Clarification Memo # 3 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 September 2012

Summary of Revisions and Rationale

1. Section 4.1 of the protocol states that each of the three study products are to be taken with food. However, according to the manufacturers' package inserts, the study products can be taken with or without food.
2. To clarify wording in the protocol, Footnote 9 of Appendix I is amended to more clearly state the timing of Hepatitis B and anti-HCV antibody testing as it is stated in Sections 5.1 and 5.2 of the protocol. Hepatitis B testing is to occur at the Screening visit for all participants. Anti-HCV antibody testing is scheduled for the Enrollment visit but may be done at screening, for logistical purposes.

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 # 3 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 4.1 Study Product Regimens/Administration/Formulation Content (fourth bullet)

- In each study arm, participants will take the three study products orally once daily with **or without** food.

Revision 2 Appendix I – Schedule of Procedures and Evaluations, Footnote 9

HBsAg, HBsAb, and HBCoreAb tests **will be performed at Screening and** ~~as well as~~ anti-HCV antibody tests will be performed at ~~Screening and~~ Enrollment~~, respectively~~. **However, for logistical purposes, the anti-HCV testing may be completed at Screening. In these cases, the results obtained during screening will be used as the Baseline measurement.** Participants who are HBsAg positive will be referred for care and are not eligible for enrollment. Participants who do not have evidence of immunity to HBV (e.g., negative HBsAb) will be referred for HBV vaccination. Evidence of immunity to HBV is not required for enrollment. **Participants who test positive for the anti-HCV antibody are eligible to be on the study and will be referred for care.**