Microbicide Trials Network

CLARIFICATION MEMO #08 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: 16 November 2012

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 the duration of the study within the *Protocol Summary* and Section 4.5, *Expected Duration of Participation*.

Section 2: Implementation

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

1. Edits have been made to the *Protocol Summary* and to Section 4.5, *Expected Duration of Participation* to clarify participants time on study:

   Protocol Summary:
   Study Duration: Until May 31st, 2013, **for HPTN 035 participants. Follow-up will continue until the end of 2013 for MTN-003 (VOICE) and MTN-020 (ASPIRE) participants,** with **the** possibility of extension

   Section 4.5, *Expected Duration of Participation*:
   The expected duration of participation for an individual participant is until May 31st 2013 **for HPTN 035 participants. Follow-up will continue until the end of 2013 for MTN-003 (VOICE) and MTN-020 (ASPIRE) participants, with the possibility of extension**.

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