Microbicide Trials Network
CLARIFICATION MEMO #01 TO:

RMP-02/MTN-006
A two-site, Phase 1, partially-blinded, placebo-controlled safety, acceptability, and pharmacokinetic trial of topical, vaginally-formulated tenofovir 1% gel applied rectally compared with oral 300 mg tenofovir disoproxil fumarate in HIV-1 seronegative adults

Version 1.0/07 April 2009
DAIDS Document ID #10769
CONRAD IND # 73, 382

Date of Clarification Memorandum: 24 April 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 overseeing the study at their site for information. This CM is official RMP-02/MTN-006 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for RMP-02/MTN-006. No change in informed consent is necessitated by or included in this CM.

The primary goal for this CM is to indicate Ross Cranston as the Site Investigator for the Pitt CRS.

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 is updated to reflect Ross Cranston as the Site Investigator for the Pitt CRS:

The Protocol Team Roster is edited as follows:

Ross D. Cranston, MD FRCP
Site Investigator
Division of Infectious Disease
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3601 Fifth Avenue
Pittsburgh, PA 15213 USA
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Section 1.4, Site Investigators, is updated as follows:

Site Investigator: ~~Ian McGowan, MD, PhD, FRCP~~ **Ross Cranston, MD FRCP**

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