

Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

**MTN-024/ IPM 031
Phase 2a Safety Study of a Vaginal Matrix Ring Containing Dapivirine
in a Postmenopausal Female Population**

DAIDS Protocol ID #11915

IND #108,743

Date of Clarification Memorandum: 5 June 2014

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-024/IPM 031 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-024/IPM 031. No change in informed consent is necessitated by or included in this CM.

This CM updates the protocol team roster and clarifies that the 1-Week and 13-Week Follow-Up Phone Call procedures may be conducted in-person.

Section 2: Implementation

With the exception of updates to the protocol team roster, text to be deleted is noted below with a ~~strikethrough~~ and text to be added is in **bold**.

1. The following individuals have been removed from the Protocol Team Roster: Vivian Bragg and Sonia Gor.
2. Section 7.4.5, *Follow-up Phone Calls: 1-Week and 13-Week Study Termination*, is updated to clarify that the 1-Week and 13-Week Study Termination visits may be conducted in-person.

7.4.5 Follow-Up Phone Calls: 1-Week and 13-Week Study Termination*

Study staff will follow-up with participants via phone call one week following the Enrollment Visit and one week following the 12-Week Final Clinic Visit/Early Termination Visit. Study staff will inquire about AEs the participant may have experienced as a result of the study product or procedures performed during the Enrollment Visit or the 12-Week Final Clinic Visit/Early Termination Visit.

Table 11: 1-Week and 13-Week Study Termination Follow-Up Phone Calls*

Component	Procedures
Administrative and Regulatory	<ul style="list-style-type: none">● Reimbursement~
Clinical	<ul style="list-style-type: none">● Record/update AEs● Concomitant medications

~ Sites to reference SOPs, ***Visit procedures may be conducted in-person, see SSP for additional details**

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