

Clarification Memo #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, V2.0

Final Version: 24 January 2013

Summary of Revisions and Rationale

1. Point of Clarification regarding the Prevention for Positives component: Anonymous health plans will print out for all subjects randomized to the intervention arm at the end of a CARE+ computer session.
 2. Point of Clarification regarding the Prevention for Positives component: All subjects enrolled will be assessed for depression, suicide and domestic violence during a CARE+ computer session.
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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 #2 is not required by the sponsor; however, sites may submit the clarification memo to the responsible IRBs/ECs for their information.

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 Template Informed Consent, Section Titled: “What will happen during this study?”

For the study group that is asked questions and shown videos, ~~people may choose to print out~~ an anonymous health plan **will print out** at the end of the computer session.

Revision 2 Template Informed Consent, Section Titled: “What will happen during this study?”

~~Also for the group that is asked questions and shown videos,~~ **For both groups** there are questions about depression, suicide and domestic violence. ~~If you are assigned to this group and~~ **if** your answers to these questions show that you may be depressed, suicidal or are currently in an abusive relationship, a health worker here at the clinic will follow-up with you **to offer support and/or referral** but will not know what you may be having trouble with.