Microbicide Trials Network

CLARIFICATION MEMO #07 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: 22 August 2011

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 clarify that recently completed procedures from other MTN studies may be used for MTN-015. This will eliminate redundant testing performed in MTN-015 as a result of prescribed procedures in a parent protocol.

Section 2: Implementation

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

1. The following clarification is being made to Section 7.0, Study Procedures:

Procedures from the parent MTN study/(ies) that a participant is enrolled in may be utilized for MTN-015, if performed in the past 30 days, if the test kit, laboratory and specified clinical assessments, and method of data collection are the same for both studies. In addition, the MTN NL must approve laboratory tests and documented permission from MTN NL for laboratory substitutions must be obtained. See MTN-015 Study-Specific Procedures Manual at www.mtnstopshiv.org for additional information.

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