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 2.0 / 15 July 2010

THE AMENDED PROTOCOL IS IDENTIFIED AS:
Version 3.0 / 14 January 2014

Prior to implementation of this amended protocol, HPTN 065 HIV test and care sites will submit this Summary of Changes document, Version 3.0 of the protocol, and the revised site-specific study informed consent forms to either their own Institutional Review Board (IRB) or the central IRB.

RATIONALE

After V2.0 of the HPTN 065 protocol was finalized in July 2010, two Clarification Memos and four Letters of Amendment were issued to revise the protocol. Currently, there are additional revisions being made to the Prevention for Positives section of the protocol to revise the endpoints, end enrollment after approximately 12 months of recruitment, and eliminate the 18-month visit. The endpoints were revised to more accurately reflect the analysis that will be done with data collected via the CARE+ software. Limiting recruitment to approximately 12 months and elimination of the 18-month visit were made as study implementation and recruitment have taken substantially longer than anticipated and resources are limited. The protocol team has verified that the primary and secondary endpoints can be determined with fewer participants and without the 18-month data point. Normally, these changes would be made via a Letter of Amendment; however, a full protocol amendment is being made to incorporate all previous changes, as well as the current revisions, per study sponsor (DAIDS) request.

SUMMARY OF REVISIONS

Protocol Team Roster

- Carlos Allende, Dr. Robert George Chin, Dr. Margo A. Smith, Dr. Nnemdi Kamanu Elias, Dr. Shannon Hader, Angela Fulwood Wood, and Dr. Fabienne Laraque were removed from the protocol team roster. (LoA #1 and LoA #3)

- Ruth Concepcion, Dr. George Pappas, Nanette Benbow, Dr. Jeffrey Meyer, Dr. Becky Grigg, Dr. Kathleen Brady, June Pollydore, and Dr. Vanessa Elharrar were added to the roster as protocol team members. (LoA #1 and LoA #3)
- Contact information was updated in the protocol roster for Dr. Lisa Fitzpatrick, Dr. Theresa Gamble, and Dr. Nirupama Sista. (LoA #3)
- Michael Kharfen replaced Dr. Gregory Pappas as the protocol team member from the DC Department of Health. (Current revision)

Schema

- The schema was 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. (LoA #2)
- The schema was revised to change the potential enrollment into the Prevention for Positives and Patient Survey study components. (Current revision)

Section 3.0: Linkage-to-Care

- The Design for Linkage-to-Care section (Section 3.2) was updated to reflect that the test 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 and linkage-to-care. Baseline data will be collected for the year 2009, and the same survey data will then be collected annually through 2013. (CM #1)
- Section 3.3 was 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. (LoA #2)

Section 4.0: Viral Suppression

- The Design for Viral Suppression section (Section 4.2) was updated to reflect that care site surveys will collect data from 2009 through 2013. The purpose of these surveys is to collect information on usual clinic practices for viral suppression. Baseline data will be collected for the year 2009, and the same survey data will then be collected annually through 2013. (CM #1)
- 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. (LoA #2)

Section 5.0 Prevention for Positives

- Sections 5.3.1 and 5.3.2 were 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. (LoA #3)
- Section 5.6.1 has been revised to allow sites greater flexibility in recruiting subjects for the Prevention for Positives component. (LoA #4)
- All references to the Month 18 visit were removed. (Current revision)
- The primary and secondary endpoints were revised to more accurately reflect the analysis that will be done with data collected via the CARE+ software. (Current revision)
- Enrollment was limited to approximately 12 months of recruitment. (Current revision)
- CD4 and VL values at ART initiation will no longer be collected. (Current revision)
- Brief, anonymous demographic data will be noted (as opposed to asking the participant) for those individuals refusing study participation, to assess comparability to study participants. (Current revision)
- References to analysis of correct condom use were eliminated, as this is not part of the component's endpoints. (Current revision)
- Section title, "5.10 Human Subjects/Ethical Considerations" added after the 3rd paragraph of Section 5.9.4. (Current revision)

Section 8.0: Administrative Procedures and Operational Considerations

- In order to keep subject confidentiality, NIAID, OHRP, government or regulatory authorities and/or IRB were added as the authorities that have access to the subject's records. (Current revision)

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

- Wording describing the Certificate of Confidentiality was corrected to accurately reflect the previously DAIDS-approved verbiage for all HPTN domestic studies. (LoA #1)
- Text was revised to more clearly indicate that only half of the subjects will receive prevention messaging (the intervention group) and may print out a health plan. (LoA #1)

- The wording for the "Persons to Contact for Problems for Questions" section was revised upon request of the central IRB used the study, Copernicus Group IRB. (LoA#1)
- Anonymous health plans will print out for all subjects randomized to the intervention arm at the end of a CARE+ computer session. (CM #2)
- All subjects enrolled will be assessed for depression, suicide and domestic violence during a CARE+ computer session. (CM #2)
- References to the Month 18 visit were removed. (Current revision)