

**CAB Conference Call
September 24, 2009
12:00 EST
Meeting Minutes**

Participants:

Delia	University of Miami
Christina	Westat
Gail	Texas Children's Hospital
Gloria	University of Florida
Joanne	Westat
Julie	Harvard University
Lonnie	St. Jude
Lisa	Children's Memorial Hospital - Chicago
Maria	University of California San Diego
Mariam	University of Southern California
Mariana	University of California
Marilyn	Bronx Lebanon
Mercy	Westat
Rosia	Westat
Samantha	Children's Diagnostic and Treatment Center
Sharan	University of Alabama Birmingham
Theresa	Texas Children's Hospital

• **MEETING MINUTES**

The group approved the minutes for August 27, 2009. **Lisa** was added to the August minutes.

• **CAB NEWSLETTER**

The newsletter will be released at the end of October. **Christina** asked if anyone would like to write an article with a "Back to School" Theme. Members can contribute to the newsletter by writing about how to help kids succeed in school while dealing with their medical issues. **Mariam** is going to see if members of her CAB will contribute to this topic. **Theresa** wants an article written about HIV disclosure in the school system, and **Samantha** agreed to write the requested article about disclosure.

• **SITE PERFORMANCE EVALUATION**

Julie discussed the role of the Site Evaluation Subcommittee (SES), which is part of the Executive Committee. **Julie** talked about the importance of conducting these evaluations to make sure our sites are maintaining high standards. There are four sections in the SES Report: Enrollment/Retention/Visit Completion, Data Management, Maintenance of

Regulatory Documentation, and Site Monitoring. An outline of the SES Report was included in the call reminder.

For **Enrollment**, each site estimates the number of subjects they can enroll in the study. This is the site's "target" number. During the review period, the site enrollment is evaluated according to the target, actual, and expected numbers. **Retention** is keeping a subject on the study. This is important so that we can see how subjects are doing over time. Retention data includes the number of subjects who are retained in the study. Sites are not penalized if the subject is lost to unavoidable situations. **Visit Completion** is the number of visits that are done compared to the number of expected visits. The number of entry visits completed, and visits completed early or late are assessed.

For **Data Management**, the SES considers data entry completeness, quality and timeliness of the data entered, responsiveness to requests from the data management center, and Summary of Data Performance. The data must be submitted correctly and in a timely manner. Responsiveness is also evaluated for the time it takes a site to reply to queries. Lastly, each site receives a Data Performance score, which takes into account all data-related tasks. All of the data, including the site documentation must be maintained as well. This is reviewed by the Site Monitors, to make sure that we receive all of the data.

The Site Monitors review all study-related documentation, including consent forms, new protocol versions, letters of amendment, Site Establishment forms, Quality Assurance (QA) plans, and IRB approvals. This makes up the **Regulatory Documentation**. Site Monitors review this paperwork and data samplings from the subject visits to determine whether the site is "Satisfactory" or not. This process is entirely confidential—patient ID numbers, rather than patient names are used, and Site Monitors undergo training to maintain confidentiality. Issues that may come up are listed on the Site Monitoring Report, which is reviewed by the SES.

• **VICE CHAIR NOMINATIONS**

Christina informed the group that no one was nominated to the Vice Chair position. The Vice Chair gives input to the monthly CAB and Leadership calls, and attends the fall and spring network meetings (paid for by the PHACS network). **Mariam** wants clarification about the CAB Vice Chair qualifications because she wants members of her CAB to consider the position. **Christina** explained that you have to be a member of CAB. **Julie** clarified that the Vice Chair candidate does not have to be on PHACS, or a parent of a child on PHACS, just an active CAB member. **Samantha** asked if there was a Standard Operating Procedure (SOP) that included the responsibilities of the Vice Chair. **Christina** will include a list of expectations for the Vice Chair when she sends out the request for the Vice Chair. **Julie** asked the group to consider having two co-Vice Chairs so that one could serve as a back-up to the other.

Action Items: Christina will send a request to the group for Vice Chair nominations.

- **NETWORK MEETING**

Christina discussed the network meeting, which will be November 9-10, 2009 at the Omni Shoreham Hotel in Washington, DC. CAB members will be notified when the agenda is final. During the meeting, Study Coordinators and Psychologists will attend trainings. The Principal Investigators and other leadership members will attend as well. Each working group (WG) will meet to discuss their activities, and there is a neuroscience plenary session for approximately two hours. At the end of the meeting on Tuesday, the WGs will report on their current and future projects.

Many of the WGs are writing abstracts for the next Conference on Retroviruses and Opportunistic Infections (CROI) right now. Once these abstracts are released, we will share them with the CAB members, and they will be posted on the website. If you have any questions or if you want to discuss the abstracts in more detail, we can have an author speak on a future CAB conference call.

Julie reminded the CAB members that we were planning to have a CAB presentation at the November meeting. Since **Samantha** may not be able to come and we still do not have a Vice Chair, we are going to postpone the presentation until the spring.

- **PROJECT UPDATES / COMMITTEE REPORTS**

Julie reported that the NIH has requested the PHACS leadership to apply for a contract renewal. The original contract was for five years. That contract has less than one year left. Normally these requests are made sooner, but the NIH has been busy handling and distributing stimulus funds. The good news is that the request for applications is only open to the current PHACS sites.

NOTE: The CAB call takes place the fourth Thursday of each month. The next CAB call is October 22, 2009.