

## Cerebral Palsy Research Network Meeting Minutes

Tuesday, March 29, 2016

via Teleconference

**Attending:** Amy Bailes (Cincinnati), Rob Bollo (Utah), Nancy Clegg (Texas Scottish Rite), Pritha Dalal (UCSD), Marcia Greenberg (UCLA), Paul Gross (CPRN), Ed Hurvitz (UMich), Jacob Kean (Utah), Jeff Leonard (Nationwide), Aga Lewelt (Jacksonville), Dennis Matthews (Colorado Children's), Tyra Mattingly (Colorado Children's), Dennis Matthews (Colorado Children's), Allison Oki (Utah), Sylvia Ounpuu (Connecticut Children's), Michael Partington (Gillette), Kristin Peters (Connecticut Children's), Yvonne Wu (UCSF)

### Action Items:

#### All:

Please approach your IRB liaison with the protocol and discuss the waiver of consent.

Please email Paul if you are interested in reviewing/testing the REDCap forms on a test server.

Please provide email or track changes feedback to the strategic plan that was distributed.

**Brian:** (continued) Email introduction of Rich Finkel to Paul regarding the SMA research agenda planning process.

**Garey:** Finalize waiver of consent issue for reliance IRB.

Review inclusion/exclusion criteria from Marcia Greenberg. Any change to protocol?

**Jacob:** Follow-up clinical site monitoring/DSMB details.

**Paul:** Re-email instructions for garnering live access to REDCap forms and how to provide feedback.

**Next Call is Monday, April 11, 2016 at noon ET**

### Agenda/Notes:

**Call Playback:** Playback Number: (605) 562-0029 Access Code: 881-975-274# Reference #18

MP3 Download of the Call: <https://www.dropbox.com/s/opzfvwcvoh9it4p/CPRN-Investigator-Call-20160329.mp3?dl=0>

#### IRB Protocol

Jacob Kean, Data Coordinating Center PI from the University of Utah, reviewed the final IRB protocol and asked investigators to use it as a discussion point with IRB liaisons at your site. **Please discuss the waiver of consent and garner any feedback.** IRB Protocol to be submitted to Nationwide pending finalization of waiver at NCH. Reliance IRB will be available through PEDSNet / Pediatric Research Alliance. Reliance site participants may opt out of reliance IRB.

Nancy raised concerns about needing a Data Safety and Monitoring Board (DSMB). Paul and Jacob felt this level of monitoring was not commensurate with the level of risk of an observational registry. Nancy

emphasized that more detail would be needed on the monitoring – who, how often, and the reporting.  
**Jacob and Paul will discuss and follow-up with Nancy.**

**Paul requested that Garey Noritz review the inclusion / exclusion criteria that Marcia Greenberg forwarded.**

Timeline expected for IRB submissions were set at four weeks post finalization of IRB protocol (anticipated in two weeks/April 11.)

#### Forms Update

**REDCAP:** Paul re-iterated that opportunity to provide feedback on the live REDCap forms. Several investigators have signed up for this already. **Paul will re-send the email with the instructions for getting an account and providing feedback.** The goal is to finish any REDCap form feedback in the coming two weeks.

**EPIC:** Paul reviewed the updated progress on Epic forms and Smart Data Elements (SDE). [SDEs are the way in which the any data elements like the CPRN Registry Common Data Model is implemented in Epic]. Nationwide Children’s Hospital (NCH) has completed the non surgical forms and they are being reviewed by Garey Noritz. They will deploy to the Playground (Epic test environment) and then to Production, i.e., use them in their CP clinic, in the coming weeks. Simultaneously, Texas Scottish Rite Hospital (TSRH) has developed a complete set of forms and the associated Smart Data Elements for CPRN. This effort is in support of an Epic rollout at TSRH. The forms / SDEs have been developed by an orthopedic surgeon, Lawson Copley, who is the assistant CMIO at TSRH and has extensive experience in Epic from his prior work at Dallas Children’s Hospital. Because of his role on the Pediatric Orthopedic Steering Board, an advisory committee formed by Epic, he has been able to submit the CPRN SDEs for inclusion in Epic Foundation. These SDEs are due to be approved and rolled out in Epic in mid June. Shortly after this time, NCH should be able to “re-wire” the NCH CPRN forms to the approved Epic SDEs and provide the initial set of forms for download and integration by other Epic sites. The SDEs for these forms will be available through an update to Epic in the same timeframe. This alignment means that sites should be able to begin experimenting with or deploying the non surgical forms in the July timeframe. The surgical forms will then be tested in the July – August timeframe in preparation for an October 1 rollout at TSRH. The complete package of forms should be available toward the end of summer. These steps have substantially simplified the level of investment for any Epic site to rollout forms for data collection. The exact details of this rollout, updates, any associated direct or indirect costs, still need to be determined but Epic implementation staff has been very accessible and helpful for CPRN.

**CERNER:** No update on Cerner forms at this time. Boston Children’s has the REDCap forms and is in discussion with Seattle Children’s and Cerner on how to best proceed.

#### Business Associate’s Agreement (BAA)

The BAA has been developed and Paul is waiting for requested contact information from University of Utah Privacy Office. Numerous sites already have an active BAA with the University of Utah for the Pediatric Emergency Network (PECARN) or the Critical Care Network (CPCCRN). We will reach out to you shortly to request specific contact information and then initiate the dialogue on getting the BAA started. The site PI will have to play a role in this process.

#### CPRN Strategic Plan

A draft strategic plan was distributed. Please provide any feedback or questions to Paul. Feel free to make edits or comments with track changes. The plan highlights our desire to balance clinical research with quality improvement.