

**CAB Conference Call  
June 26, 2014  
12:00 EST  
Meeting Minutes**

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**Participants:**

<b>David</b>	Westat
<b>Delia</b>	University of Miami
<b>Dolores</b>	St. Christopher's Hospital for Children
<b>Exzavia</b>	Children's Diagnostic and Treatment Center
<b>Jeanie</b>	University of Southern California, Los Angeles
<b>Jennifer</b>	University of Colorado, Denver
<b>Juan</b>	University of Puerto Rico
<b>Juanita</b>	Tulane University
<b>Julie</b>	Harvard
<b>Julie</b>	University of Alabama, Birmingham
<b>Julie</b>	Westat
<b>Kim</b>	Rutgers New Jersey Medical School
<b>Kim</b>	Texas Children's Hospital
<b>Laurie</b>	FSTRF
<b>Lesley</b>	Texas Children's Hospital
<b>Marilyn</b>	Bronx-Lebanon Hospital Center
<b>Megan</b>	Westat
<b>Ramona</b>	University of Florida, Jacksonville
<b>Rosetta</b>	Bronx-Lebanon Hospital Center
<b>Stephanie</b>	University of Miami
<b>Tatania</b>	Tulane University

• **APPROVAL OF MINUTES**

The minutes from the May 22, 2014 call were approved with no changes.

• **PHACS CAB EVALUATION SURVEY RESULTS**

Megan talked about the PHACS CAB Evaluation Survey results. There were 6 responses. Some suggested topics for upcoming calls are:

- Topics covered at last CAB meetings;
- Functional Cure;
- ADHD;
- Community input into protocols;
- Research opportunities in the community;
- Nutrition and HIV in children; and
- Challenges for HIV-positive mothers.

Two PHACS psychologists will talk about ADHD during the August CAB conference call.

- **INFORMED CONSENT AND ASSENT IN PHACS**

David from Westat talked about informed consent and assent in PHACS. Informed consent is based on moral rule. The informed consent document is used as proof of informed consent.

At two PHACS sites, 18-year-olds cannot consent for themselves. At some sites, child assents are offered at age 7. At other sites, child assents are offered at age 12. Some research studies only need verbal assent. Some research studies need written consent.

David talked about the Nuremberg Code. The Nuremberg Code started in 1948. This international document was created because of experiments done on Nazi prisoners of war. Experiments were done on these prisoners without their permission. This code requires voluntary participation in research studies. Consent must be obtained before any research studies are done.

In 1981, the federal law for informed consent was created. Code of Federal Regulations, 45 CFR 46.116, made informed consent a legal requirement. Informed consent must be obtained before research starts. Participants must have time to think it over. Participants must be able to decide without threat or too much reward. Informed consent documents must be given in language that is understandable to the participant. Informed consent must be a written document that is signed.

There are several consent requirements. Consents must include the purpose of the study. This includes risks and benefits. Consents must have other options to being in the study. They must explain how confidentiality is kept and explain that being in the study is voluntary. Consent must also include information about medical care for injury and who to contact with questions. Some consents may include potential unknown risks. They may also have information about ending the study, and information about leaving the study. Some may also include the number of participants in the study, costs, and new findings.

Informed consent is not a legal contract for the participant. Being in the study is always their choice. It is an understanding. Participants may still leave the study at any time.

There are good reasons for using a written document for informed consent. It is a record. It explains all details, risks, and contact information. The Institutional Review Board (IRB) controls the content of informed consent documents.

Sometimes, there are issues with participants' understanding. Informed consent documents may have too little or too much information. Participants should talk about consent with family. They can ask researchers any questions. Some studies use charts to show information. Other studies use pictures or electronic, interactive consents.

Assent requirements vary among states. Federal regulations let the states decide age requirements. Assent means a child's agreement to participate in research. IRBs must decide the content of assents. They must also decide at what age children can assent. There is no federal law for documentation of assent. Parental permission is also obtained with child assent. Parents must allow permission for the child to participate in the study.

Juan asked about informed consent and assent for emancipated children. Emancipated children may be considered adults if they are making decisions for themselves and living on their own. Requirements vary by state.

Kim asked about change in caregivers. If a child changes caregivers, the new legal guardian must also provide consent. In some cases, if risk is very low, informed consent may be waived for parents/caregivers.

- **PHACS CAB NEWSLETTER, JUNE 2014 EDITION**

Megan talked about the PHACS CAB Newsletter, June 2014 Edition. The CAB voted on a theme of "disclosure" for the newsletter. The newsletter is almost complete. The newsletter will feature additional articles about accidental disclosure, PHACS member profiles, and a site CAB spotlight on Site 16. There will also be recipes, CAB glossary, CAB kids, resources, and other disclosure-related pieces. Megan reminded the CAB that all new newsletters will be posted on the CAB section of the public part of the PHACS website. The newsletter will be released shortly.

- **PHACS FALL 2014 CAB RETREAT AND NETWORK MEETING**

The PHACS Fall 2014 CAB Retreat is scheduled for October 21, 2014 at the Bethesda Hyatt Regency in Bethesda, MD. The Fall Network Meeting will take place at the same place on October 22-23, 2014. Megan reminded the CAB about the CAB call attendance requirements for meetings and retreats. As of January 1, 2014, PHACS CAB attendees must have attended at least 60% of monthly CAB calls in order to be invited to go to the retreat and meeting. This means that CAB attendees must call-in to four monthly calls from January to August 2014. CAB attendees are typically picked in August. CAB attendees must also attend the August and September 2014 calls. This will help attendees get ready for the meeting and retreat.

There will be exceptions made as needed for reasons that are unavoidable. Exceptions will only be given to active site CAB members. Exceptions may include reasons such as: language, call availability, and illness.

Megan encouraged CAB members to volunteer to be on the CAB Retreat Planning Committee. CAB members can suggest topics for retreat sessions through the PHACS CAB Evaluation Survey.

- **HEALTH EDUCATION AND COMMUNICATION COMMITTEE**

Megan talked about the Health Education and Communication Committee (HECC). Megan talked about webinars. CAB members and PHACS Leadership have expressed the need to better connect the CAB (including site CABs) with the researchers. Last month, the CAB expressed interest in using interactive webinars during CAB conference calls. The HECC CAB Subcommittee has started looking into webinar options for CAB conference calls.

Megan talked about the disclosure comics. The comics will be for caregivers living with HIV. The purpose of the disclosure comics is to help caregivers disclose their HIV status to their children. The HECC is working on a guide to help caregivers use the comics with their children. The comics will be available on the PHACS website in different formats shortly.

Megan encouraged CAB members to sign up for the new PHACS website: <http://phacsstudy.org>.

- **SITE CAB UPDATES**

Kim talked about site CAB recruitment. Kim's site had a recruitment fair and recruited several new site CAB members. Stephanie talked about working with other CAB collaboration. Stephanie's site CAB is currently working with the ACTG CAB.

**NOTE: The next CAB call will be on Thursday, July 24, 2014 at 12:00 pm EST.**