Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-044/IPM 053/CCN019 Version 2.0 dated June 7, 2018

A Randomized, Phase 1, Open-Label Study in Healthy HIV-Negative Women to Evaluate the Pharmacokinetics, Safety and Bleeding Patterns Associated with 90-Day Use of Matrix Vaginal Rings Containing 200 mg Dapivirine and 320 mg Levonorgestrel

IND #: 126907

Date of Clarification Memorandum: 3 July 2018

Section 1: Summary of Clarifications and Rationale

The procedures clarified in this Clarification Memorandum (CM) have been approved by the IPM, NICHD and DAIDS Medical Officer and are to be implemented immediately upon issuance. IRB approval of this CM is not required; however, investigators should submit the CM to the IRB/EC overseeing the study at their site for information. This CM is official MTN-044/IPM 053/CCN019 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-044/IPM 053/CCN019.

This CM clarifies the SAE reporting process in Section 8.4.1, updates the text about the provision of study results on ClinicalTrials.gov website and clarifies the signing parties for the Clinical Trial Agreement (CTA) for this study.

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 revisions were made to Section 8.4.1, *Serious Adverse Event Reporting,* second paragraph, last sentence:

   The investigator should complete the SAE section of the Adverse Event Log eCRF within the study Electronic Data Capture (EDC) system which will send the appropriate notifications immediately to the HD Safety Review Team **and SCHARP. SCHARP will notify the** PSRT, **which includes** ~~and~~ appropriate funding agencies staff.

2) The following revisions were made to Section 13.3, *Study Coordination*, first paragraph:

   IPM holds the Investigational New Drug (IND) application for this study. Assignment of all sponsor responsibilities for this study will be specified in a Clinical Trial Agreement (CTA) executed by ~~NICHD~~ **HD** and IPM.

3) The following revisions were made to Section 14, *Publication Policy*:

   NICHD and MTN policies and a CTA between ~~NICHD~~ **HD** and IPM, **and a Confidentiality and Publication agreement between NICHD and IPM** will govern publication of the results of this study. Any presentation, abstract, or manuscript will be submitted by the investigator to the MTN Manuscript Review Committee, DAIDS, NIAID, NIMH, NICHD and IPM for review prior to submission.

4) The following revisions were made to the Sample Informed Consent, under *CLINICALTRIALS.GOV* section:

   A description of this clinical trial will be available on http://www.ClinicalTrials.gov. ~~as required by U.S. Law~~. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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