

## HPTN046 Data Communiqué #8

19 September 2008

This is official study documentation for the HPTN046 trial. Please print it and circulate among relevant staff for their review, and file it in your HPTN046 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

### CLARIFICATIONS

- 1. Error on Schedule of Forms for Infant 8 Week Visit:** It was brought to our attention that the Infant’s Laboratory Results forms (ILR-1 and ILR-2) were missing from the list of those required at visit 6.0 on the schedule of forms in Section 12 of the Study-Specific Procedures (SSP). Please note that the ILR-1 and ILR-2 are required at this visit, per the protocol. We will update section 12 of the SSP with this correction and FHI will post it to the HPTN 046 Study Documents section on the website.
- 2. AE Log Form for Grade 4 Asymptomatic Lab Values:** In order to avoid receiving QCs for grade 4 lab values that are asymptomatic and not considered to be serious adverse events (SAEs), please include a comment indicating why the grade 4 event is not considered serious (ex. “asymptomatic lab value”). This will allow SCHARP data staff to exclude these auto-generated QCs from your QC report.

### REMINDERS:

- 1. Mother’s Termination Form:** For mother’s who are terminated when it is determined their infant will not be randomized, please mark item #2n, “Infant not randomized” as the reason for termination on the Mother’s Termination CRF (TM-1).
- 2. Infant’s Lab Results Form when Lab Value is Grade 1 or 2:** Per version 3.0 of the protocol, “Lab abnormalities that are asymptomatic or not attributable to a clinical diagnosis will also be reported separately on a standard DataFax AE CRF if the severity grade is  $\geq 3$ .” Lab abnormalities that are asymptomatic or not attributable to a clinical diagnosis that are grade 1 or 2 are reported on the Infant’s Laboratory Results Form (ILR-1, ILR-2) but not on an AE Log CRF. For these lab values, line through the AE Log Page boxes on the ILR-1 and ILR-2 and initial and date.