Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-003B
Bone Mineral Density Substudy
Ancillary Study to MTN-003 (VOICE)

Version 1.0/14 July 2008
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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 goals for this CM are to clarify the examples of medications listed in Exclusion Criterion #2. Medroxyprogesterone acetate is removed from the list of examples. This clarification is consistent with the following sections of the protocol:

- Section 2.2.1, which describes the expected bone mineral density of MTN-003 participants, and the rationale for studying the possible contributory effect of medroxyprogesterone acetate on bone mineral density.
- The Sample Informed Consent Form, which lists "shot" (depot medroxyprogesterone acetate) as an effective contraception method for study participants.

Section 2: Implementation

Text to be deleted is noted by ~~strikethrough~~.

1. In Section 5.3, Exclusion Criteria, text is edited as follows:

    2. Has a medical condition known to affect bone (e.g., hyperparathyroidism, bone cancer) or taking any medication known to affect bone (e.g., glucocorticoids, heparin, warfarin, cyclosporine, ~~medroxyprogesterone acetate,~~ cancer drugs, and thyroid hormone).

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