

Microbicide Trials Network

CLARIFICATION MEMO #06 TO:

MTN-015

An Observational Cohort Study of Women following HIV-1 Seroconversion in Microbicide Trials, Version 1.0, 19 June 2007

DAIDS Document ID 10529

Date of Clarification Memorandum: 8 November 2010

Section 1: Summary of Clarifications and Rationale

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-015 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-015. No change in informed consent is necessitated by or included in this CM.

The primary goal for this CM is to clarify that Pap smear testing will only be done if clinically indicated throughout the study. This change eliminates redundant Pap smear testing performed in MTN-015 as a result of prescribed procedures in a parent protocol. Updates to the Protocol Team Roster are also included in this CM.

Section 2: Implementation

Except for modifications to the Protocol Team Roster, text to be deleted is noted by ~~strikethrough~~ and text to be added is noted below in **bold**.

1. The following updates are made to the Protocol Team Roster:

The following individual has been added to the Protocol Team Roster:

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The following individuals were removed from the Protocol Team Roster: Mala Shah and Lei Wang.

2. Appendix I, Schedule of Study Visits and Evaluations, Pap Smear at Selected Sites is updated to maintain consistency with the protocol by clarifying that Pap Smear testing should be performed at 6 month intervals in the first year after seroconversion, and then annually if the initial tests are negative or as indicated:

Appendix I: Schedule of Study Visits and Evaluations

	Screening and Enrollment	Month 1 Post-Seroconversion	Month 3 Post-Seroconversion	Mo. 6/Q6 Mo. Post-Seroconversion	Week 2, Month 1, Month 3 Post-ART Initiation	Month 6 and Q6 Months Visits After Initiation of ART	Final Visit
PAP Smear at Selected Sites	✕†	▲/†	▲/†	▲/† (Annual)	▲/†	▲/† (Annual)	▲/†

X=protocol-defined procedure; ▲=performed as indicated; *If ART is begun more than 24 months after identification of seroconversion, then the Follow-Up Behavioral Questionnaire is omitted at post-ART visits. †PAP smears should be done at 6 month intervals in the first year after seroconversion, and then annually if the initial tests are negative.

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