Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-023/IPM 030

Phase 2a Safety Study of a Vaginal Ring Containing Dapivirine in Adolescent Females

DAIDS Protocol #11927

IND #108,743

Date of Clarification Memorandum: 29 May 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-023/IPM 030 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-023/IPM 030. No change in informed consent is necessitated by or included in this CM.

This CM updates the protocol team roster, clarifies Section 5.3, Exclusion Criterion Number 2 to note that participants who are diagnosed with an RTI may be offered treatment and enroll in the trial provided that treatment is complete and all symptoms have resolved, and allows for the 1-Week and 13-Week Follow-Up Phone Call procedures to 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 individual has been added to the Protocol Team Roster:

   Lisa Levy, MPH
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   The following individuals have been removed from the Protocol Team Roster: Vivian Bragg and Sonia Gor.

2) The note attached to Section 5.3, Exclusion Criterion Number 2 is updated to clarify that participants who are diagnosed with an RTI may be offered treatment and enroll in MTN-023/IPM 030 provided that treatment is complete and all symptoms have resolved.

   2) Diagnosed with a urinary tract infection (UTI) and/or reproductive tract infection (RTI) at Screening and/or Enrollment

      *Note: Otherwise eligible participants diagnosed with UTI**/RTI** during Screening will be offered treatment and may be enrolled after completing treatment and all symptoms have resolved. If treatment is*

completed and symptoms have resolved within 56 days of obtaining informed consent for Screening, the participant may be enrolled.

3) 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	• Reimbursement~
Clinical	• 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.