

**Cincinnati Pediatric Research Group
Minutes of the Meeting
June 26, 2007**

IN ATTENDANCE: Lea Alae
Chris Bolling, MD
Deborah Boyd, MD
Joan Linhardt, MD
Bob Siegel, MD

1. ADMINISTRATIVE

- IRB Accreditation and What it Means for the CPRG

The CCHMC IRB has received AAHRPP accreditation (Association for Accreditation of Human Research Protection Programs). This accreditation ensures that the human subjects' research conducted by CCHMC meets high ethical and practice standards. To obtain this accreditation, the IRB participated in an extensive review of all aspects of its operations and made necessary modifications to meet requirements.

Some of these modifications effect CPRG, and most will be transparent to community members (they involve application, continuing review, etc. of protocols). The following changes DO effect our community members:

- Assignment of an IRB for participation in human subjects research – The US Department of Health and Human Services, Office of Human Research Protections (HHS, OHRP) requires everyone participating in human subjects research to be covered by an IRB. In the past, we had each CPRG member sign an “Unaffiliated Investigator Agreement.” HHS is no longer accepting these agreements as valid assurance and has replaced them with the Federalwide Assurance (FWA):

An FWA application is filed by an organization to provide assurance to HHS that the organization's participation in human subjects research is conducted ethically and that the organization has assigned an IRB to oversee their research protocols. It covers the entire organization. For example, CCHMC has an FWA assigning IRB responsibilities to the CCHMC IRB. A practice can file an FWA to assign CCHMC IRB to be their IRB (a separate IRB Authorization Agreement with CCHMC is also required).

- CITI Training – If a member wishes to participate in any human subjects research, and CCHMC IRB is their assigned IRB through one of the above assurance mechanisms, the member must complete the required CITI training. CITI training is recommended, **but not required**, for participation in any CPRG project that is not considered Human Subjects Research and does

fall under the oversight of the IRB (i.e. Surveillance). It is not required until you want to participate in an IRB-approved study.

We have been given permission to distribute the CITI materials in paper form and administer the “quizzes” in paper form. We will be putting together booklets for our members who prefer to complete the training in paper vs. internet format. This will, hopefully, cut down significantly on the amount of time it takes to complete the training. Quiz sheets would then be faxed to the CPRG office and we will input them into the CITI system so that the IRB has record of completion.

Further, the IRB has developed a suggested schedule of modules to complete that would space the training over 6 months. It is only a suggested schedule, however, and training may be completed sooner.

- Ohio Department of Health (ODH) Epidemiology Conference

Karen Evans of the Cincinnati Health Department invited Chris Bolling to present at the August ODH Epidemiology Conference in Columbus. He will present the Surveillance project and the CTSA (see below) grant proposal as well as our network activities in general.

Follow-up note: The presentation did not take place at the August conference. We will attempt to reschedule to a future conference date.

- OPRC (Ohio Pediatric Research Consortium) Meeting

The next OPRC meeting will be August 17 in Columbus. If anyone is interested in joining Bob Siegel, please let him know.

- Site Visits

Chris Bolling has visited with 20 practices to date to discuss our current and upcoming research activities and to solicit new members. This has resulted in 25 new members!

If you would like Chris or Bob to visit your practice and provide an update on our activities or talk to you about membership or how you can be more involved in CPRG activities, please contact them or Brenda Thompson (brendam.thompson@cchmc.org or 513-636-3382).

- Surveillance

The Surveillance system has been modified slightly to allow us to take the project state-wide. Dayton and Columbus networks have expressed some interest in collecting their data, and this will be discussed further at the OPRC meeting. The changes to the system do not impact what or how data is entered, but you will now be able to generate charts on your main page (after you login) for yourself, the Cincinnati tri-state area, or everyone (including other networks once they begin entering data).

We did have a request by Karen Evans at the Cincinnati Health Department that data be collected from PPC and Hopple Street. Occasionally, things are seen at the Health Department clinics and schools that we aren't capturing in the Community, and her belief is that PPC and Hopple street serve a similar population to their clinics.

Follow-up note: Thanks to Drs. Bain and Boyd for agreeing to enter data each week!

- CTSA - Clinical and Translational Science Award

NIH has elected to not continue funding the GCRC (General Clinical Resource Center) structure, and will be funding CTSA's instead. The University of Cincinnati, CCHMC, and the Cincinnati Veteran Affairs Medical Center are developing a grant proposal, due October 2007, to "create an academic home for clinical and translational research" that will also allow those outside the three institutions access to start studies of interest of them.

Chris Bolling notes that a PBRN is a central piece of the grant proposal and would expand the current CPRG structure to include adult medicine practices, both general and specialist in nature. The tentative name of the new Cincinnati PBRN as written in the grant is Cincinnati Lifespan Practice Research Network (CLPRN, or "Clipper Net").

- CPRG Newsletter

The CPRG Newsletter has been on hiatus but will spring back to life beginning Fall, 2007. It will be a quarterly newsletter to provide information and updates to CPRG members and the rest of the community. If you would like to contribute to the newsletter, please contact either Lea Alae or Chris Bolling. The fall issue is expected to come out in early September.

- CPRG Retreat/Meeting

It has been several years since the last CPRG retreat, and Bob Siegel expressed interest in having a meeting that would bring together much of the membership. Chris Bolling informed us that the Cincinnati Pediatric Society (CPS) wants to have a meeting/training on coding/billing/etc. and that perhaps we could partner with them on a whole-day meeting to cover those topics plus research in practice. Tentatively, it was discussed that a Saturday in November would be an ideal time.

Look for more information to come!

2. UPDATES ON CURRENT AND PENDING PROJECTS AND STUDIES

- Atkins Study

Bob Siegel reported that the Atkins study is in the final year of follow-up, with 7 active participants remaining.

- Parental Perception of Weight Study

Chris Bolling reported that this study is almost complete and that preliminary results show that caregivers have less accurate perception of children's weight as children get bigger.

- Staph Infection (MRSA) Study

The study overall has received IRB approval, and any member that completes the assurance process and CITI training will be approved by the IRB to participate.

The purpose of the study is to see how practitioners currently treat skin and soft tissue infections in the hopes of describing empiric therapy and outcomes of particular treatment regimens. No change to routine practice is required – a form will be completed at the time of enrolling a patient in the study, and the patient's chart will be reviewed one week later to capture any follow-up visits and outcomes. Each participating member will be asked to collect data on only 10 patients.

If you wish to participate in this study, please contact Bob Siegel.

- Iron Deficiency Study

This study, which is designed to learn if treatment with iron will alleviate night terror symptoms, is pending funding. Chris Bolling would like to approach Bayer.

3. NEW IDEAS

- Zofran in Practice Study

Bob Siegel is interesting in finding out if Zofran is effective in a practice setting. He noted that ERs use it, but it is expensive for patients and not often covered by insurance.

Next Meeting: September TBD