DATE: June 22, 2005

RE: CLARIFICATION MEMO #2 for PACTG P1059: Correction to blood volume in sample informed consent

TO: Pediatric PACTG PIs & Study Coordinators at Sites Participating in PACTG P1059

FROM: PACTG P1059 Protocol Team

The following serves as Clarification Memo #2 for PACTG P1059 "A Phase I, Open-Label Study to Evaluate the Safety and Tolerability of Recombinant HIV-1 Vaccines in HIV-1 Infected Young Adults with Control of HIV-1 Replication and on Stable Highly Active Antiretroviral Therapy (HAART)", version 1.0, dated January 31, 2005. This Clarification Memo is available from the Members Institutions Download Final Documents area of the Pediatric ACTG Website (http://pactg.s-3.com). The username is: pactg and the password is: cure (all lower case). The filename for retrieving the document is: P1059v1cm2_505.doc.

This memo is being issued to clarify the blood volume listed in the Screening section of the sample informed consent. In the Sample Informed Consent (Appendix VII), page 2 of 10, the fifth bullet under Screening should be changed to read as follows: “You will have about 21 teaspoons of blood taken…”

Please note that the volume given in Letter of Amendment #2, dated 6/2/05, is incorrect. A total of 103 ml are drawn at screening, which translates to just under 21 teaspoons.

This information will be added to the next version of the protocol. Please contact the protocol team at actg.teamp1059@fstrf.org if you have any questions.

Thank you for your participation in PACTG P1059.