

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, July 31, 2026
Time: 11:00 am SA Pacific Time
Location: Zoom Teleconference
Institution: Via Libre, Cercado de Lima, Lima
Principal Investigator: Yvett Pinedo Ramirez, MD
Protocol: Division of AIDS (DAIDS), HVTN 808
NCT Number: NCT07569029
Meeting Type: Initial Review of Protocol and Site
Title: A nonrandomized phase 1 clinical trial to evaluate the safety and tolerability of DV700P-RNA and DV701B1.1-RNA immunization in combination with antiretroviral analytical treatment interruption (ATI) in people living with HIV for elicitation of V3-glycan antibodies

1. Call to order:

The Meeting was called to order at 11:04 am SA Pacific 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 three 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

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

The Committee determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for DV700P-RNA and DV701B1.1-RNA since they consist of lipid nanoparticle (LNP)-encapsulated mRNA vaccines administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of DV700P-RNA and DV701B1.1-RNA locally**, provided that all biosafety criteria for study closure are also met.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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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 recommended that Biosafety SOP Section 3.4.1 be revised to indicate that absorbent material will be placed inside the Ziploc-style bag.
2. The Committee recommended that Biosafety SOP Section 3.5 be revised to indicate that the gauze and cup are disposed of as biohazardous waste if used.
3. The Committee recommended that Biosafety SOP Section 4.2 be revised to specify the parameters used for the autoclave cycle, including time and temperature, and the frequency with which biological indicators are used to confirm successful sterilization.
4. The Committee recommended that Biosafety SOP Section 5.1.1 be revised by removing the 10-minute aerosol settling time.
5. The Committee recommended that Biosafety SOP Section 5.1.4a.i. be removed as alcohol is not an effective disinfectant on its own.
6. The Committee recommended that the study agent storage unit be labelled with a biohazard symbol and that an updated photo of the labelled storage unit be provided to IBC Services.
7. The Committee recommended that the study agent be transported in a hard-sided, lidded container, labeled with a biohazard symbol, and that a photo of this container be provided to IBC Services.
8. The Committee recommended that photos of the prefilled disposable eyewash bottles be provided to IBC Services.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:16 am SA Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1.0, dated 02-11-2026

Investigator's Brochure, Edition 1.0, dated 02-2025

Biological Risk Assessment and Summary, dated 06-05-2026

Site Maps, dated 07-11-2026

Site Inspection Checklist, expires 06-15-2028

Site Inspection Checklist, Autoclave Addendum, expires 06-15-2028

Photos, dated 07-11-2026

Biohazard Sign, dated 06-08-2026

Biosafety Cabinet Certification, expires 09-2026

Biosafety Cabinet Certification, expires 03-2027

SOP, Biosafety for DV700P-RNA and DV701B1.1-RNA, dated 07-11-2026

Training, Shipping Certification, expires 10-14-2027

CV, Pinedo, Y., signed 05-28-2026