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## HPTN 027 Data Communiqué #1

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21 November 2006

This is official study documentation for the HPTN 027 trial. Please print it and circulate among relevant staff for their review, and file it in your HPTN027 SSP Manual, Section 13: Data Communiqués. This document is considered part of the SSP manual.

### UPDATES

Per HPTN027 Retraining Call of 2 November, whenever possible, infant temperature will be taken rectally. When the temperature recorded on a Reactogenicity CRF has been taken rectally, the word “Axillary” will be crossed out and “Rectal” is written next to it. If the temperature recorded is actually axillary then the word “Axillary” must be circled. If “rectal” is not written and “Axillary” is not circled the item will be QC’d. Both of these modifications must be initialed and dated.

Rectal temperatures are graded using the “non-axillary” scale in Appendix III and on the back of the Reactogenicity CRFs.

### CLARIFICATIONS

#### 1. Reactogenicity forms, Baseline through Day 2 (RCB-1, RCM-1, RCH-1, RCF-1)

##### *Recording of temperature and other reactogenicity symptoms*

Temperature and other reactogenicity symptoms recorded on all Reactogenicity CRFs are the *maximum* noted for the time period indicated on the form. Most of the time this will be the level noted during the formal reactogenicity assessment, however, if the infant is assessed between formal assessments and found to have a fever or other reactions, the form must be amended with the maximum temperature or symptom grade.

##### *Time, item 2*

The time recorded is the time of the formal reactogenicity assessment.

##### *Fevers not related to study vaccination*

If site clinicians think that a fever present during days 0, 1 and 2 of the reactogenicity period is not related to the study vaccine, but instead is due to an alternative cause (for example, otitis media), the actual elevated temperature is recorded in item 3, but item 6b “fever” is marked as “None.” The alternative cause must be reported as an Adverse Experience and the AE Log page number that condition must be recorded in the “Comments” section of the form.

##### *Visible vaccination marks without erythema and induration*

If the needle puncture due to study vaccination is visible but there is no associated erythema or induration present, mark Item 4, “Is a vaccine-related lesion visible?” as “No.”

##### *Irritability of very short duration*

Similarly to needle puncture marks discussed above, infant crying or irritability of very short duration, due to the needle stick, and not at all above what would be expected should be recorded as “none” for item 6d.

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### 2. Reactogenicity form, Post-Day 2 (RCP-1)

#### *Recording of temperature and other reactogenicity symptoms*

As with the other Reactogenicity forms, Temperature and other reactogenicity symptoms recorded on the Post-Day 2 Reactogenicity CRF are the maximum noted for the time period indicated on the form.

#### *Fevers not related to study vaccination*

Unlike the other Reactogenicity CRFs, if site clinicians think that a fever present Post-Day 2 of the reactogenicity period is not related to the study vaccine, but instead is due to an alternative cause both item 2 (Body Temperature) and item 6, (Fever), are marked as “None.” The alternative cause must be reported as an Adverse Experience.

### 3. Infant Laboratory Results form (ILR-1)

#### *Grading Hemoglobin values after age 56 days*

When the infant is  $\geq 57$  days of age, abnormal values of hemoglobin are graded according to the DAIDS Toxicity table in two ways, by the actual value or by a decrease in the value since baseline. For perinatal trials, baseline is defined as the first hemoglobin value collected after the age of 56 days. For most HPTN027 infants, this will be the hemoglobin value from the Week 10 visit.

### 4. Infant Adverse Experience Log form (AE-1)

#### *Item 9, Has this AE been reported to the DAIDS Safety Office?*

Item 9 should be marked as “yes” if site staff have reported, or plan to report, the AE as an EAE to the DAIDS Safety Office.

## REMINDERS

### Infant Adverse Experience Log form (AE-1)

Items 2-11 all refer to the event recorded in item 1. For example,

- if an infant is permanently discontinued from study vaccine for a reason other than the AE described in item 1 (HIV infection, missed vaccination) then item 5 is marked “NA,” rather than “Permanently discontinued.”
- if an infant has been hospitalized, but not for the AE described in item 1, do not mark “New/Prolonged hospitalization” for item 7 “Treatment.”