

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, Version 2.0, dated April 09, 2012

Final Version: 26 April 2012

Summary of Revisions and Rationale

1. The number of days for collecting laboratory specimens at screening is incorrectly listed as 30 days in Section 3.1 of the protocol. The number of days should be 45 days, which is consistent with other sections of the protocol (e.g. Section 5.1).

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. 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 Section 3.1 Inclusion Criteria, fifth bullet

The following laboratory values must be from specimens obtained within ~~30~~ **45** days prior to study enrollment: