

**Cincinnati Pediatric Research Group**  
**Minutes of the Meeting**  
**March 27, 2006**

**IN ATTENDANCE:** Lea Alae  
Jeralyn Bernier, MD, MPH  
Chris Bolling, MD  
Mark Deis, MD  
Elena Huang, MD  
Joan Linhardt, MD  
Bob Siegel, MD

**ADMINISTRATIVE**

- Membership – There was further discussion regarding expanded CPRG membership, including Dr. Tom DeWitt's recommendation to Drs. Bolling and Bernier that all members, whether active or not, should be required to complete the PRINS datasheet. This was agreed to be a good idea to provide the network with basic data about the member practices. Dr. Bolling will check with Medical Staff to determine if a basic level of membership in CPRG can be an available criteria for Medical Staff membership.

Membership will have two categories:

Basic membership – Requires completion of PRINS. Any member not meeting the requirements for Active membership would automatically be considered a Basic member.

Active membership – Requires completion of PRINS and at least one of the following within the previous 2 years: participation in a study, attendance at meetings, and/or active participation in the development of study ideas or development of a study protocol.

*Post-Meeting Update: Dr. Bolling spoke with Dr. Kevin Reidy, Medical Dental Staff President. They will plan on making "Active Membership" in CPRG a method for keeping full privileges. It is already in the by-laws and we believe we can define "active" to best suit our purpose. Dr. Reidy will ask the Medical Staff Bylaws Committee to verify this.*

- CITI Training – All active members are encouraged to complete the CITI training; however, it is not required unless or until you are recruiting patients or are listed on the protocol as a PI. **If you have patients enrolled in the Atkins study, you must complete the CITI training by June 1, 2006.** There is **NO FEE** for the training – it is free. If you want CME credit for the training (up to 6 hours through University of Miami), there is a \$60 fee for the CME.

The training is made up of modules that each take 10-20 minutes, depending on how fast and how much you read prior to taking each module quiz. The quiz can be retaken until a satisfactory score is obtained.

It was noted during the meeting that if anyone listed on a protocol has not completed the CITI training by June 1, the IRB can shut down the project until the requirement is met. Protocols submitted after June will not be approved until all listed participants have submitted proof of CITI completion.

*Post-Meeting Update: Those who have completed the training agree that it is very easy and straightforward; however, we have begun receiving some resistance to the training from a few community members. CPRG management staff will confer with CCHMC CITI representatives and IRB staff to further investigate the requirement for community members.*

- PAS and AHRQ Presentations – Dr. Siegel is presenting a poster on the Atkins project at PAS, and Dr. Manny Doyne is presenting a poster on the ADD training program. The Dayton group is also presenting a poster on the ADD survey. Drs. Doyne and Siegel are chairing Special Interest Groups at PAS. Dr. Bolling is to present the Sleep Terrors and Iron proposal at the PBRN SIG, and again at the AHRQ PBRN meeting as a work in progress.
- IRB Division Review – New IRB submission rules require a divisional review prior to submission of a protocol. The Research Section of the Division of General and Community Pediatrics has a standing research review meeting every Friday morning that will meet this need.

## CURRENT STUDIES

- Atkins Low-Carbohydrate Diet Study – The 6-month data will be presented at PAS. The data from 6 months to 1 year is not looking too great so far. Eleven patients have so far had their 1-year visit. While 7 of the 11 have had a decrease in BMI from the 1<sup>st</sup> visit, overall, the group has had no net weight change at one year. Individually, 3 have lost and 8 have gained with a range from +33 to -68 lbs.

The Atkins Foundation approved an expansion of the study to track the patients for another two years, and were even more supportive after learning of the one-year results to date. They are very interested in discovering what happened and why.

Summary data was also presented from the 6-month qualitative survey completed by both the child and parent. Dr. Siegel would like to collect the same survey each year and is trying to identify a validated questionnaire to better understand the study outcome.

It was also noted that the response by patients to continue with the study for another 2 years has been disappointing so far. Whitney Rich is contacting patients who completed one year to determine if they are interested in continuing, but only one has agreed so far, and most have not returned her call. It was decided to have the primary care physician contact those who have not yet responded. Dr. Siegel will obtain this list from Whitney and contact the physicians directly.

- Maternal Depression – Amy Heneghan, MD will be providing a training on maternal depression to nurses and social workers on May 22 here in Cincinnati and May 23 in Dayton. CEU will be available. Additional information will be forthcoming.

Dr. Linhardt noted that there was an article in the Cincinnati Enquirer on maternal depression, but it did not include any local information or resources. It was suggested that we could submit a letter to the editors to make physicians and parents aware of our brochure and local resources. Dr. Bernier will pursue this, perhaps with Michelle Ernst.

## PROPOSED STUDIES

- Night Terrors and Iron – The current protocol was distributed. There was much discussion about whether the study should have 2 groups (multivitamin with iron and multivitamin without iron) or 3 groups (MV with iron, MV without iron, and placebo). While the sleep group at CCHMC felt it was important to include an iron-only group, we believe it would be difficult to maintain compliance within that arm of the study, and it would make a double-blind study impossible.

After further discussion, it was decided that the best study would be one that included a placebo. It was also decided that the age range should be narrowed to allow for a narrower hemoglobin level for exclusion. Those with breathing problems/apnea would also be exempt from the study, as would those who would have an increased ferritin level due to illness. As the ferritin is expensive to obtain, FEP is to be explored as an option for this study.

Regarding funding, Dr. Bolling has a meeting scheduled with the development office, who believes they have some possible ideas for funding sources. The sleep disorders group also has a contact with Pfizer.

*Post-Meeting Update: Dr. Bolling met with Drs. Spigarelli and Walson from the Clinical Trials Office regarding funding. They are contacting Bayer and investigating some additional contacts. Dr. Bolling will meet with the Development Office on April 12. Information from Pulmonary Medicine regarding Pfizer is still forthcoming.*

*Dr. Bolling also spoke with Mrs. Jane Khoury, statistician, regarding the numbers of patients required to pursue a three-arm study. She feels that 40 per arm for a total of 120 was an appropriate number.*

- Health Foundation of Cincinnati – Dr. Bolling informed the group about a study the Health Foundation is considering that would look at parental perception of their child's weight. Ed Donovan from clinical effectiveness and Lauren Neimes from the Nutrition Council of Cincinnati endorse a study to determine how accurate parents are when asked to describe the weight of their children.

Dr. Bolling believes this may be an easy study for CPRG practices to participate in. It might involve simply having the parent complete a short questionnaire when they check in, and then taking a weight and height measurement of the child during the visit.

There was discussion about prior studies that looked at this same question, including a Whitaker study, but that was done a number of years ago with a different age population and with a group in Hyde Park and a WIC group in Louisville. By performing this study

with CPRG member practices, a better representation would be obtained that would be generalizable to the larger population.

*Post-Meeting Update: Dr. Bolling met with Lauren Niemes, Ed Donovan and Ryan Buchholtz, a med peds intern who is showing interest in pursuing this project. Lauren expressed interest in funding the project, and Dr. Bolling will work with Ryan to get it going.*

**Next Meeting: TBD**