

Clarification Memo # 1 to:

HPTN 074: Integrated treatment and prevention for people who inject drugs: A vanguard study for a network-based randomized HIV prevention trial comparing an integrated intervention including supported antiretroviral therapy to the standard of care, Version 1.0, 26 February 2014

Final Clarification Memo #1 to Version 1.0: 17 March 2015

Summary of Revisions and Rationale

1. The screening to enrollment window has been clarified.
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Implementation

The procedure clarified in this memorandum has been approved by the Division of AIDS (DAIDS) Medical Officer and are to be implemented immediately upon issuance. IRB approval of HPTN 074 Protocol Clarification Memo #1 to HPTN 074 V. 1.0 is not required by the sponsor; however, sites may submit the clarification memo to the responsible Ethics Committees for their information.

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 ~~strike through~~ will be deleted; text appearing below in **bold** will be added.

The protocol has been clarified that the screening to enrollment window exists for both Index and Partner to enroll within 45 days of the Index Screening Blood draw. The initial protocol language was contradictory specifying this period as 30 days after the confirmation of the Index Screening Blood draw (Section 3) (approximately 45 days after the initial Index Screening Blood draw), as well as only 30 days from the initial blood draw (Section 5).

Section 3.0 Study Setting and Population

Each index participant will recruit one to five HIV-uninfected network injection partners using referral identification cards; at least one partner must be enrolled before the index and his/her partner(s) are randomized to the intervention or standard of care arm. The first network injection partner enrollment must occur within ~~30~~ **45** days after the ~~confirmation of the HIV status~~ **screening blood draw** for the index participant. If the first injection network partner presents to be screened more than ~~30~~ **45** days after ~~confirmation of the index participant's HIV status~~ **screening blood draw**, the index participant may be asked to return for another Screening visit prior to randomization and the initial partner may be asked to return for an Enrollment visit.

Section 5.4.1 Screening Visit for Index Participants

It is the responsibility of the local site to determine the best approach to screening which will be documented in a site specific standard operating procedure (SOP). For each participant, independent written informed consent for Screening will be obtained before Screening procedures are initiated. For each index participant, Enrollment must occur on a separate date within ~~30~~ **45** days of the date of blood collection at the Screening visit.

Section 5.5.1 Screening visit for Network Injection Partners

It is the responsibility of the local site to determine the best approach to Screening. For each participant, independent written informed consent for Screening will be obtained before Screening procedures are initiated. For each network partner participant, Enrollment must occur on a separate date within ~~30~~ **45** days of the blood collection **for the Index at the** Screening visit. See Section 3.3 for important screening information.