

HPTN046 Data Communiqué #10

11 December 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.

UPDATES

NEW CRF - Reason Infant Not Randomized (RNR-1): We will soon be adding this new form that will be required for all infants who enroll but are not randomized. The purpose of this form is to capture the primary reason the infant was not randomized. Initially we thought the reasons for not randomizing would be clear based on information received on other CRFs but that has not been the case.

The RNR-1 is to be completed at the same time as the Infant’s Randomization form (IR-1) if item #1, “Was infant randomized?” is marked “No”. This form will be required for all infants enrolled but not randomized including those infants for whom we have already received an Infant’s Randomization form; we will provide sites with a list of PTIDs requiring the RNR-1 once the form has been finalized and distributed.

Infant’s Randomization (IR-1): This form is required for ALL enrolled infants. The IR-1 should be completed and faxed in at the infant’s randomization visit or when it is known that the infant will not be randomized, even if the visits associated with the randomization window are missed (by the end of the 8 week visit window at the latest).

HPTN 046 Schedule of Forms: The above updates require changes to the infant’s schedule of forms. A new version of this document will be provided after distribution of the new RNR-1 form.

REMINDERS

Infant’s Open-label NVP Permanent Discontinuation (IOD-1) & Infant’s Permanent Study Drug Discontinuation (IPD-1): The IOD-1 is a required form for all enrolled infants and the IPD-1 is a required form for all randomized infants, even if the visit at which the form is required is missed. Date open-label NVP/study drug was stopped is required; if the date is not known it must be estimated. When estimating the date please indicate “EST” and provide initials/date next to this item. If more accurate information becomes available at a later time the form can be updated and initialed/dated/refaxed.

The visit code on the IOD-1 and IPD-1 can be a missed visit if applicable.

Clarification

End of Study Inventory (MEI-1 and IEI-1): Item #1, "What is the last visit for which data has been submitted?" can not be a visit code for a missed visit; this must be the last visit at which the participant completed a visit at the clinic.