DATE:        July 28, 2004

RE:  CLARIFICATION MEMO #2 for PACTG P1042s

TO:  Pediatric PACTG PIs & Study Coordinators at Sites Participating in PACTG P1042s

FROM:  PACTG P1042s Protocol Team

The following serves as Clarification Memo #2 for PACTG P1042s, "Cognitive, Behavioral, and Psychosocial Correlates of Medication Adherence in Children and Adolescents with HIV-1 Infection", Version 1.0 dated October 16, 2003. 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: P1042sv1cm2_728.doc

The PACTG P1042s protocol team has received queries from participating sites regarding the coordination of neuropsychological testing for PACTG 219C and PACTG P1042s, and the procedures to follow in the event that children who are not in the appropriate testing window are inadvertently enrolled. This memo clarifies Appendix I, footnote #1 and explains the rationale for the testing windows. This memo also clarifies which versions of the Wechsler Intelligence Scale for Children (WISC) and Behavior Assessment System for Children (BASC) to use.

TESTING WINDOWS RATIONALE:

PACTG P1042s was developed as a substudy of the PACTG 219C protocol. Information on general cognitive functioning, which is important for the PACTG P1042s analyses, is already collected as part of 219C. In order to minimize the neuropsychological testing burden for participating families, PACTG P1042s was designed to use these already existing data obtained in PACTG 219C. However, relationships between these data and the information collected for PACTG P1042s cannot be examined unless they are both administered within a relatively narrow time frame.

In generating the list of PACTG 219C participants to approach for PACTG P1042s, the team attempted to identify children who were likely to be scheduled for a PACTG 219C neuropsychological evaluation within the enrollment period for PACTG P1042s. Because of the wide testing windows for PACTG 219C and the variable amount of time that sites required to get PACTG P1042s through their IRBs, some children in the random selection group for P1042s had already received their PACTG 219C neuropsychological testing and more than 3 months had passed before their PACTG P1042s testing could be scheduled. Of these children, some were inadvertently enrolled in PACTG P1042s outside of the prescribed testing window.

TESTING WINDOWS (APPENDIX I, FOOTNOTE #1) CLARIFICATION:

1. Children who are not yet within their PACTG 219C neuropsychological testing window should have their PACTG P1042s enrollment delayed until the testing window has been reached. Enrollment and completion of the PACTG P1042s testing should then occur within 3 months after the PACTG 219C testing.

2. Children should not be enrolled in PACTG P1042s if their PACTG 219C and PACTG P1042s testing cannot be coordinated because (a) the PACTG 219C testing was completed more than 3 months before the PACTG P1042s testing can be completed or (b) the child's PACTG 219C testing window will not open before January, 2005. The PACTG P1042s team must be notified that the child is not eligible for enrollment.

3. If a child in either of the two categories outlined in (2) was inadvertently enrolled on PACTG P1042s, the site is requested to complete an Off-study form with the reason checked as “Other” and an explanation provided.
TESTING INSTRUMENTS CLARIFICATION:

1. The PACTG 219C protocol has begun using the Wechsler Intelligence Scale for Children (WISC)-Fourth Edition (WISC-IV) for children age 6-16 years. Sites are reminded that they should continue to use the Wechsler Intelligence Scale for Children-Third Edition (WISC-III) for children age 8-16 years that have been selected to participate in PACTG P1042s.

2. PACTG P1042s calls for the administration of the Behavior Assessment System for Children (BASC). Continue to use this version of the questionnaire rather than the revision (BASC-2) released this year.

This clarification will be reflected in the next version of the protocol if/when it is amended. Please contact the protocol team at actg.teamp1042s@fstrf.org if you have any questions.

Thank you for your participation in PACTG P1042s.

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