

Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-041 Version 1.0 dated October 31, 2017

Qualitative Assessment of Acceptability of Vaginal Ring (VR) and Oral Pre-exposure Prophylaxis (PrEP) Use during Pregnancy and Breastfeeding

DAIDS Protocol #38161  
A Non-IND Study

Date of Clarification Memorandum: 18 December 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/EC overseeing the study at their site for information. This CM is official MTN-041 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-041. No change in informed consent is necessitated by or included in this CM.

This CM corrects inclusion criterion #8 in Section 5.3, *Inclusion Criteria*, for consistency with how this criterion is worded throughout the rest of the protocol and consent form, and also updates the Protocol Team Roster.

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*Section 2: Implementation*

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

- 1) The following revisions were made to Section 5.3, *Inclusion Criteria*, Inclusion criterion #8:

Identifies as ~~the~~ **a** maternal or paternal grandmother of ~~a~~ **whose** daughter or daughter-in-law ~~who~~ is currently or was recently (within two years) pregnant or breastfeeding

- 2) Protocol Team Roster – Additions:

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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.