

Letter of Amendment #02 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: 20 September 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 does not impact 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 Revision

This LoA permanently closes MTN-005 to accrual.

Text to be added is noted below in **bold** font.

1. Section 2.7.2, *Rationale*, the *Study Design*, directly under the *Additional IVR Information – NARI CRS* subsection, a new subsection has been appended to document the permanent discontinuation of MTN-005 study accrual.

Study Permanently Closed to Accrual

The U.S. sites completed enrollment of 102 participants in January of 2012. The NARI Arogya Aadhar Clinic Clinical Research Site in Pune, India, was slated to enroll 150 participants into MTN-005, however as noted in the *Additional IVR Information – NARI CRS*, subsection above, enrollment was paused in June 2012 after 93 participants were enrolled.

The MTN-005 study product will expire on 17-November 2012. Therefore, enrollment needed to be complete by 24-August 2012 in order for participants to adhere to 12 weeks of study product use. Consequently, MTN-005 is permanently closed to accrual, effective immediately.

The final sample size for MTN-005 is n= 195.

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