

Clarification Memo # 1 to:

**HPTN 069: A Phase II Randomized, Double-Blind, Study of the Safety and Tolerability of Maraviroc (MVC), Maraviroc + Emtricitabine (MVC+FTC), Maraviroc + Tenofovir disoproxil fumarate (MVC+TDF), or Tenofovir disoproxil fumarate + Emtricitabine (TDF+FTC) for Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission in At-Risk Men Who Have Sex with Men and in At-Risk Women, Version 3.0,
Dated January 3, 2013**

Final Version: 13 January 2014

Summary of Revisions and Rationale

1. This memorandum clarifies that urine collected for protein and glucose urinalysis should not be collected during a woman's menses.
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Implementation

The procedures clarified in this memorandum have been approved by the Division of AIDS (DAIDS) Medical Officer and are to be implemented immediately upon issuance. IRB approval of HPTN 069 Protocol Clarification Memo # 1 to HPTN 069 V. 3.0 is not required by the sponsor; however, sites may submit the clarification memo to the responsible IRBs for their information.

No change in the informed consent forms is necessitated by or included in this Clarification Memo.

The modifications included in this Clarification Memo will be incorporated into the next full protocol amendment. Text noted below by strikethrough will be deleted; text appearing below in **bold** will be added.

Revision 1 Appendix IV – Toxicity Management

A footnote sentence will be added to the proteinuria chart in the toxicity management table stating:

“Urine should not be collected during a woman’s menses as abnormal or invalid results may occur. A woman should be rescheduled for urinalysis when menstruation is complete.”