To: Principal Investigators and Study Coordinators Participating in PACTG P1055

From: PACTG P1055 Protocol Team

Reference: Clarification of Procedures and Information

The following serves as a Clarification Memo #1 for PACTG P1055, Version 1.0, dated December 10, 2004. This Clarification Memo can also be found on the PACTG web page. To access the web page, go to http://pactg.s-3.com/, then select Protocol Specific Web Pages, select P1055, type "pactg" for user name and "cure" for password. The Word document description is P1055v1cm1_331.doc.

This memo serves to clarify the following information:

1. Appendices I and III and protocol section 7.211 currently indicate that children under the age of 8 will not complete the YI-4. The team has decided that all children should complete the YI-4. Children under the age of 8 should complete the version of the YI-4 that will be completed by children ≥ 8 to < 12 years of age (NPW0021).

2. Appendix I currently states that the subject version of the Caregiver-Child Interaction is to only be completed by subjects ≥ 12 years of age; however, the team has decided that children < 12 years of age can complete this form. Appendix III and the CRF do not specify that there is an age limit.

3. In Appendix II, two of the drug codes are listed incorrectly. Abilify should be listed as drug code 28160838, rather than 99999998. Strattera should be listed as drug code 28920006, rather than 99999998.

4. Appendix III refers to form PE5809 as a means for classifying CDC clinical and immunological categories. The team has decided that only form PE0009 will be used for children of all ages.

5. A minor change was made to CRF form NPW0014 (SI-4). The phrasing of the "x" items in CRF form NPW0014 was changed from "How often do the behaviors in Category ___ interfere with the child's social or academic functioning?" to "How often do the behaviors in Category ___ interfere with your child's ability to do schoolwork or get along with other people?"
6. Section 7.3 of the protocol (Randomization/Registration and Stratification), item #3, states that “each site list will be ordered within blocks of four subjects.” The team has decided to randomly order subjects within blocks of eight, rather than within blocks of four, due to site and team concerns of limiting blocks to just four subjects each.

7. Appendix III states that the Abbreviated Sensation Seeking Scale has 16 items. The team, however, is using an 11-item version, which the primary caregiver will complete.

8. Appendix III and protocol section 7.225 state that the child/adolescent will complete the Pain Level Assessment Scale with the help of the primary caregiver, if needed. However, the child/adolescent should be helped by the research staff, rather than the primary caregiver, if help is needed.

Please forward this clarification memo, or its information, to your Institutional Review Board (IRB), if it is a requirement of your IRB’s institutional policies.

These changes will be incorporated into any future protocol amendments.

Thank you,

PACTG P1055 Protocol Team