

Clarification Memo #1 to:

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, V2.0

Final Version: 7 Nov 2011

Summary of Revisions and Rationale

1. The Design for Linkage-to-Care and Design for Viral Suppression sections have been updated to reflect that the test and care site surveys will collect data from 2009 through 2013. The purpose of these surveys is to collect information on usual clinic practices for HIV testing, linkage-to-care, and viral suppression. Baseline data will be collected for the year 2009, and the same survey data will then be collected annually through 2013.
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Implementation

The procedures clarified in this memorandum have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB approval of HPTN 0065 Protocol Clarification Memorandum #1 is not required by the sponsor; however, sites may submit the clarification memo to the responsible IRBs/ECs for their information.

No change in the informed consent forms is necessitated by or included in this Clarification Memo.

The modifications included in this Clarification Memo will be incorporated into the next full protocol amendment. Text noted below by strikethrough will be deleted; text appearing below in **bold** will be added.

Revision 1 Section 3.2 Design for Linkage-to-Care

In order to identify the SOC for linkage, against which the incentives intervention will be assessed, an appropriate facility administrator will complete a brief ~~form~~ survey that will collect key attributes of HIV testing sites, including types of navigation and support services already available to patients to facilitate linkage-to-care. **Data will be collected from sites annually from 2009-2013.**

Revision 1 Section 4.2 Design for Viral Suppression

In order to identify the SOC for ART adherence/viral suppression support, against which the incentives intervention will be assessed, we will develop a brief ~~form~~ survey to be completed by an appropriate facility administrator, which will collect key attributes of HIV care sites, including types of ART adherence support, case management services, and other support services already available to patients. **Data will be collected from sites annually from 2009-2013.**