

Microbicide Trials Network

CLARIFICATION MEMO #02 TO:  
MTN-017

**A Phase 2 Randomized Sequence Open Label Expanded Safety and Acceptability Study of Oral Emtricitabine/Tenofovir Disoproxil Fumarate Tablet and Rectally-Applied Tenofovir Reduced-Glycerin 1% Gel**

DAIDS Protocol #11857

IND #73,382

Date of Clarification Memorandum: 27 February 2014

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*Section 1: Summary of Clarifications and Rationale*

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB overseeing the study at their site for information. This CM is official MTN-017 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-017. No change in informed consent is necessitated by or included in this CM.

This CM updates an exclusion criterion to clarify that symptoms suggestive of acute HIV seroconversion are not exclusionary in the presence of a concurrent negative HIV virologic test (HIV viral load), clarifies the BAT 24 dosing regimen, notes that rectal bleeding clinically assessed to be expected following insertion of a lubricated anoscope or during swab/sponge collection is not to be reported as an AE, and for consistency with the SIC adds the risks associated with the insertion of an anoscope.

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*Section 2: Implementation*

Text to be deleted is noted below with a ~~strike through~~ and text to be added is in **bold**.

1. Section 5.3, *Exclusion Criteria*, has been modified to clarify the acute HIV seroconversion criterion:
  8. Symptoms suggestive of acute HIV seroconversion at Screening and Enrollment  
**Note: Symptoms suggestive of acute HIV seroconversion are not exclusionary in the presence of a concurrent negative HIV virologic test (HIV viral load).**
2. Section 6.2.2, *Tenofovir Reduced-Glycerin 1% Gel, RAI-Associated Tenofovir Reduced-Glycerin 1% Gel* Section, fourth sentence  

In the event that a participant does not engage in RAI in the preceding 6 days they will receive instructions to apply gel using the BAT 24 regimen on the 7<sup>th</sup> day **or use 2 doses of product at least once per week on a day that is convenient for them.**
3. Section 8.4.2, *Reporting Requirements for this Study*, has been revised to include a note indicating that rectal bleeding clinically assessed to be expected is not an AE:  
**Note: Rectal bleeding clinically assessed to be expected at the time of anoscope insertion or swab/sponge collection is not an AE.**
4. To maintain consistency with the Sample Informed Consent, Section 13.4.1, *Risks*, the third paragraph has been revised to clarify that the insertion of a lubricated anoscope may also cause bleeding:

Insertion of a lubricated anoscope will likely cause some discomfort **and possibly bleeding.**

*The above information will be incorporated into the next version of the protocol at a later time if it is amended.*