Letter of Amendment # 4 to:

HPTN 078: Enhancing Recruitment, Linkage to Care and Treatment for HIV-Infected Men Who Have Sex with Men (MSM) in the United States
Version 1.0, dated 8 October 2015
DAIDS Document ID: 11995

Final Version of LoA # 4: 20 December 2016

The following information impacts the HPTN 078 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 impact the sample screening informed consent form (ICF).

Upon receiving final IRB approval for this LoA, sites should implement the LoA immediately. Sites are still required to submit a 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. 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 078 protocol is amended in the future, this LoA will be incorporated into the next version. Deletions to the protocol text are indicated by ~~strikethrough~~.

Summary of Revisions and Rationale

1. Not all sites have been able to meet their screening and enrollment goals; however, at these same sites, there have been some transgender women who have sex with men who have shown interest in the study. This change would allow participation of transgender women in the study, potentially increasing enrollment.

2. A typographical revision was made to the contact information of one protocol team member.

Implementation

Revision 1

3.2 Exclusion Criteria

Individuals who meet any of the following criteria will be excluded from study screening

- Unable or unwilling to provide consent/assent for study participation
- ~~Transgender women~~
- Active or previous participation in an HIV vaccine trial, unless evidence can be provided documenting randomization to the placebo arm.
- Any condition that, in the opinion of the Investigator of Record (IoR), would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

Revision 2

Protocol Team Roster

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