

**Notification of Change to:
HPTN 052 Study-Specific Procedure (SSP) Manual, V 1.6**

Attention: HPTN 052 Investigators of Record, Study Coordinators, and site teams

Subject: Confirmation of CD4+ cell count measurement for participants in the delay arm when an initial CD4+ cell count measurement is between 200 and 250 cells/mm³

Date: 27 August 2009

This Notification of Change adds Section 9.2.2.4 to HPTN 052 Study-Specific Procedure (SSP) Manual, V 1.6

Note that a ~~strike through~~ indicates deletions and **bold** indicates additions.

Section 9.2.2.4: Confirming CD4+ cell count measurements for Index Cases in the Delay Arm

When an Index case in the delay arm has a CD4+ cell count measurement within or below the range of 200 and 250 cells/mm³, a repeat CD4+ cell count measurement should be performed as soon as possible within the next 2 weeks, but no later than 4 weeks from the time of the initial CD4+ cell count measurement. It is recognized that there may be participants who cannot be located or who are not available for a repeat blood draw within this timeframe; in such cases, sites should document all efforts made to locate and schedule the repeat test within the timeframe outlined above, and schedule the repeat test as soon as possible. In addition, in cases when the timeframe of 4 weeks has been exceeded, please email 052mgmt@fhi.org to report the details of the situation.
