## PHACS SMARTT Participant Summary

## Title: Combination Antiretroviral Use and Preterm Birth

<u>Authors:</u> D. Heather Watts, Paige L. Williams, Deborah Kacanek, Raymond Griner, Kenneth Rich, Rohan Hazra, Lynne M. Mofenson, Hermann Mendez for the PHACS Team.

**Study Description:** Some past studies have found that women with HIV taking combination antiretroviral (ARV) therapy during pregnancy had a higher chance of their baby being born early. This was especially true for ARV combinations which included a protease inhibitor (PI). However, other studies have not found the same increase in risk of early birth with these ARV combinations. We studied this question in mothers enrolled in SMARTT.

**Study Population:** We included 1869 pregnancies with a single baby (we did not include twins and triplets). We looked at how many had preterm birth. Preterm birth happens when the baby is born before 37 of the 40 weeks of a full term pregnancy.

We also looked at type of preterm birth. Preterm birth can be spontaneous or indicated. Spontaneous preterm birth happens when either the water bag breaks or labor starts on its own. Indicated preterm birth happens if the doctor decides the woman needs to have her baby early because of problems like high blood pressure or poor growth of the baby. We also looked at small for gestational age (SGA). We defined SGA as babies in the lowest 10% of weight for their age.

**<u>Results</u>**: We didn't find a higher risk of preterm birth for women who used combination ARVs when they were pregnant overall. There was also no higher risk of spontaneous preterm birth. We did find that women who took combination ARV with protease inhibitor drugs early in pregnancy had a higher risk of early birth. This risk was about 55% higher than for women who took ARVs later during pregnancy. This increased risk did not go away even when we accounted for other factors like race and low income. We also took into account how sick the mother was while pregnant, based on her CD4 count. The only individual drugs linked to higher risk of preterm birth were ritonavir, saquinavir, and lopinavir/ritonavir. We didn't find any increased risk of SGA babies with any type of ARV drugs used in pregnancy.

<u>**Conclusions:**</u> Further studies are needed to figure out why use of combination ARVs early in pregnancy might increase the risk of early birth. However, women should not stop their drugs during the first trimester. Pregnant women on ARV drugs should be educated about signs and symptoms of preterm labor so they can seek medical care if they have symptoms.

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