

**LETTER OF AMENDMENT #01 TO:**

**MTN-032**

**Assessment of ASPIRE and HOPE Adherence**

**Version 2.0, dated 5 September 2017**

**DAIDS Protocol #12058  
A Non-IND Study**

**Date of Letter of Amendment: 28 March 2018**

---

*Site Instruction*

The following information impacts the MTN-032 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. Your IRB/EC will be responsible for determining the process of informing participants of the contents of this Letter of Amendment (LoA).

*Implementation*

Upon receiving final IRB/EC and any other applicable Regulatory Entity (RE) approval(s) for this LoA, sites should implement the LoA immediately. DAIDS sites are still required to submit a LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). DAIDS 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.

*Summary of Revisions*

This LoA does not impact the overall design or the study visit schedule for MTN-032. The primary purpose of this LoA is to correct protocol language related to the timing when current or former MTN-025 study participants are approached for permission to allow their male partners to be contacted for participation in MTN-032 Phase 2. This LoA also updates the Protocol Team Roster and the Investigator Signature Form.

Text to be deleted is noted by ~~strike through~~ and text to be added is noted below in **bold**.

---

*Detailed Listing of Revisions*

1. The following revision has been made to the second sentence in the second paragraph of Section 13.5, *Informed Consent Process*:

Furthermore, **current and former HOPE** participants ~~who consent to have their male partners contacted while in HOPE~~ will be asked to provide written consent ~~at the HOPE PUEV~~ for MTN-032 study staff to contact their male partners for recruitment into MTN-032 **at or after the HOPE PUEV and before the male partners are contacted**.

*Additional minor modifications include:*

2. Protocol Team Roster – Removals: Makandwe Nyirenda, Felix Mhlanga.
3. Protocol Team Roster – Additions:

**Neetha Morar, MMedSci**  
**Site Investigator of Record**  
MRC- HIV Prevention Research Unit  
South African Medical Research Council  
123 Jan Hofmeyr Road, Westville, 3630  
Durban, KwaZulu-Natal, South Africa  
Phone: 27-31-242-3600  
Fax: 27-31-242-3800  
E-mail: Neetha.Morar@mrc.ac.za

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

**APPENDIX: MTN-032 INVESTIGATOR SIGNATURE FORM**

**MTN-032**

**Assessment of ASPIRE and HOPE Adherence**

**INVESTIGATOR SIGNATURE FORM**

Version 2.0; September 5, 2017  
Letter of Amendment #01; March 28, 2018

A Study of the Microbicide Trials Network

**Funded by:**

Division of AIDS (DAIDS), US National Institute of Allergy and Infectious Diseases  
US Eunice Kennedy Shriver National Institute of Child Health and Human Development  
US National Institute of Mental Health  
US National Institutes of Health (NIH)

**IND Sponsor:**

A Non-IND Study (DAIDS Protocol ID: 12058)

I, the Investigator of Record (IoR), agree to conduct this study in full accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug Administration (FDA) regulations; standards of the International Conference for Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., NIH, DAIDS) and institutional policies.

I agree to maintain all study documentation for a minimum of three years after submission of the site's final Financial Status Report to DAIDS, unless otherwise specified by DAIDS or the Microbicide Trials Network (MTN) Leadership and Operations Center (LOC). These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. DAIDS will inform the investigator/institution as to when these documents no longer need to be retained.

I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study.

\_\_\_\_\_  
Name of Investigator of Record (print)

\_\_\_\_\_  
Signature of Investigator of Record

\_\_\_\_\_  
Date