

**Cincinnati Pediatric Research Group
Minutes of the Meeting
May 23, 2006**

IN ATTENDANCE:

Lea Alae
Jeralyn Bernier, MD, MPH
Chris Bolling, MD
Deborah Boyd, MD
Jim Davis, MD
Mark Deis, MD
Emanuel Doyne, MD
Elena Huang, MD
Joan Linhardt, MD
Bob Siegel, MD
Brenda Thompson

Guest attendee:
Jennifer Ruocco, Director of ORCRA

ADMINISTRATIVE

- CITI Training - Jennifer Ruocco, Director of ORCRA (CCHMC Office of Research Compliance and Regulatory Affairs) discussed compliance issues regarding CITI training. Members are required to complete CITI to participate in CPRG human-subjects research such as the Atkins study because they are identifying, enrolling, and tracking patients, and are technically involved in the conduct of the study.

We do, however, have some flexibility regarding the June 1 deadline for our members, but we need a plan for bringing members into compliance. Ms. Ruocco suggested that we could work with 2 modules a month, providing information and assistance to to reduce the time the training requires. Those present agreed this would be a good approach, and we could provide training via the CPRG meetings, emails, and or the newsletter.

Going forward with new studies, Ms. Ruocco informed us that we need to ensure member practitioners are listed as key investigators on protocols submitted to the IRB This will require a pre-certified group of members who have completed the CITI training and are interested in actively participating in research studies. Dr. Bolling will address this with various members during site visits.

There was further discussion regarding growing the CPRG membership and the active participation of members and the impact that additional educational requirements and regulations will have on that effort. Government-imposed changes mean our program will become more regulated instead of just involving a small amount of research. In the

long term we will have to be creative about getting members certified to participate in research.

- Credentialing - Dr. Bolling informed the group that the medical staff bylaws allow CPRG to state that a member has full privileges based on criteria we can establish. The criteria would be included as an addendum to the bylaws. This should help make the CPRG an attractive option for community physicians who no longer round on patients. It was noted that the number of Gen Peds patients going to GIS is 60%.
- Contracting Issues / Unaffiliated Investigator Research Agreements - There are two types of agreements – investigator agreements and institutional agreements. The CPRG has unaffiliated investigator agreements with each member that only covers the specific member. Institutional agreements cover an entire practice.

Ms. Ruocco informed us that if only the community physician is involved in the study, an unaffiliated investigator agreement is acceptable, but if nurses and office staff are involved (discussing the study or ordering blood draws, for example), an institutional agreement would be needed. She will review our current agreement to be sure it covers what the IRB requires it to cover, and if new agreements need to be signed we will distribute them to the members.

- CPRG Leadership Changes - Dr. Bernier is relocating to Washington, DC in July and Dr. Bolling will be assuming the remainder of her responsibilities. Dr. Bernier may remain involved with the Surveillance project, but that has not yet been determined.

It was also announced that Dr. Huang is moving to CHOP this summer.

- Update on Presentations at PAS and AHRQ Meetings
 - Drs. Bolling and Siegel presented the Sleep Terrors study proposal at both PAS and the AHRQ meetings. Please see below for additional information regarding the study.
 - Dr. Siegel presented the results of the Atkins study to date.
 - Dr. Doyne presented the ADD/ADHD follow-up survey results.
- AHRQ PBRN Research Contract - At the AHRQ meeting, Dr. Bernier learned that they want to contract with 5-10 PBRNs who are interested in and capable of quick turnaround research work. Dr. Bolling believes we should pursue it, and those in attendance agreed as long as we are able to choose the projects we do and there are pediatric research projects to select. It will be a competitive process, depending on how many PBRNs apply, and the contract includes ample funding. We will also look at the possibility of having the entire OPRC apply as a single PBRN, instead of applying individually as the CPRG.
- OPRC Meeting - There is an OPRC meeting on June 23 in Columbus. Dr. Bolling will represent the CPRG.

CURRENT PROJECTS AND STUDIES

- Atkins Study - Recruitment for the extended study (years 2 and 3) is ongoing. Whitney Rich is contacting patients who completed the first year. Dr. Siegel will be writing up the results from the first six months for publication.
- Maternal Depression - Amy Heneghan from Rainbow Babies was in Cincinnati May 22 to give an educational presentation about maternal depression to nurses, social workers, and other medical professionals. We received several new requests for brochures after that session, and still have about half of our stock left.

Dr. Heneghan will be leaving Rainbow Babies and relocating to San Francisco. The state-wide maternal depression project will be run by Dr. Frank Putnam here at CCHMC.

NEW & UPCOMING INITIATIVES

- Sleep Terrors and Iron Study - Drs. Bolling and Siegel presented the Sleep Terrors study proposal at both PAS and the AHRQ meetings. At both meetings, the attendees felt it was important to do a case control study first. Drs. Dies, Bolling and Siegel will revisit the protocol. David Lami commented that this is the type of study PBRNs should be doing, but he is skeptical we could get it funded.
- Soft Tissue - Treatment of staph and skin infections is a growing problem that interests physicians, but there is disagreement about whether treatment with Bactrim or clindamycin is better. Dr. Siegel and Dr. Bolling through the CPRG are interested in a possible study looking at the different treatment methods in a practice setting.