

Clarification Memo #02 to:

MTN-020

**A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 3 Safety and Effectiveness Trial
of a Vaginal Matrix Ring Containing Dapivirine for the Prevention of HIV-1 Infection in Women**

DAIDS Document ID#: 11840

IND#: 108,743

Version 1.0 / 28 September 2011

Clarification Memo Date: 12 November 2014

Site Instruction and Implementation

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-020 documentation and is effective immediately. A copy of this CM must be retained in the study site's Essential Documents file for MTN-020. No change in informed consent is necessitated by or included in this CM.

Summary of Revisions

The purpose of this CM to clarify protocol text that was previously modified in MTN-020 LoA #01 (issued on November 7, 2011) to ensure that the collection of plasma, as well as the completion of CD4+ T cell count and HIV-1 RNA PCR, continues for the duration of HIV-positive participants' follow-up.

Except for modifications to the Protocol Team Roster, text to be added is noted below in **bold**.

Implementation

1. The following Protocol Team Roster has been updated as follows:

Jennifer M. Berthiaume, MPH, MSW
Project Manager
FHCRC – SCHARP
1100 Fairview Ave. North, E3-314
P.O. Box 19024
Seattle, WA 98109-1024
Phone: 206-667-1230
Fax: 206-667-4812
Email: jberthia@scharp.org

Katie Doolan Schwartz, MPH
Senior Clinical Research Manager
FHI 360
359 Blackwell St., Ste. 200
Durham, NC 27701 USA
Phone: 919-544-7040 Ext.11425
Fax: 919-544-7261
Email: kschwartz@fhi360.org

Ashley Mayo, MPH
Clinical Research Manager
FHI 360
359 Blackwell St., Ste. 200
Durham, NC 27701 USA
Phone: 919-544-7040 Ext. 11164
Fax: 919-544-0904
Email: amayo@fhi360.org

Rachel Scheckter, MPH, IBCLC
Clinical Research Manager
FHI 360
359 Blackwell St., Ste. 200
Durham, NC 27701 USA
Phone: 919-544-7040 Ext. 11392
Fax: 919-544-7261
Email: rscheckter@fhi360.org

2. Section 7.5.1, *Participants Who Become Infected with HIV-1*, fourth paragraph, second bullet, has been updated to clarify the frequency of the collection of plasma as well as the completion of CD4+ T cell count and HIV-1 RNA PCR, in order to maintain consistency with MTN-020 LoA #01 issued on November 7, 2011.

- The 1st, 3rd, 6th, 12th, and 18th scheduled ASPIRE visit **and every 6 months** after the participant is informed of her HIV-infection.

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