

Microbicide Trials Network
CLARIFICATION MEMO #04 TO:

MTN-015
An Observational Cohort Study of Women following HIV-1 Seroconversion in
Microbicide Trials, Version 1.0, 19 June 2007

DAIDS Document ID 10529

Date of Clarification Memorandum: 07 July 2009

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-015 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-015. No change in informed consent is necessitated by or included in this CM.

The primary goal for this CM is to update the Protocol Team Roster.

Section 2: Implementation

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

1. The following updates are made to the Protocol Team Roster:

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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.