

**Microbicide Trials Network
CLARIFICATION MEMO #01 TO:**

**MTN-016
DAIDS Document ID #10622**

**HIV Prevention Agent Pregnancy Exposure Registry:
EMBRACE Study**

Version 1.0 / 17 December 2008

Date of Clarification Memorandum: 01 July 2009

Section 1: Summary of Clarifications and Rationale

The items 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/EC overseeing the study at their site for information. This CM is official MTN-016 documentation and is effective immediately. 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 update the Protocol Team Roster.

Section 2: Implementation

1. The Protocol Team Roster is updated to reflect modifications to the Protocol Team.

The following additions are made to the Protocol Team Roster:

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The following listings are deleted from the Protocol Team Roster: Annelies Van Rie and Shay Ganesh.

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