

Letter of Amendment # 2 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 # 2: 5 May 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 informed consent forms.

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~~; additions are indicated in **bold**.

Summary of Revisions and Rationale

1. The inclusion criterion requiring a self-reported history of anal intercourse with another man within the last 6 months is unnecessarily restrictive as the study is not trying to identify men who have sex with men (MSM) with acute infections. This change from sexual activity in the last 6 months to the last 12 months would loosen the criterion, allowing more men to be eligible for the study, while still ensuring that we recruit our population of interest (MSM).

Implementation

Revision 1

3.1 Inclusion Criteria

- Self-report of history of anal intercourse with another man within the last ~~6~~ **12** months