HIV Prevention Trials Network

LETTER OF AMENDMENT #1 TO:

HPTN 067

DAIDS Document ID#10852

A PHASE II, RANDOMIZED, OPEN-LABEL, PHARMACOKINETIC AND BEHAVIORAL STUDY OF THE USE OF INTERMITTENT ORAL EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE PRE-EXPOSURE PROPHYLAXIS (PREP)

Version 5.0 / 10 June 2013

Date of Letter of Amendment: July 18, 2013

The information contained in this Letter of Amendment (LoA) impacts the HPTN 067 study and must be forwarded to your Institutional Review Board (IRB) and/or Ethics Committee (EC) as soon as possible for their review and approval. This LoA must be approved by all responsible IRBs/ECs before implementation.

The following information does not impact the sample informed consents. However, some sites may be required to include the inclusion/exclusion criteria in their site-specific informed consents. In such cases, your IRB will be responsible for determining the process of informing subjects of the contents of this letter of amendment (LoA).

Upon receiving final IRB/EC and any other applicable regulatory entity approval(s) for this LoA, your site should implement the LoA immediately. Your site is still required to submit a LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). Your site will receive a registration notification for the LoA once the DAIDS PRO verifies that all the required LoA registration documents have been received and are complete. An LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with this letter and any IRB/EC correspondence should be retained in the site's regulatory files.

If the HPTN 067 protocol is amended in the future, this Letter of Amendment will be incorporated into the next version.

Summary of Revisions and Rationale

1. Section 5.8 is modified to remove the Protocol Safety Review Team (PSRT) access to HIV seroconversion information.

Changes in the protocol are summarized below by section. Added text appears in **bold face** and deleted text appears with a ~~strike through~~.

Section 5.8 Participants who have suspected or documented HIV infection during the study

If any enrolled participant has one or more reactive HIV rapid tests or a positive GenAptima HIV RNA test, study drug must be discontinued immediately and the Site IoR and the HPTN NL must be notified. ~~If HIV infection is subsequently confirmed, the site should notify the Protocol Safety Review Team (PSRT).~~ A decision to resume study drug in participants who are subsequently confirmed to be HIV-uninfected requires approval of the Protocol Chair, PSRT and HPTN NL.