

Microbicide Trials Network

Clarification Memorandum #01 to:

MTN-005

Expanded Safety and Acceptability Study of a Non-medicated Intravaginal Ring, Version 1.0, dated 03 April 2008

DAIDS PROTOCOL #10635

A Non-IND Study

Date of Clarification Memorandum: 22 April 2008

Section 1: Summary of Clarifications and Rationale

The procedures 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-005 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-005. No change in informed consent is necessitated or included in this CM.

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

Section 2: Implementation

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

1. The Protocol Team Roster has been updated.

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2. Section 1.4 Site Investigators has been updated.

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