

**Microbicide Trials Network
CLARIFICATION MEMO #01 TO:**

**MTN-003
DAIDS Document ID #10622**

**Phase 2B Safety and Effectiveness Study of Tenofovir 1% Gel, Tenofovir
Disoproxil Fumarate Tablet and Emtricitabine/Tenofovir Disoproxil Fumarate
Tablet for the Prevention of HIV Infection in Women**

**Version 2.0 / 31 December 2010
IND #: 55,690**

Date of Clarification Memorandum: 27 October 2011

Section 1: Summary of Clarifications and Rationale

The items clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. Institutional Review Board/Ethics Committee (IRB/EC) approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/EC overseeing the study at their site for information. This CM is official MTN-003 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-003. No change in informed consent is necessitated by or included in this CM.

This CM provides clarification on the following items:

1. Updates to Protocol Team Roster, to reflect changes to the Protocol Team
 2. New name for Study Operations Center (FHI 360)
 3. Update to Clinical and Laboratory Procedures, with corresponding updates to Appendix I: Schedule of Study Visits
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Section 2: Implementation

With the exception of the modifications to the Protocol Team Roster, text to be deleted is noted by strikethrough and text to be added is noted below in **bold**.

1. The Protocol Team Roster is updated to include changes to Site Investigators.

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The following individuals have been removed from the Protocol Team Roster:
Shahnaaz Kadwa, Kathy Mngadi, Vimla Naicker, Linda Zako.

2. References to FHI have been changed to FHI 360 throughout the document. Email addresses ending in fhi.org have been changed to fhi360.org throughout the document.
3. In Section 7.5.2, Clinical Procedures, the following update is made under the ninth sub-bullet of the fourth bullet, regarding Pap smear:
 - ecto- and endocervical cells for Pap smear (at selected sites):
 - At PUEV, **when clinically indicated**
 - When clinically indicated and/or per local clinical guidelines

The corresponding update (addition of ▲•, to specify “as indicated, at sites with capacity where local standard of care”) is made to Appendix I in the column for PUEV:

Pap Smear		▲•		▲•	▲•	▲•	▲•	▲•	▲•
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In Section 7.5.3, Laboratory Procedures, the timing of PBMC archive is clarified:

- PBMC archive (for consenting participants at selected sites approved by NL)
 - At the first quarterly visit following consent and every six months thereafter, during scheduled study participation
 - **At PUEV**
 - As indicated (**including** in Section 7.6.1)

The following table in Appendix I was updated to include clarifications to Section 7.5.3:

SCHEDULE OF PBMC COLLECTION

	First QRT	Q 6 Months	INT	PUEV
PBMC Collection at Sites with NL Approval	X*	X	▲	X
TFV-DP and FTC-TP Levels	X*	X	▲	X

*Applies to the participant's first QRT visit following consent for PBMC collection, then every six months thereafter during study participation, **plus PUEV**.

▲ If a scheduled collection is missed, PBMC should be collected at the next completed visit (scheduled or interim), unless the next visit is less than 4 weeks away from the next scheduled PBMC collection, (in which case collection ~~could~~ **should** occur at the latter visit). Participants who are temporarily held or permanently discontinued from study product should continue to have scheduled PBMC collection unless otherwise specified in the MTN-003 SSP Manual.

The above information will be incorporated into the next version of the protocol at a later time if it is amended.