

Letter of Amendment # 1

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, DAIDS Document ID #: 11685

Final Version: 24 June 2011

Instructions to the Study Sites from the Sponsor

The following information impacts the HPTN 065 study and must be forwarded to your Institutional Review Board (IRB)/Ethics Committee (EC) as soon as possible for their information and review. This must be approved by your IRB/EC before implementation.

The modifications in this LoA result in changes to the informed consent forms for the Prevention for Positives study component.

This LoA and any IRB/EC correspondence must be filed in the site regulatory file and in other pertinent files.

The above information will be incorporated into the next version of the protocol at a later time if it is amended.

Summary of Revisions and Rationale

- 1) Corrections have been made to the text of the informed consent form (ICF) for the Prevention for Positives study component. None of the corrections are significant to the study design or negatively impact study subjects. All wording changes are listed below.
- 2) Updates to the protocol roster have been made. Since approval of V2.0 of the protocol, several original team members have changed jobs and are no longer able to support this study. Those team members have been replaced. In addition, the HPTN 065 team decided to formally add names to the roster of the representatives from the departments of health in the four non-intervention cities.

Implementation of the Protocol Modifications

The modifications detailed below will be incorporated into the next full protocol amendment. Text to be deleted is noted below by ~~strikethrough~~; text to be added is noted below in **bold**.

- 1) The following revisions were made to the ICF for the Prevention for Positives study component.

- i. Wording describing the Certificate of Confidentiality was corrected to accurately reflect the previously DAIDS-approved verbiage for all HPTN domestic studies.

In addition to the efforts made by the study staff to **help** keep your personal information confidential, we have obtained a Certificate of Confidentiality from the U.S. ~~nited States~~ ~~federal~~ ~~g~~Government. This certificate protects researchers from being forced to tell people who are not connected with this study, such as the court system, about your participation. Any publication ~~that results from~~ of this study will not use your name or identify you personally.

People who may review your records include: **the U.S. Food and Drug Administration (FDA), (insert name of site IRB), National Institutes of Health (NIH), ~~government or regulatory agencies, study staff, and the study monitors, and drug companies supporting this study.~~** Also, the Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study. The ~~e~~Certificate cannot be used to resist a demand for information from personnel of ~~keep~~ the United States ~~g~~Government that is used for ~~from~~ auditing or evaluation of ~~ng~~ ~~f~~Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). ~~such as this one.~~

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to you or others, we will tell the proper authorities.

- ii. Text in a few places in the ICF 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.
 - a) You have been asked to take part in a study that is testing a new computer program to help HIV-positive people. The research will use a computer to privately ask you questions ~~and give you feedback.~~ You will be asked to use the computer a total of 6 times. You will use the computer every three months when you come in for your clinic visits for twelve months and again at 18 months.
 - b) Computer sessions for both study groups are anonymous. No names or identifying information will be attached to the computer. ~~You will get an anonymous printout at the end of your session, which you can choose to share with your provider, if you want. You do not have to show your provider the printout.~~
 - c) For the study group that is asked questions and shown videos, **people may choose to print out an anonymous health plan at the end of the computer session. If you are assigned to this group, you can decide whether to share the health plan print out with your provider. You do not have to show your provider the print out.**

Also for the group that is asked questions and shown videos, 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 but will not know what you may be having trouble with. For example, the healthcare worker will not know whether you indicated that you are suicidal or whether you indicated that you are in an abusive relationship. We will not share your actual answers with study staff at the clinic. You can decide what information you want to share with the healthcare worker.

- d) The programming for the CARE+ intervention has now been completed. For subjects randomized to the control arm, completion of the CARE+ session will take approximately 15 minutes. For subjects randomized to the intervention arm receiving automated, tailored, feedback we anticipate it will take approximately 30 minutes to complete.

Computer sessions are anticipated to take you approximately ~~30-60~~ 15-40 minutes to complete.

- iii. Wording in a few places in the “Persons to Contact for Problems or Questions” section of the ICF was revised upon request of the central IRB used for the study, Copernicus Group IRB.

