

Clarification Memo # 1 to:

HPTN 058: A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection among opiate dependent injectors, Final Version 1.0 7 October 2005

21 December 2005

Summary of Revisions and Rationale

1. The protocol is clarified throughout to allow for site specific choice for HCV testing. For study purposes Hepatitis C infection may be diagnosed by two different reactive HCV antibody enzyme immunoassays, a positive HCV RNA assay, or a positive HCV recombinant immunoblot assay (RIBA).

Implementation

The procedures clarified in this memorandum have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB approval of HPTN 058 Protocol Clarification Memorandum #1 is not required by the sponsor; however, sites may submit the clarification memo to the responsible IRBs/ECs 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 in the ~~striketrough~~ font will be omitted.

Section 5.1 Screening Visit

Next to last paragraph in this section:

When laboratory results are received by the site, approximately one week after the blood draw, staff will determine if individuals meet entry criteria. If a potential participant has abnormal test results, the site clinician may conduct further testing before determining eligibility and should provide participants with appropriate referrals if necessary.

~~Reactive HCV antibody tests will be confirmed by HCV RIBA or HCV RNA.~~ If laboratory tests indicate an individual is eligible, s/he will be asked to return to the site to provide informed consent for enrollment and randomization after the study is thoroughly explained to him/her. Those who are not eligible will be informed that they do not meet the requirements of the study and, if necessary, will be referred for appropriate medical care.

Appendix I-A

Footnote #6

⁶After screening, hepatitis testing may be performed at any point during first year of participation if clinically indicated. ~~Reactive HCV antibody tests will be confirmed by RIBA or RNA test.~~
Hepatitis B vaccine will be offered to randomized participants if appropriate

Appendix I-B

Footnote #3

³~~Reactive HCV antibody tests will be confirmed by RIBA or RNA test.~~ Hep B vaccine will be offered to randomized participants if appropriate.