

**Microbicide Trials Network  
CLARIFICATION MEMO #03 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: 16 November 2011**

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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-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 (VOICE-C). No change in informed consent is necessitated by or included in this CM.

The purpose of this clarification memo is to allow the MTN-003C protocol to respond to changes to the parent protocol as a result of DSMB or SMC recommendations. Any modifications to the parent protocol and their consequent changes to VOICE-C operations will be documented with notes to file and/or other site developed guidance documents.

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

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*Section 2: Implementation*

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

The following individual is removed from the roster: Katharine Rivett

The following addition is made to the Protocol Team Roster:

**Miriam Hartmann, MPH**  
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1. Edits are made to Section 4.1, Identification of Study Design, a new paragraph has been added to clarify that changes to the parent protocol may result in modifications to the VOICE-C protocol:

**MTN-003C is an exploratory substudy of MTN-003 (VOICE), thus any changes to the parent protocol, such as protocol modification(s) or early study termination as a result of Data and Safety Monitoring Board or Study Monitoring Committee recommendations may impact MTN-003C. Alterations to study operations, implementation or adjustments in timelines may be required as a result of changes to VOICE.**