This is Clarification Memo #1 for IMPAACT P1074 "A Prospective Surveillance Study of Long-Term Outcomes in HIV-infected Infants, Children and Adolescents” Version 1.0 dated, February 2, 2009.

This Clarification Memo can be obtained from the P1074 Protocol Specific Web Page (http://www.impaactgroup.org/). Enter the Member/MIS area using your individual username and password. Search for the study number. From the protocol [P1074] web page you will have the option to click the PSWP tab. The document is located under the section titled Current Protocol Related Documents.

The purpose of this memo is to clarify the enrollment criteria for sites participating in P1074.

Participants are eligible for enrollment P1074 if:

- They are HIV-infected infants, children, or adolescents who participated in PACTG 219C during 5/1/06-5/31/07 and are not currently participating in ongoing LTFU studies (e.g., PHACS AMP, LEGACY).

OR

- They are HIV-infected infants, children and adolescents at domestic sites who have participated in or are currently participating in IMPAACT treatment studies (including studies that have rolled over from the PACTG into IMPAACT) designated by the IMPAACT Network Executive Committee (NEC) for subsequent long-term follow-up in P1074, and are not currently participating in ongoing LTFU studies. The participant must have been enrolled into a study approved for co-enrollment into P1074 prior to 25 years of age. A participant who was enrolled into a study approved for co-enrollment into P1074 prior to 25 years of age may be enrolled into P1074 if he/she is 25 years or older if the IMPAACT research site continues to have access to the participant’s clinical care data in order to complete the chart abstraction.

Please refer to the IMPAACT website for the current list of studies or contact the protocol team (actg.teamp1074@fstrf.org). As a reminder to sites, when participants reach 18 years of age, a signed informed consent must be obtained for follow-up continuation.

This clarification will be included in the next version of the protocol when it is amended. Please contact the Protocol Team at actg.teamp1074@fstrf.org with any questions about this correspondence.

Thank you for your participation in IMPAACT P1074.