

Letter of Amendment #3

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: 09 October 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. Sections 5.3.1 and 5.3.2 have been revised to change the minimum time between the patient's last visit to the clinic and the time when the patient is eligible for PFP from four months to seven months. This allows sites with established, well-controlled patients who are seen at less frequent intervals e.g. every 6 months to be eligible for the study.
 2. Updates to the protocol roster have been made. Two team members have been removed and two team members have been added. Several edits have been made to contact information for three other team members.
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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 5.3.1 Inclusion Criteria and Section 5.3.2 Exclusion Criteria

Inclusion Criteria for PFP

- Have attended the clinic one or more times in the last ~~four~~ **seven** months

Exclusion Criteria for PFP

- Not seen in the clinic in the last ~~four~~ **seven** months

Revision 2 Protocol Team Roster

The following names and corresponding contact information have been removed from the protocol roster:

Angela Fulwood Wood, M.S.W.
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The following name and corresponding contact information has been added to the protocol roster:

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Contact information for the following team members has been updated in the protocol roster:

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