- a) If you have any questions about your participation in this research study, **your rights as a research subject**, or if you feel that you have experienced a research-related injury, contact:

Investigator of Record Name: *(site insert name of the investigator or other study staff)*

Research Site Address(es): *(site insert physical address of above)*

Daytime telephone number(s): *(site insert telephone number)*

24-hour contact number(s): *(site insert telephone number)*

~~For questions about your rights as a research participant, contact:~~

If you have any questions or concerns about your rights as a research subject or want to discuss a problem, get information or offer input, you may contact:

- 2) The following changes were made to the protocol and roster.

The following names and corresponding contact information have been removed from the protocol roster:

Carlos Allende, MHSA
VIP Community Services
1910 Arthur Ave., 5th floor
Bronx New York, NY 10457
Phone: (718) 583-5150 Ex 8065
Fax: (718) 902-4875
Email: callende@vipservices.org

Robert George Chin, M.D.
Associate Chair, Department of Emergency Medicine
Lincoln Medical and Mental Health Center
234 East 149th Street
Bronx, NY 10451
Phone : (718) 579-6010
Fax: (718) 579-4822
Email: robert.chin@nychhc.org

Margo A. Smith, M.D.
Director, Section of Infectious Diseases
Washington Hospital Center INF
110 Irving Street, NW
Suite 2A-56
Washington, D.C. 20010
Phone: (202) 877-7164
Email: Margo.A.Smith@medstar.net

Nnemdi Kamanu Elias MD MPH
HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA)
District of Columbia Department of Health
64 New York Avenue, Suite 5001
Washington DC 20002
202-671-4933
nnemdi.kamanuelias@dc.gov

Shannon Hader, M.D., M.P.H.
Vice President and Director of the Center for Health Systems and Solutions
Futures Group
One Thomas Circle, NW
Suite 200
Washington, DC 20005
Phone (202) 775-9680
Fax (202) 775-9694
Email: info@futuresgroup.com

The following names and corresponding contact information have been added to the protocol roster:

Ruth Concepcion, MSW

Psychosocial Counselor/ Walk-In Supervisor
Ryan White Part D and Linkage to Life Program
Dominican Sisters Family Health Service, Inc.
279 Alexander Avenue
Bronx NY 10454
Phone: (718) 665-6558, x1413
Fax: (718) 665-9297
Email: RConcepcion@dsfhs.org

Gregory Pappas, MD, PhD

Senior Deputy Director
DC DOH, HAHSTA
899 North Capitol Street, NE
4th Floor
Washington, DC 20002
Phone: (202) 671-4843
Fax: (202) 671-4860
Email: gregory.pappas@dc.gov

Nanette Benbow, MAS

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Chicago, IL 60604
Phone: (312) 747-9620
Fax: (312) 745-3923
Email: nanette.benbow@cityofchicago.org

Jeffrey Meyer, MD, MPH

Epidemiologist Supervisor
Bureau of Epidemiology, 4th Floor
Houston Department of Health and Human Services
8000 N Stadium Drive
Houston, Texas 77054
Phone: (832) 393-4567
Fax: (832) 395-9955
Email: jeffrey.meyer@houstontx.gov

Becky Grigg, PhD

Bureau of HIV/AIDS

4052 Bald Cypress Way, Bin #A09

Tallahassee, Florida 32399-1715

Phone: (850) 245-4432

Fax: (850) 922-4263

Email: Becky_Grigg@doh.state.fl.us

Kathleen A. Brady, MD

Medical Director/Medical Epidemiologist

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E-mail: Kathleen.A.Brady@phila.gov

**COMPUTER-DELIVERED INTERVENTION AND SURVEY
SUBJECT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO USE
AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH**

Title of Research Study: 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

Protocol #: HPTN 065, Version 2.0, 15 July 2010
DAIDS ID: 11685

Sponsor: National Institute of Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institutes of Health (NIH)

Investigator of Record: *(insert name)*

Research Site Address(es): *(insert address)*

Daytime telephone number(s): *(insert number)*

24-hour contact number(s): *(insert number)*

Purpose of the Subject Information and Consent Form

This Subject Information and Consent Form may contain words you do not understand. Please ask the study investigator or the study staff to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study and, if signed, will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

Your study investigator will be paid by the sponsor to conduct this research study.

Introduction

You have been asked to take part in a study that is testing a new computer program to help HIV-positive people. This research will use a computer to privately ask you questions. You will be asked to use the computer a total of 6 times. You will use the computer every three months when you come in for your clinic visits for twelve months and again at 18 months.

