

**Microbicide Trials Network**

**LETTER OF AMENDMENT #02 TO:**

**MTN-024/ IPM 031  
Phase 2a Safety Study of a Vaginal Matrix Ring Containing Dapivirine in a Postmenopausal  
Female Population**

**Version 1.0 dated 21 March 2013**

**DAIDS Protocol ID: 11915**

**IND #: 108,743**

**Date of Letter of Amendment: 10 April 2014**

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*Site Instruction*

The following information impacts the MTN-024/IPM 031 study and must be forwarded to your Institutional Review Board (IRB)/Ethics Committee (EC) as soon as possible for their information and review. This must be approved by your IRB/EC before implementation. The following information does not impact the sample informed consent, however your IRB/EC will be responsible for determining the process of informing participants of the contents of this letter of amendment, if needed.

*Implementation*

Upon receiving final IRB/EC and any other applicable Regulatory Entity (RE) approval(s) for this LoA, sites should implement the LoA immediately. Sites are still required to submit a LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). Sites will receive a registration notification for the LoA once the DAIDS PRO verifies that all the required LoA registration documents have been received and are complete. A LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with this letter and any IRB/EC correspondence should be retained in the site's regulatory files.

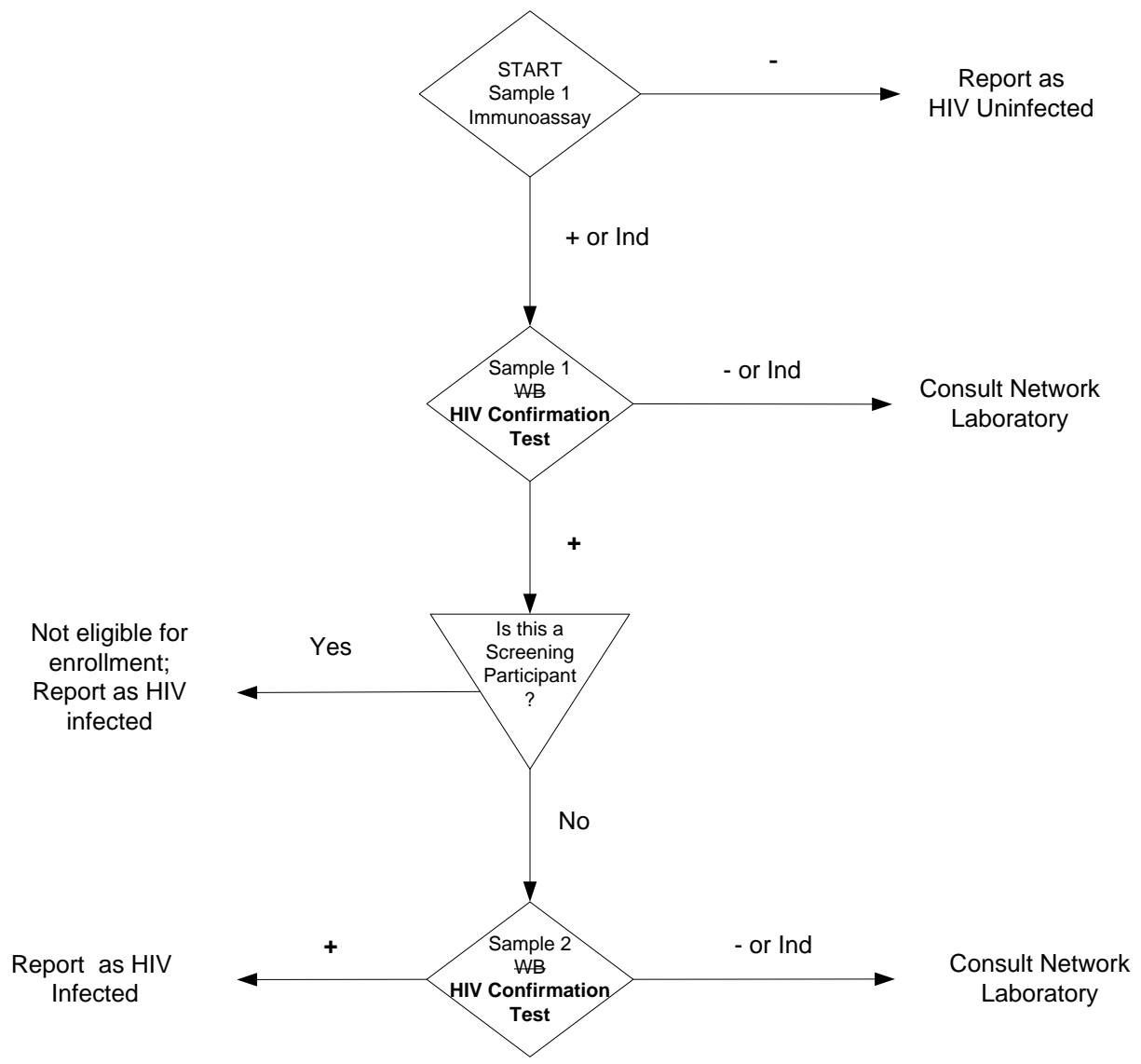
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*Summary of Revisions*

The purpose of this LoA is to allow for the use of alternative assays when confirming HIV serostatus.

Except for modifications to the Protocol Team Roster, text to be deleted is noted by ~~strike through~~ and text to be added is noted below in **bold**.

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1. **APPENDIX II: ALGORITHM FOR HIV ANTIBODY TESTING FOR SCREENING AND ENROLLED PARTICIPANTS**, has been modified to remove the specific assay to confirm HIV serostatus to allow for the use of alternative assays:



Ind: Indeterminate test results

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