**Protocol #**

**[Protocol Title]**

**DAIDS Study ID #**

**Version #, Letter of Amendment #**

**Dated [Month Day, Year]**

**LETTER OF AMENDMENT SIGNATURE PAGE**

**I will conduct the study in accordance with the provisions of this protocol and all applicable**

**protocol-related documents. I agree to conduct this study in compliance with United States (US)**

**Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug**

**Administration regulations; standards of the International Conference on Harmonization**

**Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee**

**determinations; all applicable in-country, state, and local laws and regulations; and other**

**applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and**

**institutional policies.**

**I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study.”**

Signature of Investigator of Record Date

Name of Investigator of Record

(printed)

**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 (LoA) must be approved by all responsible IRBs before implementation.**

**The information contained in this LoA *does not (or does)* impact the informed consent forms (ICFs).**

**Upon receiving final IRB approval for this LoA, sites should implement the LoA immediately. Sites are required to submit a LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). As part of the registration package, sites must submit the Letter of Amendment Investigatory Signature Page, signed and dated by the Investigator of Record. 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. A LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with the LoA and any IRB correspondence should be retained in the site’s regulatory files.**

If the HPTN XXX protocol is amended in the future, this LoA will be incorporated into the next version. Deletions to the protocol text are indicated by ~~strikethrough~~; additions are indicated in **bold**.

**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