Around 1320 people who are HIV-positive in Washington, D.C. and in the Bronx will participate in the study. You do not have to know how to use a computer or be able to read to be in this study.

What will happen during this study?

If you agree to take part in this study, you will first sign this Subject Information and Consent Form before any study-related procedures are performed.

We will use a computer to talk about what is going on for you with HIV. During your first and 12-month visit, we will also ask you questions about your knowledge of HIV, your knowledge of medications for treating HIV and your feelings about medical care for people with HIV.

You will be asked to answer all of the questions openly and honestly, but you may refuse to answer any of the questions or stop at any time if you feel uncomfortable. You will also be provided with contact and referral information if any of the questions raises issues that you would like to talk about further, at this or some later time.

Computer sessions are anticipated to take you approximately 15-40 minutes to complete.

For your time and effort, we will reimburse you \$10.00 per visit. There is no cost to you to participate in this part of the study.

Subjects who choose to join the study will be randomly assigned to a study group. There are only two groups:

- One study group will be asked questions by the computer program.
- The second study group will be asked the same questions and will also be shown some videos. The videos will be short and will include HIV risk reduction topics. After the videos are shown, the computer then will help people create a health plan.

You will have a 50% chance of being in the group that is asked questions by the computer program. You will also have a 50% chance of being in the group that is asked questions and shown videos. The group assignment will be made randomly by the computer program. Staff at the site where you get your HIV care cannot assign you to a group, and the staff will not know which group to which you are assigned.

Computer sessions for both study groups are anonymous. No names or identifying information will be attached to the computer.

For both study groups, we would like permission to access medical records at the HIV clinic. We will use this information to evaluate HIV Viral Load, CD4 cell count, and other information relevant to your health, at each computer session. We would only like to access your information for as long as you are enrolled in the study. Once you have completed the study, we will no longer access your medical records at any HIV clinic. We will not share information with the study clinic staff about your answers to the questions on the computer. If you decide to

allow us to access your health information for the study, you will need to sign an authorization form at the end of this consent form document giving permission to let us see your records.

For the study group that is asked questions and shown videos, people may choose to print out an anonymous health plan at the end of the computer session. If you are assigned to this group, you can decide whether to share the health plan print out with your provider. You do not have to show your provider the print out.

Also for the group that is asked questions and shown videos, 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 but will not know what you may be having trouble with. For example, the healthcare worker will not know whether you indicated that you are suicidal or whether you indicated that you are in an abusive relationship. We will not share your actual answers with study staff at the clinic. You can decide what information you want to share with the healthcare worker.

What are the possible risks or discomforts?

It is possible that answering the questions on the computer may make you embarrassed or upset. You may refuse to answer any of the questions or stop answering at any time. The greatest risk may involve your privacy. The steps that the study team has taken to protect your privacy are described in this form.

What are the potential benefits?

There may be no direct benefits to you. We hope the information we collect will help us find better ways to provide HIV care in your community. You may feel a benefit from sharing your experiences with someone who is interested in your opinions.

Are there any alternatives to participation?

The study coordinator will explain other programs at this site that can help HIV-positive people change their behavior so that they do not pass HIV on to others.

How will my confidentiality and privacy be protected?

We cannot guarantee absolute confidentiality. However, we will do everything possible to protect your confidentiality if you join this study.

To protect your privacy, you will meet with a healthcare provider in a private area where others cannot overhear conversations with you. While you are participating in the computerized session, you will be given headphones and a place to sit where no one can look over your shoulder to see what you are doing.

Every effort will be made to keep your personal information confidential. Your personal information (name, address, phone number) will be protected by the research clinic. This information will not be used in any publication of information about this study.

In addition to the efforts made by the study staff to help keep your personal information confidential, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This certificate protects researchers from being forced to tell people who are not connected with this study, such as the court system, about your participation. Any publication of this study will not use your name or identify you personally.

People who may review your records include: the U.S. Food and Drug Administration (FDA), (insert name of site IRB), National Institutes of Health (NIH), study staff, study monitors, and drug companies supporting this study. Also, the Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to you or others, we will tell the proper authorities.

What happens if I am injured by participating in this study?

Because this study only involves answering questions, reading messages and viewing videos, it is very unlikely that you could be injured. However, if you are injured as a result of joining this study, you will be given immediate treatment for your injuries. You may have to pay for this care. There is no program for compensation either through this institution or the United States NIH.

