**DRAFT/FINAL**

**Letter of Amendment # 1 to:**

**HPTN XXX: Title, Version X.0, Day Month Year**

 **DAIDS Document ID:**

**Draft/Final Version of LoA # 1: Day Month Year**

**The following information impacts the HPTN XXX study and must be forwarded to all responsible Institutional Review Boards (IRBs) as soon as possible for their information and review. This Letter of Amendment must be approved by all responsible IRBs before implementation.**

**The following information impacts/does not impact the sample informed consents. 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 and any other applicable Regulatory Entity (RE) approval(s) for this LoA, sites should implement the LoA immediately. Sites are still required to submit an LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). Sites 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 correspondence should be retained in the site’s regulatory files.**

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

**Summary of Revisions and Rationale**

1. X

1. Y
2. Z

**Implementation of the Protocol Modification**

The modifications detailed below will be formally incorporated into the body of the protocol with the next full amendment. Deletions to the protocol text are indicated by ~~strikethrough~~; additions are indicated in **bold**.

Revision 1 X

Revision 2 Y

Revision 3 Z