

CLARIFICATION MEMO #02 TO:

MTN-029/IPM 039

Phase 1 Pharmacokinetic Study of the Dapivirine
Vaginal Ring in Lactating Women

DAIDS Protocol #: 12036

IND#: 108,743

Version 1.0 / 30 June 2015

Clarification Memo Date: 14 July 2016

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-029/IPM 039 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-029/IPM 039. No change in informed consent is necessitated by or included in this CM.

This document clarifies language regarding the exclusionary criterion for participant report of complication of lactation requiring treatment. Additionally, this document updates the Protocol Team Roster to reflect recent staffing changes.

Section 2: Implementation

With the exception of updates to the protocol team roster, text to be added is in **bold**.

- 1.) Section 5.3, *Exclusion Criteria*, Criterion 1d has been modified to specify timing and to clarify that the exclusion criterion applies to *both* milk production (lactation) and breastfeeding, see bolded text below:
 1. Participant report of any of the following:
[...]
 - d. Complication of lactation/**breastfeeding** requiring treatment **within 14 days prior to the Enrollment Visit (Day 0)**, e.g., mastitis

Note: All clinical manifestations must have resolved prior to Enrollment, and treatment must be completed 14 or more days prior to Enrollment.

- 2.) The following individual has been deleted from the Protocol Team Roster:

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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.