**Clarification Memo # 3 to:**

**HPTN 052: A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples, Version 3.0, November 20, 2006, DAIDS Document ID: 10068**

**Final Version: 7 November 2013**

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## Summary and Rationale

An extension of the existing interviewer-administered adherence questionnaire was developed in order to expand on reasons why participants are adherent to their study medications in the study named above. The expanded questionnaire is included in the case report forms set and is referred to as the Index Altruism Questionnaire. These additional questions are covered by the existing protocol objectives, specifically the following secondary objective: "Assess factors associated with adherence and compare the adherence rate of two antiretroviral treatment strategies". No changes to the current informed consent form are required by these additional adherence-related questions.

Sites should follow their local IRB/EC guidelines regarding implementation of the Index Altruism Questionnaire as outlined below under "Scenarios".

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## Implementation

Sites should determine which of the four scenarios outlined below pertains to their local situation and proceed according to the instructions, if they have not already.

The information contained in this memorandum has been approved by the Division of AIDS (DAIDS) Medical Officer and should be followed immediately upon issuance. IRB approval of HPTN 052 Protocol Clarification Memo # 3 to HPTN 052 V3.0 is not required by the sponsor; however, sites may submit the clarification memo to the responsible IRBs for their information.

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

All sites must file this CM in their regulatory files along with a note-to-file documenting which scenario they fall under and any action taken.

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**SCENARIO # 1:** IRB/EC approval has already been obtained or is in the process of being obtained prior to implementation of the questionnaire. In this scenario, no further action is required, other than ensuring that this CM is placed in the regulatory file. The site may submit this CM to the responsible IRBs/ECs for their information; however, this is not required.

**SCENARIO # 2:** IRB/EC approval is not required for interviewer-administered questionnaires or case report forms. In this scenario, sites should create a note-to-file that specifies that IRB/EC approval is not required for interviewer-administered questionnaires or case report forms and placed in the regulatory file. The site may submit the CM to the responsible IRBs/ECs for their information; however, this is not required.

**SCENARIO #3:** If a site is unsure whether IRB/EC approval is required for interviewer-administered questionnaires, the site is responsible for seeking guidance from their IRB/EC as to whether it is required, and documenting the IRB/EC's decision. This documentation should be placed in the regulatory file. If a site has already administered the Index Altruism Questionnaire to study participants and IRB/EC approval is required, the site should follow specific IRB/EC guidance regarding data that were collected prior to IRB/EC approval. The site may submit the CM to the responsible IRBs/ECs for their information; however, this is not required.

**SCENARIO # 4:** IRB/EC approval is required but was not obtained prior to implementation. All IRB/EC guidelines should be followed in this case. The site may submit the CM to the responsible IRBs/ECs for their information; however, this is not required.