

Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-005

**Expanded Safety and Adherence Study of a Non-medicated Intravaginal Ring,
Version 2.0, dated 19 October 2010**

DAIDS Document ID 10635

Date of Clarification Memorandum: 9 March 2011

Section 1: Summary of Clarifications and Rationale

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB overseeing the study at their site for information. This CM is official MTN-005 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-005. No change in informed consent is necessitated by or included in this CM.

This CM clarifies that vaginal swabs for vaginal flora assessment will be performed at the local laboratory at the India site, and clarifies what adverse events (AEs) will be reported on case report forms (CRFs), and updates the procedures to be performed at the interim visit. Updates to the Protocol Team Roster are also included in this CM.

Section 2: Implementation

Except for modifications to the Protocol Team Roster, text to be deleted is noted by ~~strike through~~ and text to be added is noted below in **bold**.

1. Section 7.9.1, *Local Laboratory Testing, Pelvic Specimens* subsection, eighth bullet added to clarify vaginal swabs for vaginal flora assessment will be processed at the local lab in India.

Pelvic Specimens

- **Vaginal swab for vaginal flora assessment (India site only)**
2. Section 8.4.2, *Reporting Requirements for this Study*, fourth bullet and two sub-bullets have been removed to maintain consistency Section 8.3.1, *Adverse Events*.
 - ~~Study staff will also report on CRFs the following subset of AEs reported by or observed in enrolled participants:~~
 - ~~All genital, genitourinary, and reproductive system AEs~~
 - ~~All AEs of severity Grade 3 or higher~~

3. Appendix I, Schedule of Study Visits and Evaluations, has been updated to indicate that Pap Smear testing will be performed, if clinically indicated, at the Screening Visit only:

Appendix I: Schedule of Study Visits and Evaluations

	SCR	ENR	4W	8W	12W	16W/Study Term	Interim
	Up to and incl. 45 days prior to ENR	Day 0	Must occur within ± 7 days of scheduled visit				
Pap Smear	▲						▲

▲ if clinically indicated ● For group A (randomized to Study IVR) ■ For group A (if permanently discontinued and removed by study clinician)◦ For group A (randomized to Study IVR and removed by study clinician) † Per local standards + For Group A if indicated, + if applicable

4. The following modifications are made to the Protocol Team Roster:

Removed:

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Added:

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