

## Clarification Memo # 2 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 #2 to Version 1.0: 20 April 2015**

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#### Summary of Revisions and Rationale

1. Partners who are HIV positive at screening may be screened and enroll as an Index participant if the initial referring Index participant is not enrolled.

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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 any partner who fails screening because they have one or more reactive/positive HIV tests may later be screened as an Index participant **IF** the Index participant who originally referred him/her does not enroll into the study.

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#### **Section 3.0 STUDY SETTING AND POPULATION**

Referred network injection partners who have one or more reactive/positive HIV tests at study entry (Screening and/or Enrollment) will not be eligible for enrollment **as network injection partners, but may re-screen as index participants if the initial referring index does not enroll**. At Screening, all partners will be asked to complete a brief behavioral risk and HIV care questionnaire and provide a blood sample for storage. If the partner has one or more reactive/positive HIV tests **but does not enroll as an index** and is therefore ineligible, and if the participant agreed to specimen storage, then the stored specimen will be saved for possible use in phylogenetic analyses. These ineligible partners will be referred to local care centers for confirmation of HIV diagnosis (if the diagnosis is not established during the Screening and/or

Enrollment visits), as well as HIV care (if HIV-infected) and substance use treatment; referrals to HIV care and substance use treatment will be made in the same manner as the standard of care group, as described in site-specific SOPs.

### **Section 3.2 Exclusion Criteria**

Men or women who meet any of the following criteria will be excluded from this study as an index participant:

- Current participation in any HIV prevention study
- Previous or current participation in an HIV vaccine trial
- Appearance of psychological disturbance or cognitive impairment that would limit the ability to understand study procedures, as determined by the investigators
- Any other condition that, in the opinion of the investigators, would make participation in the study unsafe, or otherwise interfere with the study activities
- Prior screening as a potential network member of another **enrolled** index participant in this study (**screened Partners who fail screening because they have one or more reactive/positive HIV tests may re-screen as an Index participant only if the original referring Index participant does not enroll**).
- Currently or previously a partner of an index participant