To: IMPAACT Principal Investigators and Study Coordinators at Sites Participating in IMPAACT P1094

From: IMPAACT P1094 Protocol Team

Date: May 24, 2012

Re: Clarification Memo #2 for Protocol IMPAACT P1094, Version 2.0, dated March 07, 2012, entitled “Evaluation of 3TC or FTC Monotherapy Compared to Continuing HAART as a Bridging Antiretroviral Strategy in Persistently Non-adherent Children, Adolescents, and Young Adults who are Failing HAART and have the M184V Resistance Mutation”

This is Clarification Memo #2 for IMPAACT P1094, Version 2.0, dated March 07, 2012. This Memo can be obtained from the P1094 Protocol Specific Webpage (https://impaactgroup.org/). Enter the Member/MIS area using your individual username and password. Search for the study number. From the P1094 web page you will have the option to click the PSWP tab.

This memo serves to provide an explanation for what is expected in regard to exclusion criterion Section 4.27 which reads as follows:

“Renal disease (as defined by estimated creatinine clearance <50 mL/min/1.73m² confirmed on two occasions within 3 months of screening).”

This memo is being issued in response to requests for clarification of this exclusion criterion by the sites. If a subject has an estimated creatinine clearance of <50 mL/min/1.73m² which is subsequently confirmed to be <50 mL/min/1.73m² on another measure within 3 months of screening, that subject is not eligible for participation in P1094. However, if a subject has an estimated creatinine clearance ≥ 50mL/min/1.73m² within 3 months of screening, there is no need to obtain a second value confirming the absence of renal disease before the official screening visit is performed. Participants will still need to meet eligibility criterion 4.211 prior to enrollment.

Please contact the protocol team at impaact.teamp1094@fstrf.org if you have any questions. Thank you for your interest in IMPAACT P1094.

Sincerely,

The P1094 Protocol Team