Microbicide Trials Network
CLARIFICATION MEMO #01 TO:

MTN-003
DAIDS Document ID #10622

Phase 2B Safety and Effectiveness Study of Tenofovir 1% Gel, Tenofovir Disoproxil Fumarate Tablet and Emtricitabine/Tenofovir Disoproxil Fumarate Tablet for the Prevention of HIV Infection in Women

Version 1.0 / 22 May 2008
IND #: 55,690

Date of Clarification Memorandum: 27 May 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/EC 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-003 documentation and is effective immediately. A copy of this CM must be retained in each study site’s Essential Documents file for MTN-003. 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. A clarification to Section 8.2, Adverse Events Definitions and Reporting Requirements is also made in this CM.

Section 2: Implementation

With the exception of the modifications to the Protocol Team Roster, text to be deleted is noted by strikethrough and text to be added is noted below in bold.

1. The Protocol Team Roster is updated to reflect modifications to the Protocol Team and updates to contact information.

The following additions are made to the Protocol Team Roster:

Kathy Mngadi, MBChB, MPhil, Dip HIV Man SA, Dip Epi
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The following listings have updated contact information:

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2. A note is added to the end of the fifth paragraph, first bullet in Section 8.2, Adverse Events Definitions and Reporting Requirements, to clarify the grading for glycosuria.

*Note: The severity of glycosuria will be graded using the same grading scale as for proteinuria.*