

**Microbicide Trials Network**

**CLARIFICATION MEMO #01 TO:**

**MTN-036/IPM 047**

**A Phase 1, Randomized Pharmacokinetics and Safety Study of Extended Duration  
Dapivirine Vaginal Rings**

**DAIDS Protocol #: 30009**

**IND#: 108,743**

**Version 1.0 / 28 June 2017**

**Clarification Memo Date: 14 September 2017**

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*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-036/IPM 047 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-036/IPM 047. No change in informed consent is necessitated by or included in this CM.

This document clarifies an inclusion criterion regarding contraception, and updates the version of the Division of AIDS (DAIDS) Table for grading of adverse events.

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*Section 2: Implementation*

Text to be deleted is noted below with a ~~strike through~~, text to be added is in **bold**. This information will be included in the protocol the next time the protocol is updated.

1. Inclusion criterion 9d has been updated:
  - d) having sex exclusively with ~~cis-women~~ **individuals assigned female sex at birth**
2. The version of the DAIDS Table for Grading Adult and Pediatric Adverse Events to be used in this study has been updated throughout the protocol document:

Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, **Corrected** Version 2.1, ~~March~~ **July** 2017

This information will be incorporated into the next version of the protocol when it is updated.