dated 07-12-2026
Biological Safety Cabinet Certifications, Galter 17th Floor, expire 05-2026
Bioquell CACI Certification, Galter 17th Floor, dated 06-17-2025
Bioquell CACI Certification, HEPA, Galter 17th Floor, expires 05-2026
SOP, Biosafety for CMV-MVA Triplex, dated 06-02-2025
Training, Shipping Certification, expires 06-05-2027
CRRF, dated 04-01-2026
Prior Meeting Minutes, Continuing, dated 07-28-2025