

Clarification Memo # 2 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 2.0, May 24, 2004

FINAL Version: 14 December 2004

Summary of Revisions and Rationale

1. The Study Procedures, Clinical Procedures, and Laboratory Evaluations section has been updated to remove the collection of plasma and serum from the index case at the screening visit. The collection of these samples is not necessary at the screening visit, and was inadvertently included in the protocol.
2. Appendix I A has been updated to remove the collection of plasma and serum from the index case at the screening visit. The collection of these samples is not necessary at the screening visit, and was inadvertently included in the protocol.

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 052 Protocol Clarification Memorandum #2 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 noted below by strikethrough will be deleted; text appearing below in **bold** will be added.

Revision 1 Section 5 Study Procedures, Clinical Procedures, and Laboratory Evaluations

5.1.1.3 Laboratory Evaluations – Index Case

- Urine pregnancy test (women only)
- HIV EIA antibody test/Western blot/IFA
- CBC (including hemoglobin and platelets)
- Blood chemistry (defined as sodium, potassium, chloride, phosphate, bicarbonate, creatinine, and albumin)
- LFTs (defined as AST [SGOT], ALT [SGPT], alkaline phosphatase, and total bilirubin)

- CD4+ cell count
- ~~Sample storage:~~
 - ~~— plasma~~
 - ~~— serum~~

Revision 2 Appendix IA Schedule of Procedures and Evaluations – Index Case

For Appendix IA, only the rows for plasma and serum sample storage are included here.

| | Screening | Enrollment | Week 2 ⁸ | Monthly (other than quarterly/yearly) | Quarterly | Yearly | Partner Seroconverts | Confirmed Virologic Failure |
|-----------------------|-----------|----------------|---------------------|---------------------------------------|-----------|--------|----------------------|-----------------------------|
| Sample Storage | | | | | | | | |
| Plasma | X | X ² | | | X | X | X ² | X ² |
| Serum | X | X | | | X | X | | |