CAB Conference Call December 7, 2017 12:00 EST Meeting Minutes

Participants:

Alex FSTRF

Andrea Jacobi Medical Center

Brandon University of Florida, Jacksonville

CamilleUniversity of Puerto RicoClaireHarvard UniversityDebHarvard UniversityDeliaUniversity of Miami

Exzavia Children's Diagnostic and Treatment Center

Gena University of Miami
Jennifer San Juan Hospital
Joel University of Puerto Rico

Julie University of Alabama, Birmingham

Julie Westat

KimbraeTexas Children's HospitalKylieTexas Children's HospitalLakeshaUniversity of Illinois, ChicagoLatoniaUniversity of Illinois, Chicago

Lourdes San Juan Hospital

Megan Westat

MonicaTexas Children's HospitalRaikoUniversity of Colorado, DenverShannonUniversity of Alabama, BirminghamStephanieUniversity of California, San Diego

StephanieUniversity of MiamiTheresaTexas Children's HospitalZenaUniversity of Miami

APPROVAL OF MINUTES

The minutes from the October 26, 2017 call were approved with no changes.

• WOMEN'S HEALTH ADMINISTRATIVE SUPPLEMENT

Deb Kacanek gave an overview of the Women's Health Administrative Supplement. **Deb** explained that the supplement is one year of funding to collect additional data on women's health in SMARTT. The Women's Health team recently got a second request to submit another grant. This grant would include funding for a much larger Women's Cohort. The team is currently working on putting together the grant. The grant is due by next Friday.

The supplement funding will help pave the way for the possible larger Women's Cohort. The goal for the larger study is to study issues relating to women's long-term health. This includes reproductive health, social health, and mental health. It also includes oral health, and HIV medical care. If the grant is won, the larger study would open in early 2019.

The supplement activities will start in 2018. The study will start as a Letter of Amendment (LOA) to the SMARTT study. An LOA is a written description of a protocol change. The team is in the process of finalizing the questionnaires and interviews that will be included in the LOA. The aim for the supplement is to look at changes in maternal and HIV disease status. This includes the time during pregnancy and

after pregnancy (postpartum). The focus will be on looking how women's disease status and health is connected to their child's health. The reason why this is the aim is because the SMARTT study focuses on children's health.

In the next year, the team will expand the data that is being collected from mother's medical charts. The data collection will especially focus on mothers' health after birth. The study should start by January 2018. The data collection will go on for about a year.

Participants in the supplement will include mothers who are enrolling in the SMARTT Dynamic Cohort during pregnancy or at delivery. Participants will also include mothers of children in the SMARTT Dynamic Cohort who are younger than 5 years old. These eligibility criteria were chosen in order to be able to collect the data within 1 year. It might have been difficult to collect data from mothers' medical charts if it had been more than 5 years since her pregnancy. Every woman who is eligible will be given an opportunity to consent. Mothers will need to sign this additional consent because the team will be collecting extra information about their medical history. The data will be collected at the time of their child's 1, 2, 3, or 4 year study visit.

Most of the supplement will focus on getting information from mothers' medical records. The team will collect data on women's diagnoses and health conditions. They will also collect information on viral loads and CD4 counts. Blood pressures will also be collected to help learn more about heart and metabolic risk factors. Additionally, some body measurements will be done at the in-person visits for mothers who have a child between ages 1-4.

The study will also include 3 possible interviews. The 1st will be an in person interview. This interview will be given to mothers who are enrolling during pregnancy or who have a child who is 1 years old. The questions will be on intimate partner violence. The 2nd will be an in person interview. This interview will also be given to mothers who are enrolling during pregnancy or who have a child who is 1 years old. The questions will be on depression. The 3rd will be a computer survey that will be done on a computer in the clinic. This survey will be given only to women who are attending their child's age 1 study visit. The questions will focus on healthcare seeking after giving birth. There will also be questions about adherence and future pregnancies. There will also be questions about birth control and sex.

Kim asked if the team will collect data on fibroids. **Deb** explained that the team will be collecting data on women's health, but that fibroids may not necessarily be captured. This is because the team will be collecting information using existing PHACS Case Report Forms. Those forms do not currently ask about fibroids. The team may collect information on fibroids in the larger study (if the grant is won).

Theresa suggested that the team consider giving referrals to women who report violence during the intimate partner violence interviews.

Deb asked the CAB whether it will be easy or hard to obtain mother's medical records. Several CAB members felt that it wouldn't be hard to collect information up to 5 years after pregnancy. Many CAB members had doctors that were somehow connected to PHACS sites.

For the computer survey, **Deb** asked the CAB about preferences for whether mothers would rather read the survey questions by themselves, or have the computer read the questions aloud. Several CAB members preferred to have the computer read the questions aloud. **Stephanie** suggested that the survey be given as an interview. If not able to given as an interview, many CAB members may prefer to just read them by themselves.

NOTE: The next CAB call will be on Thursday, January 25, 2018 at 12:00 pm EST.