

Microbicide Trials Network
CLARIFICATION MEMO #02 TO:

MTN-016
DAIDS Document ID #10737

HIV Prevention Agent Pregnancy Exposure Registry:
EMBRACE Study

Version 1.0 / 17 December 2008

Date of Clarification Memorandum: 9 April 2013

Section 1: Summary of Clarifications and Rationale

The item clarified in this Clarification Memorandum (CM) has been approved by the NIAID Medical Officer and is effective immediately upon issuance. IRB approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/EC overseeing the study at their site for information. This CM is official MTN-016 documentation. A copy of this CM must be retained in each study site's Essential Documents file for MTN-016. 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.

Section 2: Implementation

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

1. Edits have been made to the Protocol Summary to clarify anticipated study duration.

Study Duration: Until ~~May~~ **December** 31st, 2013, with possibility of extension

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