

**Microbicide Trials Network**

**CLARIFICATION MEMO #01 TO:**

**MTN-025**

**A Phase 3B Open-Label Follow-on Trial to Assess the Continued Safety of and Adherence to a Vaginal Ring Containing Dapivirine in Women**

**DAIDS Protocol #: 11985**

**IND#: 108,743**

**Version 2.0 / 16 December 2014**

**Letter of Amendment #01 / 11 April 2016**

**Clarification Memo Date: 5 August 2016**

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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-025 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-025. No change in informed consent is necessitated by or included in this CM.

This document clarifies language regarding the insertion of one study vaginal ring at the Enrollment Visit, and adds language to the laboratory section for consistency with other protocol and consent language regarding hair specimen collection. Additionally, this document updates the location of DAIDS laboratory policy and guidance documentation, and 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.) Section 7.3, *Enrollment Visit (Day 0)*: Table 6, *Enrollment Visit* has been modified to correct the omission of an asterisk indicating that the insertion of one study vaginal ring at the Enrollment Visit is an "if indicated" procedure, see bolded text below:

Table 6: Enrollment Visit

<b>Study Product/Supplies</b>	<ul style="list-style-type: none"><li>• Offer condoms</li><li>• Provision of study VR use instructions*</li><li>• Offer and, if accepted, provide study VR(s)</li><li>• Insertion of one study VR*</li><li>• Digital exam by clinician to check VR placement*</li></ul>
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- 2.) Section 7.11, *Laboratory Evaluations*, has been modified to add language at the end of the section regarding hair collection for consistency with similar language elsewhere in the protocol and consent forms.

IPM or MTN Designated Laboratories:

- Study Product- Vaginal Ring
  - Adherence assessment(s)

- **Hair for biomarkers and archive**

- 3.) Section 7.13, *Specimen Collection and Processing*, has been modified to update the URL where the current DAIDS standards of good clinical laboratory practice can be found.

Each study site will adhere to the standards of good clinical laboratory practice

(~~<http://apps.who.int/tdr/publications/tdr-research-publications/gclp-web/pdf/gclp-web.pdf>~~)

(<https://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf>)

- 4.) Section 7.14, *Specimen Handling*, has been modified to update the URL where the current DAIDS Laboratory Policy can be found.

Specimens will be handled in accordance with current requirements for DAIDS Sponsored and/or Funded Laboratories in Clinical Trials-

(~~<http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/documents/labpolicy.pdf>~~)

(<https://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Laboratories.aspx>)

- 5.) Protocol Team Roster-Updates:

- Gonasagrie Nair will be Site Investigator of Record for the Cape Town Emavundleni CRS instead of the CAPRISA eThekweni CRS.
- Logashvari Naidoo will be Site Investigator of Record for the MRC-Chatsworth CRS instead of the MRC-Tongaat CRS.
- Zip codes for all US NIH protocol team roster members changed from 20892 to 20852.
- Addresses for all MTN LOC – FHI 360 protocol team roster members edited to add FHI 360 and remove P.O. Box 21059.
- Ashley Mayo's title changed to Sr. Clinical Research Manager.
- MRC CTU Site Investigator titles for Zakir Gaffoor, Nitesha Jeenarain and Samantha Siva changed to CRS Leader.

- 6.) Protocol Team Roster- Removals: Danielle Crida, Newton Kumwenda, Jeffrey Stringer, Vaneshree Govender, Beth Galaska, Kailazarid Gomez, and Fatima Glyn Zulu.

- 7.) 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.