

Sheila Clapp

From: Sheila Clapp**Sent:** Thursday, August 03, 2006 6:47 PM**To:** 'Sharon L Hillier'; 'sjoshi@nariindia.org'; 'Craig J Hoesley'; 'jj2158@columbia.edu'; 'Hala Fawal'; 'Cortney Thompson'; 'ahelova@uab.edu'; 'Anne Elise Schley'; 'mc2675@columbia.edu'; 'Karen Patterson'; 'Sarah Dawson'; 'seeksoma@rediffmail.com'; 'joglekarneelam@yahoo.com'; 'imacgowen@ucla.edu'**Cc:** 'Soto-Torres, Lydia (NIH/NIAID) [E]'; 'Mathias, Cherlynn (NIH/NIAID) [E]'; Elena Cyrus**Subject:** FW: HPTN 059 DRAFT Clarification Memo - REVISED

Dear HPTN 059 Investigators, Study Coordinators, and other team members:

Clarification Memo # 1, with a 31 July 2006 date in the document's footer has another typo. Although this will not have any direct impact on the implementation of the study, in order to ensure all regulatory documents are maintained effectively, we have made the correction and are now resending it.

IMPORTANT: The corrected version is attached to this email and it is identified as Clarification Memo # 1, dated 03 August 2006, and it supercedes Clarification Memo # 1, dated 31 July 2006.

Here is a summary of the typo and its correction:

Typo in Clarification Memo # 1, dated 31 July 2006:

Page one (body of the text) - Date of the Clarification Memo - 03 July 2006

Corrections in Clarification Memo # 1, dated 03 August 2006.

Page one (body of the text) - Date of the Clarification Memo - 03 August 2006

Please keep all versions of the Clarification Memo along with a copy of this email in your regulatory files. The email will serve as documentation that Clarification Memo # 1, dated 03 August 2006, supercedes Clarification Memo # 1, dated 31 July 2006.

To reiterate:

Clarification Memo # 1, dated 03 August 2006 is in effect on the date listed in the memo - 03 August 2006.

DAIDS recommends, but does not require, Clarification Memos be submitted to IRB/ECs for informational purposes. IRB/EC approval is not required for implementation of Clarification Memos. For those of you that have not yet submitted the CHAVI 001 protocol to your IRB/ECs, it is advised that you include the Clarification Memo as part of your submission.

If you plan to submit Clarification Memo # 1 to your IRB/EC, submit the 03 August 2006 version.

I again apologize for any confusion or inconvenience this has caused. Please let me know if you have any questions.