

Clarification Memo # 4 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: 25 September 2012

Summary of Revisions and Rationale

1. The use of **actual** body weight (in kg) should be used instead of **lean** body weight in the Cockcroft-Gault formula for calculating creatinine clearance. This corrects an error in Footnote 10 of Appendix I.
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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 # 4 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 Appendix I – Schedule of Procedures and Evaluations, Footnote 10

The chemistry panel includes: sodium, potassium, chloride, CO₂, glucose, creatinine, blood urea nitrogen, phosphate, creatinine clearance calculated using the Cockcroft-Gault formula, where CrCl (male) in mL/min = [(140 – age in years) x (~~lean~~**actual** body weight in kg)] / (72 x serum creatinine in mg/dL). If any abnormalities are observed at screening that do not meet the criteria for exclusion from the study, repeat testing and/or further evaluation may be performed at the discretion of study personnel prior to enrollment.