SUMMARY OF CHANGES
INCLUDED IN THE FULL PROTOCOL AMENDMENT OF:

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 1.0 / 01 March 2010

THE AMENDED PROTOCOL IS IDENTIFIED AS:
Version 2.0 / 15 July 2010

Prior to implementation of this amended protocol, HPTN 065 HIV test and care sites will submit this Summary of Changes document, Version 2.0 of the protocol, and the revised site-specific study informed consent forms to either their own Institutional Review Board (IRB) or the central IRB.

The study will begin under Version 2.0 upon receipt of IRB approval and activation by the HPTN CORE.

RATIONALE

HPTN 065 was granted a conditional approval from the central IRB, Copernicus Group Independent Review Board (CGIRB), contingent upon several requested minor modifications to the template Patient Computer-Delivered Intervention and Survey Informed Consent Form. As several other minor revisions were deemed necessary as well, a decision was made by the Protocol Chair to move to Version 2.0 of the protocol so as to incorporate all required modifications. The bulk of these changes are non-substantive and do not affect the study design.

SUMMARY OF REVISIONS

General Updates

- "Regulatory Compliance Center (RCC)" was changed to "Regulatory Support Center (RSC)" per DAIDS memorandum dated 18 May 2010.
- Minor grammatical and typographical errors were fixed throughout the document.

Title Page

- The role of Dr. Bernard Branson was clarified as "Protocol Co-Chair."

List of Abbreviations and Acronyms

- New acronyms were added as needed based on the addition of new text.

Protocol Team Roster

- Dr. Fred Gordin was added to the roster as a protocol team member.
- Dr. Nnemdi Kamanu Elias was added to the roster as a protocol team member (to replace the position of Dr. Shannon Hader at the Washington, D.C. Department of Health).
- Contact information for Dr. Shannon Hader was revised.

Section 3.0: Linkage-to-Care

- Language was included referencing an evaluation of surveillance data for a period of one year after the completion of the financial incentive (FI) intervention. This follow-up time period will provide information on the durability of the effect of FIs (Section 3.2).
- HIV test site selection criteria were revised: previously listed criteria were clarified as being "primary" criteria, and language was added to allow additional site selection criteria to be considered if the required number of HIV test sites cannot be chosen based on the primary criteria (Section 3.4).

Section 4.0: Viral Suppression

- Language was included referencing an evaluation of surveillance data for a period of one year after the completion of the FI intervention. This follow-up time period will provide information on the durability of the effect of FIs (Section 4.2).
- HIV care site selection criteria were revised: previously listed criteria were clarified as being "primary" criteria, and language was added to allow additional site selection criteria to be considered if the required number of HIV care sites cannot be chosen based on the primary criteria (Section 4.4).
- The word "the" was deleted throughout the section headers and sub-headers when it occurred before the words "viral suppression," for grammatical correctness. (Note: this change also appears in the table of contents).

Section 6.0: Survey of Patients and Providers

- Reference to "paired test statistics" was deleted from the paragraph discussing the analysis of provider surveys of knowledge, attitudes, and practices about the use of ART, as pre- and post-provider surveys will not be linked (Section 6.8).

Section 7.0: HIV Surveillance, Routinely-Collected and Other Survey Data

- Language was included allowing the use of other or site provided data as source data for site selection, process, and outcome measures in certain circumstances.

Section 8.0: Administrative Procedures and Operational Considerations

- New required protocol registration template language was incorporated into existing study activation, protocol compliance, and human subjects/ethical considerations language per 05 April 2010 email from the Division of AIDS, after minor modifications to reflect the unique design of the HPTN 065 study (Sections 8.1, 8.4, and 8.5, respectively).
- Language referencing regular review of the study by an external monitoring committee was added to the Study Monitoring section (Section 8.3) in order to better monitor for

evidence of HIV-test-site and HIV-care-site migration due to the availability of financial incentives for linkage-to-care and viral suppression at some sites. Language was also added to this section to clarify the study elements that will be monitored.

Appendix IIA: Patient Computer-Delivered Intervention and Survey Informed Consent Form

- The Patient Informed Consent Form (ICF) was modified as requested by CGIRB (the Central IRB) and DAIDS regulatory review (Appendix IIA):
    - Formatting of the template ICF was changed slightly in order to conform to CGIRB standard template format.
    - Some information was reorganized or slightly revised to improve clarity.
    - A "Subject's Statement of Consent" summarizing the ICF content was added to the subject's signature page.
    - "Authorization to Use and Disclose Personal Health Information for Research" was added to the end of the ICF.