

**Microbicide Trials Network**  
**CLARIFICATION MEMO #02 TO:**  
**MTN-003B**  
**Bone Mineral Density Substudy**  
**Ancillary Study to MTN-003 (VOICE)**

**Version 1.0/14 July 2008**  
**DAIDS Document ID 10709**  
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**Date of Clarification Memorandum: 16 September 2009**

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*Section 1: Summary of Clarifications and Rationale*

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officers 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 MTN-003B documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-003B. No change in informed consent is necessitated by or included in this CM.

The primary goal of this CM is to allow height and weight measurements taken at a MTN-003 study visit to be used at the MTN-003B study visit if the MTN-003 study visit takes place no more than 14 days prior to the MTN-003B study visit. This CM also provides further clarification regarding timing of the DXA scan at the Enrollment Visit. Updates to the Protocol Team Roster are also included.

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*Section 2: Implementation*

With exceptions to modifications to the Protocol Team Roster, text to be deleted is noted by ~~strikethrough~~.

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

The following individuals have been added to the Protocol Team Roster:

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The following individuals have been removed from the Protocol Team Roster: Nomapondo Barnabas, Missy Cianciola, David Humiston, Corey Kelly, Morenike Ukpang.

2. The following sections have been updated to allow height and weight measured at VOICE Study Visits to be used at MTN-003B Study Visits.

Section 7.1, Schedule of Study Visits, Table 1: Schedule of BMD Substudy Visits and Evaluations

Nutrition Assessment – Anthropometric (height and weight)**	X	X	X
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**\*\* Height and weight measurements performed and documented for VOICE within 14 days (inclusive) of an MTN-003B visit may be used for MTN-003B**

Section 7.2.2, Anthropometric and Clinical Procedures, third bullet:

- Nutrition assessment - anthropometric (height and weight) **Note: Height and weight measurements performed and documented for VOICE within 14 days (inclusive) of an MTN-003B visit may be used for MTN-003B**

Section 7.3.2, Anthropometric and Clinical Procedures, second bullet:

- Nutrition assessment - anthropometric (height and weight) **Note: Height and weight measurements performed and documented for VOICE within 14 days (inclusive) of an MTN-003B visit may be used for MTN-003B**

3. The timing of the DXA scan is further clarified in Section 7.1, Schedule of Study Visits, end of first paragraph:

**As indicated in the SSP Manual, all MTN-003B visits may be conducted as split visits.**

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