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
Site Investigator
The Aurum Institute Klerksdorp, Jade Square Building
Cnr Oliver Tambo and Margeretha Prinsloo Streets
Klerksdorp, 2571 South Africa
Phone: 27-18-406-4214
Fax: 27-18-406-4240
Email: kmngadi@auruminstitute.org

Thesla Palanee, MMed Sci, PhD
Site Investigator
Reproductive Health and HIV Research Unit
Tshireletso Wellness Centre
Chris Hani Baragwanath Hospital P.O. Bertsham 2013
Soweto, Johannesburg 2013 South Africa
Phone: 27-2711-9899269-269
Fax: 27-2711-9899294
Email: tpalanee@rhru.co.za

The following listings have updated contact information:

Katherine Bunge, MD
MTN Protocol Safety Physician
Magee-Womens Hospital of UPMC
300 Halket Street
Pittsburgh, PA 15213 USA
Phone: 412-917-9936
Fax: 412-641-6170
Email: kbunge@mail.magee.edu

Henry L. Gabelnick, PhD
CONRAD Representative
CONRAD
Eastern Virginia Medical School
1611 North Kent Street
Arlington, VA 22209 USA
Phone: 703-524-4744
Fax: 703-524-4770
Email: hgabelnick@conrad.org

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.