PHACS Adolescent Master Protocol Participant Summary

<u>**Title:**</u> Antiretroviral Therapy (ART) Among Children with Perinatally-Acquired HIV Infection: Temporal Changes in ART and Virologic and Immunologic Outcomes for the PHACS Team.

<u>Authors</u>: Russell Van Dyke, Kunjal Patel, Jennifer Read, Miriam Chernoff, Lynne Mofenson, George Siberry, Sandra Burchett, Hermann Mendez, Zoe Rodriguez and George Seage III, for the PHACS Team.

<u>Study Description</u>: Currently, about 8,500 children in the US have been HIV-infected since birth. Most are between 7 and 18 years of age. We studied what HIV treatment these children have received over time and how they are doing.

Study Population: As of January 2009, there were 247 children enrolled in AMP with information on their therapy. They are between 7 and 16 years of age and have been HIV-infected since birth.

<u>Results</u>: This report includes 247 children in AMP. Their median age at study entry was 12 years. Fifty-five percent were female, 77% were African-American, and 16% Hispanic. Their median CD4 percentage was 32% at study entry and two-thirds had an undetectable viral load. At entry, 92% were receiving HIV treatment and all had previously received therapy. Treatment was started at a median age of 0.6 years. Children born in earlier years started therapy at an older age. Their median duration of therapy was 11.2 years. The number of different regimens each child had received was between 1 and 19, with a median of five. Prior to 1998, most children received only 1-2 drugs. After that, the use of HAART increased. At entry, 89% were receiving HAART, 3% non-HAART therapy, and 8% no therapy. The most common drugs at entry were 3TC, ZDV, d4T, abacavir, and lopinavir/ritonavir (Kaletra). Their average CD4 percentage has been stable since 1999 and their median HIV viral load has been undetectable since 2002. Children who were born after 1995 have maintained higher CD4 counts than those born before 1995.

Conclusions: Most children in AMP have undetectable HIV and normal CD4 counts. Children who were born after 1995 have maintained higher CD4 counts than those born before 1995. Very few children are currently receiving the newer classes of HIV drugs.

Support: This study was supported by NICHD with co-funding from NHLBI, NIAID, NIDA, NIMH, and NIDCD.