What are my legal rights?

The above section does not restrict your right to seek legal assistance. You will not be giving up any of your legal rights by signing this Subject Information and Consent Form.

Your participation is voluntary

You are not required to join this study. You do not have to participate in the computer sessions for us. If you decide to participate, you may refuse to answer any of the questions or stop at any time without reducing or affecting any care that you receive at this site. If you do decide to leave the study we will ask you to complete one final computer session, however, you will not be required to do this.

What are some reasons why I may be withdrawn from this activity without my consent?

You may be withdrawn from the study without your consent for the following reasons:

- The research study, or this part of the study, is stopped or canceled
- The study staff feels that completing the study or this part of the study would be harmful to you or others

Persons to Contact for Problems or Questions

If you have any questions about your participation in this research study, your rights as a research subject, or if you feel that you have experienced a research-related injury, contact:

Investigator of Record Name: *(site insert name of the investigator or other study staff)*

Research Site Address(es): *(site insert physical address of above)*

Daytime telephone number(s): *(site insert telephone number)*

24-hour contact number(s): *(site insert telephone number)*

If you have any questions or concerns about your rights as a research subject or want to discuss a problem, get information or offer input, you may contact:

Independent Review Board: *(site insert name or title of person on the IRB or other organization appropriate for the site)*

Address of Independent Review Board: *(site insert physical address of above)*

Daytime Telephone Number: *(site insert telephone number of above)*

SUBJECT'S STATEMENT OF CONSENT

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

- I have been given sufficient opportunity to consider whether to participate in this study.
- My taking part in this research study is voluntary. I may decide not to take part or to withdraw from the research study at any time without penalty or loss of benefits or treatment to which I am entitled.
- The research study may be stopped at any time without my consent.
- I have had an opportunity to ask my study investigator questions about this research study. My questions so far have been answered to my satisfaction.
- I have been told how long I may be in the research study.
- I have been informed of the procedures and tests that may be performed during the research study.
- I have been told what the possible risks and benefits are from taking part in this research study. I may not benefit if I take part in this research study.
- I do not give up my legal rights by signing this form.
- I have been told that prior to any study related procedures being performed, I will be asked to voluntarily sign this Subject Information and Consent Form.
- I will receive a signed and dated copy of this Subject Information and Consent Form.

If you have either read or have heard the information in this Subject Information and Consent Form, if all of your questions have been answered, and if you agree to take part in the computer assisted interview and subject survey questionnaire, please sign and your name on the line below.

I voluntarily agree to take part in this research study.

Subject's Name (print)

Subject's Signature and Date

I certify that the information provided was given in a language that was understandable to the subject.

Name of Study Staff
Conducting Consent Discussion (print)

Study Staff Signature and Date

Witness' Name (print)
(As appropriate)

Witness' Signature and Date

Authorization to Use and Disclose Personal Health Information for Research

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

In working with the sponsor, the study investigator, (*insert the name of site's study investigator*), will use and share personal health information about you. This is information about your health that includes information in your medical record and information created or collected during the study. This information may include laboratory test results. Some of these tests may have been done as part of your regular care. The study investigator will use this information about you to complete this research.

The study investigator will assign a code number to your information that is shared with the sponsor. The sponsor and its representatives may review or copy your personal health information at the study site. Your IRB, (*insert name of your IRB*), may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

By signing this Authorization, you allow the study investigator to use your personal health information to carry out and evaluate this study. You also allow the study investigator to share your personal health information with:

- the sponsor and its representatives
- (*insert name of your site's IRB*)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health information confidential.

You have the right to see and get a copy of your records related to the study for as long as the study investigator has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization at any time, but you must notify the study investigator in writing. Send your written withdrawal notice to *[insert study investigator's name & address]*.

If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns social harms (a bad effect) related to the study. If a social harm occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about a social harm related to the study, will be sent to the study sponsor.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study investigator will keep this Authorization for at least 6 years.

If you do not sign this Authorization, you cannot participate in this research study. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

I authorize the release of my medical records and personal health information related to this study to the sponsor and its representatives, (*insert name of site's IRB*), and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Authorization for my records.

Printed Name of Subject

Signature of Subject

Date

Printed Name of Person Obtaining Authorization

Signature of Person Obtaining Authorization

Date