

Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-003-P-01

The Wisebag Observational Pilot Study: Feasibility, Acceptability and Performance of an Electronic Event-based Monitoring System (Wisebag)

DAIDS Document ID: 11835

Date of Clarification Memorandum: 27 June 2011

Site Instruction and Summary of Clarification

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer 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-003-P-01 documentation and is effective immediately. A copy of this CM must be retained in the study site's Essential Documents file for MTN-003-P-01. No change in informed consent is necessitated by or included in this CM.

The primary goal of this CM is to clarify that participants who have tested HIV negative in the past 90 days will be eligible for the Wisebag Observational Pilot Study. This modification will permit VOICE screen outs who meet study eligibility criteria to participate, regardless of when the VOICE HIV testing occurred.

Implementation

Text to be deleted is noted by ~~strikethrough~~ and text to be added is noted below in **bold**.

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1. In Section 5.2, *Inclusion Criteria*, sixth numbered bullet, clarifies requirements for Wisebag Pilot participants to be tested for HIV serostatus within 90 days of enrollment:
 - 6) Has tested HIV-negative within 90 days of enrollment, ~~per VOICE screening laboratory results~~
 2. In Section 7.1, *Screening and Enrollment*, first paragraph, first sentence, has been removed to allow for the enrollment of VOICE screen-out participants regardless of when the VOICE Screening occurred:

~~The Screening and Enrollment Visit for the Wisebag pilot should take place within approximately 4 weeks of the last VOICE Screening Visit; however participants may be enrolled up to 90 days after the date of the last VOICE Screening Visit.~~

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