

Cerebral Palsy Research Network Meeting Minutes

Monday, April 11, 2016

via Teleconference

Attending: Amy Bailes (Cincinnati), Nancy Clegg (TSRH), Pritha Dalal (UCSD), Paul Gross (CPRN), Susan Horn (Utah), Christopher Lunsford (UVA), Freeman Miller (Al duPont), Bill Oppenheim (UCLA), Michael Partington (Gillette), Ken Rogers (Al duPont), Ben Shore (Boston Children's), Michele Shusterman (CP NOW), Brian Snyder (Boston Children's), Debbie Thorpe (UNC—Chapel Hill)

Action Items:

All: Hold off on IRB Protocol submission until Nationwide Children's Hospital receives approval.

Amy: Schedule call with Sam and Chris at the DCC to resolve feedback that hasn't been addressed.

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

Jacob: Email deadline for CDM feedback to the group.

Next Call: April 26, 2016 at 2 pm EDT.

Agenda/Notes:

Call Playback: (605) 562-0029 Access Code: 881-975-274# Reference #19

[Download Playback as MP3](#)

IRB Protocol Status

Paul clarified the issue raised by Rob Bollo in email regarding submission sequence. All sites should hold off on submitting the finalized IRB Protocol until Nationwide Children's Hospital (NCH) has submitted and received approval. We had mistakenly indicated that non reliance sites could proceed but the protocol would have to be modified to support this sequence.

Garey Noritz of NCH reviewed the status of the IRB protocol submission. He is awaiting feedback from Elaine Wakely who manages the external IRB (reliance) process at NCH and from Paul Gross and Jacob Kean before submitting. He has completed the IRB forms and waiver request. Submission is imminent.

Steps to Leverage Reliance IRB Process

Paul distributed an email to all CPRN site investigators as to how to leverage the reliance IRB process. Key points are summarized below.

For sites that are part of PEDSNet, including:

- Boston Children's Hospital
- Cincinnati Children's Hospital
- Children's Hospital of Colorado
- The Nemours Foundation
- Seattle Children's Hospital

NCH we will have the sites listed above IRB's complete and send NCH their PEDSNet determination form and NCH project-specific checklist, which indicates their willingness to cede review to the NCH IRB. The appropriate forms will be mailed once the IRB protocol is approved.

For any sites that are not PEDSNet, the option to participate in the reliance process will require a different set of forms. NCH will have them sign a project-specific NCH Institutional Review Board (IRB) Authorization Agreement that is based on the OHRP format and NCH project-specific checklist

We will distribute the NCH IRB application pdf and the NCH IRB approval letter – most relying IRBs will want to have these before they will cede review to NCH IRB.

NCH will want relying sites to sign the IAA first and when Garey amends the NCH study to add their site, we will fully execute the IAA and send them the final document, along with the amendment approval letter.

Sites that are not using the reliance IRB will be able to submit using the CPRN developed IRB Protocol and the above referenced NCH documents in accordance with the reference to NCH approval in the IRB Protocol.

Please direct any questions with regard to the reliance process to elaine.wakely@nationwidechildrens.org and CC paul@cpresearch.net and garey.noritz@nationwidechildrens.org.

REDCap / CDM finalization

A significant number of investigators have signed up for review of the REDCap forms online. We had a challenge with the feedback method that we had prescribed as reviewers could only comment. Paul has sent around a new email with a [link for providing feedback on the forms](#). Amy Bailes raised the issue of feedback that had not been addressed from comments in the spreadsheet. Amy is going to schedule a call with Chris and Sam at the DCC to resolve.

Jacob will mail out a completion deadline for feedback on the CDM.

Epic Demonstration and Update

Everyone should have received email from Molly Dempsey who is the associate CMIO at Texas Scottish Rite Hospital (TSRH). She is organizing a WebEx demonstration of the CPRN forms and data model in Epic lead by TSRH Assistant CMIO Lawson Copley. You may forward the invite to other providers who will be participating in the collection of data through EMR forms and to IT people that are interested in the demonstration. The presentation will take place on May 9, 2016 at Noon ET in place of our bi-weekly meeting scheduled for that time.

Nationwide will deploy the non surgical forms in the next week into its production environment.

We are still exploring providing Epic Playground access through a Citrix login to other sites from TSRH. The CPRN Registry elements will be released by Epic in a Special Update (SU) in June. The SU will not be useful to sites until the forms are released in October with the exception of to Nationwide which will “re-wire” its deployed smart form to the Epic elements when they are released.

We need to determine along what timeline the updates to the CDM will get included in the Epic distribution. Paul explained that this will likely require new SDEs unless the existing SDEs can be augmented without violating the data integrity of any data collected in them prior to our updates.

Patient Reported Outcomes

TSRH implemented all of CPRN with the exception of the PROs because of licensing issues. We have connected Unni Narayanan and SickKids which owns the license to our two PROs (CP-Child and GOAL) to Epic. The plan of record is that Epic will implement those PROs for use in MyChart but each institution will have to sign a (royalty free) license with SickKids specifying the terms of use.

Long Term Outcomes Registry – we have been looking at platforms to collect PROs from people that are not treated at CPRN sites and to follow people long term if they transition from a pediatric institution. It is looking like we will select REDCap and host this capability at the University of Utah. This would facilitate the future connection of the CPRN clinical data set with patient reported outcomes for longitudinal studies.

Other Updates

Cerner Forms – Boston Children’s Hospital is taking the lead on this and Ben Shore plans to meet with their CMIO soon to start work in earnest. The hope is to have some thing ready concomitant with the Epic forms release in October.

Research Planning Meeting -- we are considering a PCORI application to support a research agenda planning meeting. The meeting will proceed independent of external funding but will have more robust support for patient advocates if funding can be obtained. It was asked if we could have a meeting in conjunction with the AACPD meeting. This will be considered but given the overlap with CPRN and AACPD leadership, we are concerned about feasibility of a one to one and half day meeting.