

Letter of Amendment # 2 to:

HPTN 061: Feasibility Study of a Community-Level, Multi-Component Intervention for Black Men Who Have Sex with Men, Version 2.0, dated 02 April 2009, DAIDS Document ID# 10666

Letter of Amendment Date: 08 January 2010

The following information impacts the HPTN 061 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 following information may also impact the Sample Informed Consent. Your IRB/EC will be responsible for determining the process of informing subjects of the contents of this Letter of Amendment.

This Letter of Amendment and any IRB/EC correspondence must be filed in the site regulatory file and in other pertinent files. Submission of these documents to the DAIDS/RCC Protocol Registration Office is not required unless the changes result in a change to the informed consent form for your site.

Section 1: Summary of Revisions and Rationale

1. A clarification was made to section 5.2 and Appendix I that circumcision status will not be verified by a clinician if the participant identifies as being female at birth. The study is open to people who identify as male even if they were born anatomically female, whether or not they have had gender reassignment surgery (GRS). The prior wording made it clear that participants who have had GRS do not need to be checked for circumcision status: the additional wording makes it clear that no one born anatomically female will need to be checked for circumcision status.
2. A clarification was made, pertaining to the study procedures listed in sections 5.2 and 5.3 of the protocol, that asking the participant if they are currently taking, or have previously taken, antiretroviral medications is how sites are expected to obtain HAART history for this study. Answers to these questions are collected as part of the study CRFs.
3. Changes were made to the sampling scheme of the qualitative interview component of the study to allow procurement of a more appropriate sample and to correct an overly ambitious sample diversity target.

The objectives for the qualitative component of the study are focused on exploring the factors that influence study and intervention uptake, and the roles of stigma and discrimination in HIV testing and access to care. The protocol had stated that sites would strive for an interview sample that was composed of approximately half gay-identified and half not gay-identified participants, as well as half under 35 years of age and half 35 or over, and half with high school or less education and with half more than high school education. The sampling would also strive to include participants refusing HIV testing. Since the minimum required number of participants any site is expected to interview is ten, it was not possible to create a sampling mechanism that could achieve these many aims. As well, it was generally agreed by the qualitative working group that a participant's HIV status was more likely to affect their experience of stigma, discrimination, and uptake of intervention components than whether they identified as gay. And so, the team decided that creating a sample with diverse HIV status would be the primary goal of the sampling scheme, with diversity of age as the secondary target. The protocol was amended to reflect these changes.

Section 2: 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 strikethrough; additions are indicated in bold.

Implementation

Revision 1 A clarification was made to section 5.2 and Appendix I that circumcision status will not be verified by a clinician if the participant identifies as being female at birth.

5.2 Enrollment Visit

Clinical/Counseling Procedures

- Examine for circumcision, unless participant identifies **that they were female at birth or states** that they have had gender reassignment surgery.

APPENDIX I: SCHEDULE OF STUDY VISITS AND PROCEDURES FOR HPTN 061

PROCEDURES	Enroll Visit ¹	26 Week Follow-up Visit ¹	52 Week Follow-up Visit ¹
Confirm circumcision status by examination, unless participant identifies that they were female at birth or states that they have had gender reassignment surgery.	X		

Revision 2 A clarification was made, that asking the participant as part of the study CRFs if they are currently taking, or have previously taken, antiretroviral medications is how sites are expected to obtain HAART history for this study.

5.2 Enrollment Visit

Clinical/Counseling Procedures

- For HIV-positive participants, obtain HAART history **by asking about antiretroviral medications currently taking, or previously taken, as part of CRF completion.**

Revision 3 Changes were made to the sampling scheme of the qualitative interview component of the study to allow procurement of a more appropriate sample and to correct an overly ambitious sample diversity target.

2.4 Study Design: Qualitative Component

This convenience sampling frame will allow interviews to be completed in a timely manner, so that enough time is allotted to code and analyze the data before the end of the study. Some data suggest that not identifying as gay may increase HIV risk among some MSM;⁶² therefore, we will purposely select participants from the main study so that up to half the participants identify as "other than gay" and approximately half identify as "gay" in order to explore whether our findings vary by sexual identity. To the extent possible, within each of these two groups, we will purposely sample for diversity by age (half <35 and half >35), and socioeconomic status (SES) (half high school or less and half more than high school). The team will also strive to include participants who refuse HIV testing into the qualitative interviews, to gain insight into reasons Black MSM refuse HIV testing.

Sites will follow a systematic approach to selection of the 10 interview participants at each site who will be used for the cross-site qualitative analysis, so that a diversity of participants is obtained. This approach, which is detailed in the SSP manual, prioritizes recruitment of a sample that is approximately balanced between HIV positive and HIV negative participants and includes at least one participant who refuses

testing. The sampling scheme is designed to prioritize diversity of participant age as a secondary target. Achieving a diverse sample for participant interviews will be important in understanding the breadth of experiences among Black MSM as they relate to the four study aims enumerated above.