

LETTER OF AMENDMENT #01 TO:

MTN-042B

Assessing Baseline Pregnancy Outcomes in Sub-Saharan Africa

Version 1.0, dated January 16, 2019

**DAIDS Protocol #38607
A Non-IND Study**

Date of Letter of Amendment: 5 December 2019

Site Instruction

The following information impacts the MTN-042B 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.

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.

Summary of Revisions

This LoA does not impact the overall design of MTN-042B. The purpose of this LoA is to allow sites the flexibility to abstract data from birth records of women at more than two facilities, if needed to reach their target number of deliveries. This will only apply to the Zimbabwe MTN-042B site since the other three sites have already achieved their targets. This LoA will also update the protocol team roster.

Unless otherwise noted, text to be deleted is noted by ~~strikethrough~~ and text to be added is noted below in **bold**.

Detailed Listing of Revisions

1. The following revision was made to "Study Population" in *Protocol Summary* to give sites that have not reached their target number of deliveries the flexibility to abstract birth records of women delivering or receiving immediate postpartum care at more than two facilities affiliated with their site:

All women delivering or receiving immediate postpartum care (within one week of delivery) at one or ~~two~~ **more primary care and referral** facilities affiliated with each of the 4 sites, ~~a primary care facility and a referral facility~~

2. Protocol Team Roster – Deletions: Jennifer Thomas and Nicole Macagna.

3. Protocol Signature Page was updated to include Letter of Amendment #1; it is appended to the end of this document.

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

MTN-042B

Assessing Baseline Pregnancy Outcomes in Sub-Saharan Africa

INVESTIGATOR SIGNATURE FORM

Version 1.0; January 16, 2019
Letter of Amendment #01; December 5, 2019
A Study of the Microbicide Trials Network

Funded by:

Division of AIDS (DAIDS), US National Institute of Allergy and Infectious Diseases
US National Institutes of Health (NIH)

IND Sponsor:

A Non-IND Study (DAIDS Protocol ID: 38607)

I, the Investigator of Record, 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); standards of the International Council on Harmonisation (ICH) Guideline for Good Clinical Practice (E6); Institutional Review Board/Independent 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 MTN study records in accordance with protocol-specified protections of participants' confidentiality and with site IRB/IEC policies and procedures. Study records must be maintained on-site for the entire implementation period of the study and a minimum of at least three years after completion of research as per 45 CFR 46.115 (b). DAIDS/designee 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