

## HPTN046 Data Communiqué #11

06 March 2009

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.

### UPDATES

**Reason Infant Not Randomized (RNR-1) CRF:** This new CRF was distributed to sites and should now be used. Complete this form when it is determined that an enrolled infant will not be randomized and item 1 on the Infant’s Randomization form (IR-1) is marked “no”. If the visits within with the randomization window (visits 05.0 and 06.0) are missed, this form is required by the end of the target visit window for visit 06.0.

There is an instruction on the back of the original version of the RNR-1 (dated 15-JAN-09) that you can disregard and which will not appear on this CRF next time you receive it (revised instructions date will be 18-FEB-09) - the last bullet point under form-specific instructions that reads "If an infant permanently discontinues...".

### CLARIFICATIONS

**Positive HIV Test Result at Termination Visit:** If an infant’s HIV test comes back positive at their termination visit, sites must complete all required confirmatory testing except in the case of mother refusal. The Infant’s Termination form (TM-1) should not be completed until the infant’s HIV status has been confirmed, but if it has already been faxed, the termination date on the form should be updated (and the CRF initialed/dated/re-faxed) to be on or after the last sample collection date.

### REMINDERS

1. **Faxing CRFs:** It is important that sites transmit completed CRFs to SCHARP within 24-48 hours whenever possible, and that they respond promptly to requests for clarifications and corrections included in QC reports (per section 12.4 of the HPTN 046 SSP Manual). Understandably, lab forms may take longer to send in due to waiting for results.
2. **Termination of Non-Randomized Infants & Their Mothers:** Non-randomized infants should be terminated by the end of the 3 month Allowable Visit Window. Some infants who are lost to follow up and past the Allowable Visit Window have not been terminated. We are adding QCs to remind sites when it is time to terminate these infants. Mothers should be terminated as soon as it is known her infant will not be randomized.
3. **Mothers of Randomized Infants:** Mothers of randomized infants should be followed along with their infant for 18 months regardless of breastfeeding status.