

**Clarification Memo #1 to:**

**HPTN 061: Feasibility Study of a Community-Level,  
Multi-Component Intervention for Black Men Who Have Sex with Men**

**DAIDS Document ID# 10666**

**Protocol Version 2.0 dated 2 April 2009**

**Clarification Memo Date: 30 July 2010**

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**Summary of Revisions and Rationale**

1. It was clarified in the protocol that participants who meet all enrollment criteria for entry into the study, but are physically unable to provide blood for HIV testing, may be enrolled into the “Participant refused HIV testing” category.

Participants physically unable to provide blood for HIV testing are similar to “refused testing” participants, in that they will not be able to generate laboratory results regarding their HIV status. However, such participants are different in that they are willing to provide the samples but unable to do so, whereas true “refused testing” participants are unwilling but able. In order that the difference between these two groups be captured in the study database, the study CRFs were modified to document whether a person classified as “refusing HIV testing” was so categorized because of the physical inability to be phlebotomized.

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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 by the HPTN CORE.

No change in the informed consent forms is necessitated by or included in this Clarification Memo.

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.

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**Revision 1**

**3.3 Participant Categories and Enrollment Caps**

An enrollment cap of 83 participants will apply to those willing to enroll in the study but **who have not consented** ~~consenting~~ to (or, are **physically unable to give blood for**) HIV testing. An enrollment cap of 10 community recruited participants will apply to those with a prior diagnosis of HIV infection who are already in care or report only having unprotected anal sex with HIV positive partners.