

From: David Metzger

To: HPTN 058 Protocol Team

Re: Final Visit Clarification

Date: May 2, 2011

This is to provide a description of the procedures and rationale for our decision to end follow-up at Visit 156 at the Site in Chiang Mai and Visit 104 at the sites in China.

Final visit clarification: While the protocol for HPTN 058 allows for final visits to be completed at Visit 104 or Visit 156, the decision has been made to establish final study visits at Visit 156 at the site in Chiang Mai and Visit 104 at all three of the sites in China. Sites are encouraged to complete these final visits within the 28 day window.

As you are aware, Visit 104 and all of the 6-month visits have a targeted visit window (28 days) and an extended visit window (up to 30 days prior to the next 6-month visit). In terms of Visit 104, it is of particular importance to our primary analysis that the visit be conducted as close to the targeted date as possible (preferably WITHIN the 28 day window). Participants who miss both the target window and expanded window of Visit 104 should continue to be sought in order to complete a final study visit. Participants should be terminated only after completing their last visit or at the time when the site has completed all visits for all subjects, whichever occurs first.

SCHARP will send a Communiqué with instructions on what visit codes to use based on when a participant comes for his/her final study visit.

Rationale: This decision reflects the protocol team's desire to devote all available resources to the collection of data necessary to answer the primary and secondary objectives with as much power as possible. Additional time is being allowed at the Chiang Mai site given the early end of enrollment and will increase opportunities to identify incident cases.

