

Letter of Amendment #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

Population Council IND #: 109,767

Letter of Amendment date: 23 May 2012

Site Instruction

The following information impacts the MTN-005 study and must be forwarded to your Institutional Review Board (IRB)/Ethics Committee (EC) as soon as possible for their information and review. This must be approved by your IRB/EC before implementation.

The following information also impacts the sample informed consent. Your IRB/EC will be responsible for determining the process of informing subjects of the contents of this Letter of Amendment (LoA).

Implementation

Upon receiving final IRB/EC and any other applicable Regulatory Entity (RE) approval(s) for this LoA, sites should implement the LoA immediately. Sites are still required to submit an LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). Sites will receive a registration notification for the LoA once the DAIDS PRO verifies that all the required LoA registration documents have been received and are complete. An LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with this letter and any IRB/EC correspondence should be retained in the site's regulatory files.

Summary of Revisions

This LoA revises the anticipated length of study duration, allows for the completion of a final behavioral assessment at a time point other than the 16-Week/Study Termination Visit, if needed, and adds an exit questionnaire for participants at the NARI Arogya Aadhar Clinic CRS site.

Text to be deleted is noted by ~~strikethrough~~ and text to be added is noted below in **bold**.

1. The Protocol Summary and Section 4.4, *Time to Complete Enrollment*, is updated to reflect the revised study duration:

Protocol Summary:

Study Duration: 16 weeks for each participant; ~~419~~ **441** months approximate total study duration

Section 4.4, *Time to Complete Enrollment*:

The approximate time to complete study enrollment is expected to be six months for the US sites and ten months for the India site. The time of total study duration is expected to be a minimum of approximately 4419 months, including the study follow-up period.

2. Section 7.4, *16-Week/Study Termination Visit*, Table 7, the behavioral row and Appendix I: *Schedule of Study Visits and Evaluations* are updated to clarify when the final behavioral assessment should occur:

Behavioral	<ul style="list-style-type: none"> • Administer final behavioral assessment (in the event that a participant drops out terminates of the study participation prior to the 16-Week Visit or permanently discontinues study product prior to the 12-Week Visit, the final behavioral assessment will not be administered according to guidance from the protocol team) • Provide counseling <ul style="list-style-type: none"> ○ Contraceptive ○ HIV testing process ○ HIV/STI risk reduction/male condom • Administer final acceptability assessment (for Group A in the event that use of the study IVR is permanently discontinued at an earlier visit)*
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*=if clinically indicated

3. Section 7.4, *16-Week/Study Termination Visit*, Table 7, behavioral row, a fourth bullet has been added, Section 7.8.2, *Acceptability and Behavioral Change* a second paragraph has been added, Appendix I: *Schedule of Study Visits and Evaluations* and the *Enrollment Sample Informed Consent* have been updated to reflect that an Exit Questionnaire will be administered at the NARI Arogya Aadhar Clinic CRS site in India only.

Table 7: *16-Week/Study Termination Visit*, new fourth bullet:

Behavioral	<ul style="list-style-type: none"> • Administer final exit questionnaire ◇
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◇= required at the NARI CRS

Section 7.8.2, *Acceptability and Behavioral Change*, new second paragraph:

Data Collection on Study Procedures

A final exit questionnaire will be administered to assess participants' perception of the various modes of behavioral data collection used in MTN-005. This will occur at the NARI CRS 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				
Administer final exit interview						◇	

◇= required at the NARI CRS

Appendix V: *Sample Informed Consent Document (Enrollment), Additional Procedures*
section, new 9th bullet:

- **[NARI CRS only] Answer questions about your experience using the computer, filling out the diary cards and talking to study staff. (16-Week Visit)**

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