

Clarification Memorandum #1 for:
HPTN 057
A Phase I Open Label Trial of the Safety and Pharmacokinetics of
Tenofovir Disproxil Fumarate in HIV-1 Infected
Pregnant Women and their Infants

DAIDS Document ID 10143

Clarification Memo Date: 15 July 2010

Summary of Revisions and Rationale

To address an internal inconsistency between the body of the protocol (Section 5.3) and the Schedule of Evaluations (Appendix IB), the infant chemistry tests in the Schedule of Evaluations are corrected. These modifications represent no additional testing or change in participation requirements.

Implementation

This Clarification Memorandum has been approved by the NIAID and NICHD Medical Officers. IRB approval of this Clarification Memorandum is not required by the sponsor prior to implementation; however, sites may submit it to the responsible IRBs/ECs for their information or, if required by the IRBs/ECs, for their approval prior to implementation.

The modifications included in this Clarification Memorandum will be incorporated into the next full protocol amendment. *Deletions to the protocol text are indicated by strikethrough.*

The following change is made to Appendix IB Schedule of Infant Evaluations:

APPENDIX IB
SCHEDULE OF INFANT EVALUATIONS

Chemistries: ALT [SGPT] AST, bilirubin, creatinine, ~~CPK~~, calcium, albumin, phosphorous, alkaline phosphatase, ~~total protein, glucose~~