

Letter of Amendment #2 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 Version 2.0, July 15, 2010, DAIDS Document ID #11685

Final Version of LoA: 20 October 2011

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. The schema has been revised to reflect that patients with coupons will be given a \$25 gift card upon completion of CD4 and viral load (VL) HIV laboratory tests at the initial HIV care visit. A confirmatory HIV test is not required.
 2. Section 3.3 has been revised to reflect the inclusion of minors, 12 and older, in the linkage-to-care component of the study, who are permitted to consent to HIV care or can be consented for care by a parent/legal guardian according to the New York State or Washington, DC law. This will enable the study to examine this important subgroup of the target population.
 3. Section 4.3 has been revised to reflect the inclusion of minors, 12 and older, in the viral suppression component of the study, who are permitted to consent to HIV care or can be consented for care by a parent/legal guardian according to the New York State or Washington, DC law. This will enable the study to examine this important subgroup of the target population.
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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 ~~striketrough~~; additions are indicated in **bold**.

Revision 1 Section 3.3 Study Population for Linkage-to-Care

The Linkage-to-Care component of the study will include all individuals ~~who are permitted to consent for HIV care~~ **ages 12 and older who are permitted to consent, or can be consented for HIV care by a parent/legal guardian** according to New York State or Washington, D.C. law, **and who are** newly found to be HIV-positive at HIV test sites participating in the study. This study component will also include individuals who have been previously diagnosed with HIV but have been out of care for at least a year and are reconfirmed for HIV infection by standard laboratory tests.

Revision 2 Section 4.3 Study Population for Viral Suppression

The study population for the viral suppression component of the study will include all individuals **ages 12 and older who are permitted to consent, or can be consented for HIV care by a parent/legal guardian** ~~permitted to consent for HIV care~~ according to New York State or Washington, D.C. law, who have initiated care at participating HIV care sites.

Revision 3 Schema

Linkage-to-Care: HIV test sites will be randomized to either the FI intervention or to the SOC for linkage of HIV-positive patients identified at the testing sites to HIV care sites. At HIV test sites assigned to FIs, HIV-positive patients will be provided with a coupon to redeem at participating HIV care sites in the community. Upon completion of ~~confirmatory~~ HIV laboratory testing, patients with coupons will be given an FI (\$25 gift card) at an HIV care site. A \$100 gift card will be provided to patients upon completion of a care visit that includes interaction with a healthcare provider and discussion of HIV laboratory test results (*e.g.* CD4 cell count and viral load (VL) measurements).