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:	**Chad Achenbach, MD, PhD**
Protocol:	National Institute of Allergy and Infectious Diseases (NIAID), **A5374**
NCT Number:	NCT06071767
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase I/IIa Randomized, Placebo-Controlled Trial of Conserved-Mosaic T-cell Vaccine in a Regimen with Vesatolimod and Broadly Neutralizing Antibodies in Adults Initiated on Suppressive Antiretroviral Therapy during Acute HIV-1

1. Call to order:

The Meeting was called to order at 9:31 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 two 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.

Points of Discussion:

1. An Institutional Representative confirmed that the Sponsor has not developed a Pharmacy Manual for this study.

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for ChAdOx1.tHIVconsv1, ChAdOx1.tHIVconsv62, MVA.tHIVconsv3 and MVA.tHIVconsv4 since they consist of recombinant adenoviral vectors and a replication-defective derivative of the Modified Vaccinia Ankara (MVA) 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 dose of ChAdOx1.tHIVconsv1**, ChAdOx1.tHIVconsv62, MVA.tHIVconsv3 or MVA.tHIVconsv4 locally, provided that other biosafety criteria 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 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.
6. The Principal Investigator confirmed that the Galter and Arkes buildings just across the street from each other and are connected by a walkway bridge.
7. 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.
8. An Institutional Representative confirmed that a study staff member instructs subjects about post-dosing at-home bandage care, but could not confirm if formal instructions (e.g., post-dosing informational sheet for subjects and their caregivers) are provided. The Committee recommended that the Institution look into this and if formal instructions are not provided that the Institution consider creating a post-dosing informational sheet for subjects and their caregivers.
9. The Committee recommended that the dosing rooms in Biosafety SOP Section 5.2 be updated to reflect the rooms listed on the corresponding Site Map (e.g., remove the additional onsite terminology).
10. An Institutional Representative confirmed that the location of dosing has changed since the last review, and this was evaluated by the IBC.

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:

	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 Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:45 am Central Time.

15. Post-meeting notes: 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 12-17-2025
Investigator's Brochure, ChAdOx1.HIVconsv62, Version 5.0, dated 05-01-2025
Investigator's Brochure, ChAdOx1.tHIVconsv1, Version 7.0, dated 12-08-2025
Investigator's Brochure, MVA.tHIVconsv3, Version 8.0, dated 05-21-2025
Investigator's Brochure, MVA.tHIVconsv4, Version 8.0, dated 05-21-2025
Research Modification Evaluation, Protocol, Version 4.0
Research Modification Evaluation, MVA.tHIVconsv3, Investigator's Brochure, Version 8.0
Research Modification Evaluation, MVA.tHIVconsv4, Investigator's Brochure, Version 8.0
Research Modification Evaluation, ChAdOx1.tHIVconsv1, Investigator's Brochure, Version 6.0
Research Modification Evaluation, ChAdOx1.tHIVconsv1, Investigator's Brochure, Version 7.0
Research Modification Evaluation, ChAdOx1.HIVconsv62, Investigator's Brochure, Version 5.0
Biological Risk Assessment and Summary, updated 04-23-2026
Research Modification Evaluation, Change in Dosing Location, dated 02-23-2026
Site Map, Arkes Building, 14th Floor, dated 06-11-2026
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 14th Floor, dated 05-29-2026
Photos, Galter, 17th Floor, IDS Pharmacy, dated 04-07-2026
Photos, Feinberg and Olson Loading Dock, dated 03-25-2026
Biohazard Sign, A5374, dated 10-27-2024
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 ChAdOx1.tHIVconsv and MVA.tHIVconsv, dated 02-18-2026
SOP, Biosafety for Spills, dated 06-17-2024
Training, Shipping Certification, expires 06-05-2027
CRRF, dated 04-20-2026
Prior Meeting Minutes, Continuing, dated 07-02-2025