DATE: October 12, 2004

RE: REVISED CLARIFICATION MEMO #2 for PACTG P1057

TO: Pediatric PACTG PIs & Study Coordinators at Sites Participating in PACTG P1057

FROM: PACTG P1057 Protocol Team

The following serves as Clarification Memo #2 for PACTG P1057 "A Phase I/II Randomized Trial of the Safety and Immunogenicity of Cold Adapted Influenza Vaccine (Flumist™) in HIV-Infected Children and Adolescents", version 1.0, dated August 13, 2004. This Clarification Memo can be obtained 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: P1057v1cm2_o12.doc.

1. In section 4.16 (Inclusion Criteria) and Appendix IV, the requirements for laboratory certifications should state: "CLIA or equivalent or DAIDS VQA-approved laboratories."
   A. Section 4.16, Inclusion Criteria. 4th bullet, parentheses should read “CLIA or equivalent or DAIDS VQA-approved laboratories”
   B. Appendix IV, Virology Collection and Shipping Instructions. Under Designated Laboratory/Contact Person, the 2nd sentence should be changed to read “Each site MUST use the same CLIA (or equivalent) or DAIDS VQA-approved laboratory for the duration of the study to prevent inter-lab variability.

2. The P1057 team would like to clarify that while on study, viral load must be measured by Amplicor 1.5 (Roche); however, bDNA determinations may be utilized to satisfy the diagnostic criteria for HIV infection.

3. Changes to Appendix VII:
   A. The room number for shipping saliva samples (Appendix VII) should be changed to 301L.
   B. Serum samples should be shipped on dry ice (not cold pack).

This information will be added to the next version of the protocol. Please contact the protocol team at actg.teamp1057@fstrf.org if you have any questions.

Thank you for your participation in PACTG P1057.