DATE: February 27, 2006

RE: CLARIFICATION MEMO #1 for PACTG P1061s – Change in procedures for provision of Prevnar®

TO: Pediatric PACTG PIs & Study Coordinators at Sites Participating in PACTG P1061s

FROM: PACTG P1061s Protocol Team

The following serves as Clarification Memo #1 for PACTG P1061s " Evaluation of Immunologic Memory Following Pneumococcal, Hepatitis B, and Measles Vaccination in HIV-Infected Children Treated with Highly Active Antiretroviral Therapy (HAART)", Version 1.0 dated 8/2/05. This Clarification Memo can be obtained from the Protocol Specific Web Pages area of the Pediatric ACTG Website (http://pactg.s-3.com), on the P1061s page. The user name is pactg and the password is cure.

This Clarification Memo will change how Prevnar® will be provided for subjects. Modifications to section 5.3 of the P1061s protocol are described below:

Section 5.3, Study Agents Supply, Distribution, and Pharmacy.
The 1st sentence should be changed to read: “Pneumococcal 7-Valent Conjugate Vaccine (Prevnar®) will be provided by each site. The PACTG will reimburse sites up to $100 per vaccine.”

Prevnar will not be available through the NIAID CRPMC and Wyeth is no longer providing pharmaceutical support for this trial. Sites are asked to record the lot number of the Prevnar® dose given as required on the PACTG P1024/P1061S Immunization Record (TXW2020). Details regarding the reimbursement procedure are described in the attached document. Please note that sites will be reimbursed based on the number of Prevnar® doses given, not the number of subjects enrolled. The above information will be incorporated into the next version of the protocol at a later time if it is amended.

Thank you for your interest in PACTG P1061s. Please contact the protocol team at actg.teamp1061s@fstrf.org if you have any questions.