

**Microbicide Trials Network  
CLARIFICATION MEMO #04 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: 1 February 2012**

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*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-003C documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-003C (VOICE-C). No change in informed consent is necessitated by or included in this CM.

The purpose of this CM is to clarify that when a potential participant stops using VOICE study product as part of the normal course of VOICE study participation they will still be eligible per inclusion/exclusion criteria to enroll in MTN-003C. In addition, this document clarifies that participants may consent to Focus Group Discussion (FGD) procedures on the day of the FGD or prior to the FGD.

Text to be added is noted in bold.

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*Section 2: Implementation*

1. A note has been added to Exclusion Criteria number one in Section 5.3, *Exclusion Criteria: Group 1 (VOICE Participants)*, to clarify that the criteria only applies to participants who have been discontinued from study product use by the site IoR for a reason other than the natural termination of participation:

- 1) Permanently or long term (> 2 months) discontinued from study product use by the site Investigator of Record (IoR)/designee, per the specifications of the VOICE protocol, by the time of the scheduled ethnographic visit, IDI, or FGD

**Note: This criterion does not apply to participants who discontinue study product use as a result of completing VOICE protocol requirements.**

2. Edits are made to Section 7.3.2, *Focus Group Discussion Procedures*, to clarify that Focus Group Discussion participants who have previously signed the informed consent do not need to re-sign the informed consent at the FGD:

Once participant questions are thoroughly addressed, participants who wish to participate in the FGD will be asked to sign or make their mark on the informed consent document, **if not previously completed**, and remain present for the FGD.

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