

Letter of Amendment # 5 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 # 5: 19 April 2017

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. The primary reason why sites have not been able to screen individuals for this study is because potential participants report not having had anal intercourse in the past 12 months (52% of pre-screen failures for DC-RDS and 34% of pre-screen failures for direct recruitment). In addition, of everyone screened via both methods of recruitment, we are finding a very high percentage (66%) of HIV-positive MSM. Because we know we are finding high-risk MSM, and we may be losing HIV-positive and virally unsuppressed MSM who are eligible for the CM intervention, we are removing the time restriction associated with having anal sex with another man. This change allows the study team to screen all potentially eligible MSM, even if they have not had anal sex recently. This revision also allows sites to follow-up with all MSM who were pre-screen failures due to this reason and rescreen them for study eligibility.

Implementation

Revision 1

3.1 Inclusion Criteria

Individuals who meet all of the following criteria are eligible for screening:

- Biological male (currently and at birth)
- Self-report of history of anal intercourse with another man ~~within the last 12 months~~
- 16 years or older