Cerebral Palsy Research Network Meeting Minutes
Wednesday, June 15, 2016
via Teleconference

Attending: Anastasia Arynchyna (Alabama), Anita Bagley (Sacramento), Amy Bailes (Cincinnati), Kristie Bjornson (Seattle), Rob Bollo (Utah), Taryn Bragg (Phoenix), Fay Callejo (Columbia), Nancy Clegg (TSRH), Pritha Dalal (UCSD), Kerry Day (UVA), Eileen Fowler (UCLA), Paul Gross (CPRN), Susan Horn (Utah), Ed Hurvitz (Michigan), Chris Joseph (Kennedy Krieger), Jacob Kean (Utah), Carla Lewis (Atlanta), Dennis Matthews (Colorado) Tyra Mattingly (Colorado), Garey Noritz (Nationwide), Jerry Oakes (Alabama), Allison Oki (Utah), Michael Partington (Gillette), Gadi Revivo (Chicago), Brandon Roque (Alabama), Aloysia Schwabe (Texas Childrens), Manish Shah (UT Houston), Rich Stevenson (Virginia), Jilda Vargus-Adams (Cincinnati)

Action Items:

All: Update grant admin information in survey by Friday, June 17.
Complete site survey by Wednesday, June 22.
Review Milestones and Deliverables Document and send questions to: Kerry Day.

Rich: Resolve questions / issues raised about study exclusions and gait scales.

Agenda/Notes:

- ◦   **Call Playback:** Download MP3 of call recording or

- ◦   **Playback Number:** (605) 562-0029 **Access Code:** 881-975-274# **Ref** #24

Welcome and Overview
Paul Gross gave a brief overview of the study as a revision to last year's effort with more narrow inclusion criteria. He touched on CPRN's progress with the CPRN Registry having launched at Nationwide Children's Hospital and other IRB submissions.

PCORI CER application
Rich Stevenson, lead PI for the PCORI study application entitled "Comparative Effectiveness of Surgical and Non-Surgical Interventions for Ambulatory Children with Bilateral Spastic (Diplegic) Cerebral Palsy using Patient Centered Outcomes,"reviewed the highlights of the planned study and how the proposed study responded to issues raised in the review of last year's submission. Rich opened the floor to questions. Questions to be addressed included:

- What clinical measures in addition to the Patient Reported Outcomes will be included (gait lab, video, CPRN registry existing gait scales?) The study steering committee will discuss and take into consideration.

- Will the SDR arm be of equal proportion? That is the goal and one reason for a large number of sites. Not all sites are required to do SDR. But we will re-evaluate this when site surveys are completed.

- When will the intervention happen with regard to enrollment? Goal is to enroll patients indicated for surgery and capture them no later than pre-op clinic.

- Do you think prior surgery is a fair exclusion? There was good discussion on this topic where multiple surgeries were considered common and important to understand. Accrual with this exclusion criterion will be more difficult. It would be important to set a clear timeline for exclusion post surgery and important to be sure that the analysis could support this. But the study might be less "clean" if this population is included. The study steering committee will consider this further.

It was emphasized that the study team does not believe that the two year follow up is the end of critical follow-up and that registry and follow-on studies will be important to study long term outcomes.

Site Selection Process

Given the inclusion / exclusion criteria, it is important that we have accurate information about each center's population and average annual interventions for the target population. The timeliness and accuracy of this information will be very important in evaluating sites. We will not be able to support very small sites but should be able to support a wide range of centers. We anticipate requiring 18-25 centers. We realize that there is significant work, including the site survey, that must be done in advance of site selection. Site surveys are due June 22 and the study team will do its best to make selections very quickly – no later than June 29.

Rich also addressed that the inclusion / exclusion criteria necessitated involving many sites. This factor has changed our budgeting process to specify a much smaller amount up front ($25K) and $1500 per patient to enable us to support many more sites.

Milestones and Deliverables

Kerry Day, grants manager for this project at UVA, reviewed the key documents and timing that were needed and when they were due to UVA. Kerry's email address is KRD5Y@hscmail.mcc.virginia.edu. The key first step is to update the information about your grant manager in the survey. Sites that participated in last year's application will have a head start on many key documents such as budget. Budgets will be constructed based on an assumption of patients to accrue at $1500 per patient based on information from the site survey. But sites will need to determine how to divide that payment among PI time, coordinator time and other resources. The deliverables have been organized to allow sites to turn in the easiest documents first and the more difficult documents the following week.