

Letter of Amendment #4

HPTN 065: TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the United States Version 2.0, 15 July 2010, DAIDS Document ID #11685

Final Version of LoA: 20 November 2012

Instructions to the Study Site from Sponsor

The following information impacts the HPTN 065 study and must be forwarded to all responsible Institutional Review Boards (IRBs)/Ethics Committees (ECs) as soon as possible for their information and review. This Letter of Amendment must be approved by all responsible IRBs/ECs before implementation.

The modifications in this Letter of Amendment do not result in any changes to the informed consent forms.

The Letter of Amendment and any IRB/EC correspondence must be filed in the site regulatory file and in other pertinent files.

Summary of Revisions and Rationale

1. Section 5.6.1 has been revised to allow sites greater flexibility in recruiting subjects for the Prevention for Positives component.
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Implementation of the Protocol Modifications

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 Section 5.6.1

- “~~Using a randomized approach algorithm,~~ **Clinic or** study staff will ~~sequentially~~ **systematically** approach potential subjects in the waiting room **or during consultation** and inform them of the study ~~using a brief, standardized recruitment script.~~”