

Clarification Memo # 2 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, Version 2.0, dated April 09, 2012

Final Version: 24 August 2012

Summary of Revisions and Rationale

1. Urinalysis is to be completed at Screening, Weeks 8, 24, 48 and 49. The Schedule of Procedures and Evaluations (SOE) erroneously left off the superscript for footnote #5 in the urinalysis block for Weeks 8, 16, 32 and 40. Footnote #5 denotes that a test is completed only at the Week 8 visit. The test is not to be completed at Weeks 16, 32 and 40. This information is correct in Section 5.4 and the SSP. This change corrects the SOE error.

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 # 2 to HPTN 069 V. 2.0 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 Schedule of Procedures and Evaluations (SOE)

	Screening	Enr	Wk 2	Wk4	Wk 8, 16, 32, 40
HIV RNA for acute HIV infection ⁸	X				
HIV testing ²	X	X	X	X	X
HBV serology ⁹	X				
HCV serology ⁹		X			
CBC with differential and platelets	X		X	X	X
Chemistry panel ¹⁰	X		X	X	X
LFTs (AST, ALT, total bilirubin, alkaline phosphatase)	X		X	X	X
Lipid profile (fasting 8 -- or preferably, 12-- hrs - see Section 5.2)		X			
25-OH-Vitamin D level	X				
Parathyroid (PTH) level	X				
Urinalysis ¹¹	X				X⁵
Urinary phosphate and urinary creatinine	X				X⁵