Microbicide Trials Network
CLARIFICATION MEMO #02 TO:

MTN-003C
DAIDS Document ID #10746

Household and Community Level Factors Associated with Study Product Adherence in VOICE: A Substudy of MTN-003

Version 1.0 / 15 July 2009

Date of Clarification Memorandum: 24 November 2010

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-003C. No change in informed consent is necessitated by or included in this CM.

This CM provides clarification on the following items:

- Updates to the Protocol Team Roster
- Coenrollment
- Timing of Focus Group Discussions with CAB members
- Entities that may audit VOICE C

Section 2: Implementation

1. The following modifications are made to the Protocol Team Roster:

   The following individuals are removed from the roster: Mala Shah and Daniel Gondwe

   The following individual is added to the roster:

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2. Section 5.10, Co-enrollment Guidelines, is updated to clarify that VOICE-C participants may enroll in one group:

   For this substudy, all participants in Group 1 will be participants in the VOICE trial. Therefore, the VOICE guidelines for co-enrollment into other studies apply to this substudy.

   There are no ~~co-enrollment~~ restrictions **regarding enrollment into other trials** for participants in Groups 2, 3 and 4. **Participants in Groups 1, 2, 3, and 4 may only be enrolled into one VOICE-C group.**

3. Section 7.2.3, Focus Group Discussion Procedures, third paragraph, first full sentence the timing of the focus group discussion is updated.

   <u>CAB Members</u>
   FGDs with CAB members will occur **approximately** every six months for the duration of the study.

4. Section 13, Human Subjects Protections, is updated to allow for an audit of VOICE C by the FDA.

   Site investigators will make efforts to minimize risks to participants. Participants and study staff members will take part in a thorough informed consent process. Before beginning the study, the IoR will have obtained IRB/EC approval. The IoR will permit audits by the **FDA,** NIH or any of their appointed agents.