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## Professional Organizations for Clinical Researchers

**P**ECARN is comprised of a unique group of professionals from a wide variety of backgrounds, and with varied job descriptions. Individuals in this network come from diverse fields including medical technology, public health, business administration, health information management, statistics, biology, teaching, anthropology and many others. Despite these varied experiences, we are all clinical research professionals within PECARN. While each PECARN member's unique background brings with it special expertise that add greatly to our network's ability to perform the highest quality research, we are also required to stay abreast of a standard body of knowledge and conform to a common standard of practice for clinical research professionals. Organizations for clinical research professionals provide excellent resources to support us in our effort to ensure that all PECARN members and affiliates are informed about the principles of GCP. In this article, I will provide a brief background of the two leading organizations for clinical research professionals, and highlight what these organizations have to offer PECARN.



**SHARI NICHOLS**  
UC Davis Study Coordinator

The Society of Clinical Research Associates (SoCRA) was founded in 1992 as a professional membership organization, developed to provide educational programs, certification, and a forum for research professionals to exchange information. SoCRA was originally created to benefit researchers at the site, yet membership has grown to include monitors, data managers, quality assurance, and regulatory representatives from industry, academia, research centers, NIH and regulatory agencies. Their mission is to provide a forum in which members can learn and exchange information to grow professionally in clinical research and to build strong foundations for successful clinical research outcomes. They encourage professionals working in clinical research to collectively support each other and

participate in their educational programs. SoCRA currently has 7,000 members.

### WHAT DOES SoCRA HAVE TO OFFER?

SoCRA offers a certification exam leading to the CCRP (Certified Clinical Research Professional). They also have an annual conference with poster presentations, and offer members an opportunity to publish articles in their quarterly magazine, SoCRA Source. SoCRA sponsors a 5-day Clinical Science course, in addition to multiple 1-day seminars in Clinical Monitoring, Clinical Site management and other relevant topics. SoCRA has Chapters located throughout the United States.

### HOW DO I BECOME CERTIFIED?

To become a member of SoCRA, you must have two or more years experience in clinical research and you must successfully complete a written examination. For a list of detailed requirements, see their website: <http://socra.org>. The cost of SoCRA membership is \$75.00 per year, plus \$195 for the initial certification exam.

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### WHAT IS SoCRA?

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U03MC00008, MATERNAL AND  
CHILD HEALTH BUREAU, HEALTH  
RESOURCES AND SERVICES  
ADMINISTRATION, DEPARTMENT OF  
HEALTH AND HUMAN SERVICES.

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RITA GERARD, BS, CCRP  
SITE MONITOR

**I**nformed consent is a process that involves giving a participant (or legally acceptable representative) adequate information concerning a research study; providing sufficient opportunity for the participant to consider all options; responding to the participant's questions; ensuring that the participant comprehends the information; and finally obtaining the participant's voluntary consent to participate.

There are a number of challenges

## The Short Form Consent

to providing informed consent. Inability to comprehend a large volume consent form is a significant barrier. In order to fully inform the research participant and manage liability, consent form content has increased dramatically over the years. However, there is a point at which consent form volume actually decreases comprehension(1) The difficulty for all researchers is to balance the quantity of information with quality and readability of the consent form.

The Department of Health and Human Services and U.S. Food and Drug Administration regulations (45CFR46.116 and §46.117 and 21CFR50.20) require that consent information given to prospective participants be given in a language that they understand. This applies to readability and language.

Along with standard consent form volume and readability, our network has additional challenges to the consent process. Our studies are performed in fast paced emergency de-

partments. Parents may be anxious, distracted or busy providing care for their child. Time pressure and parental stress are not conducive to comprehension of information.

Another consideration in our network is that our study participants are children. Children are identified as "vulnerable persons" in clinical research under federal regulations. This necessitates that researchers ensure that this population is not exploited. However, adding more verbiage to an already lengthy consent form may not protect children in research studies and can cause more confusion and difficulty in understanding.

Due to the consent challenges outlined above, the Safety and Regulatory Affairs subcommittee of the PECARN steering committee has proposed that our network consider the "short form" as an option for PECARN studies requiring consent.

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# Six Easy Steps to Help with Informed Consent



**BOBBE THOMAS**  
STUDY COORDINATOR

From my own experiences, one of the most challenging aspects of research is consenting and explaining a research protocol to a parent that is in the midst of a crisis. Despite the storm of nurses, doctors, emergency department technicians, and ill children, we still manage to make sure the participant is fully informed and less anxious about participating in a research trial.

Important factors that give us guidance in consenting in these environments are well-written consent and consents that are easy-to-read for the participants. Below are some simple tips to obtaining informed consent:

1. Do your homework: Make sure you know as much as you can about the study protocol, the drug (if any), the consent form, and any other pertinent information regarding the study. It is our obligation to be prepared for any type of question that may arise.
2. Scene safety: Check with the physician or nurse attending to the patient and parent to ensure they are an approachable candidate for the study. In some cases a parent may be too emotional to hear about information not directly related to standard care.

3. Human factor: Ask the parents permission to discuss the study. Remember, to use parent's name in a formal manner, unless given permission to do otherwise.

4. Review: Once you have acquired permission to discuss the study, review the vital sections of the consent form (i.e. purpose, blood draws, and patient's rights) and all other vital sections, such as randomization or time constraints. When reviewing, give eye contact and address parents' concerns with care.

5. Give them time: Give the parents enough time to read over the information and ask any additional questions. If they ask medical questions that an RA is unable to answer, look to the knowledge of the medical staff.

Most consent forms go through a rigorous screening process from the investigators, IRB, and other researchers invested with a particular study. However studies have shown that consent forms for clinical trials are approved by IRBs are often above the average American's comprehension level. Consenting a participant is more than gaining a signature on a form, but a reminder of the information describing their participation in the study and ensuring their rights. The steps above may result in a higher patient comprehension of the research treatment, less patient anxiety, and more compliance with the study protocol.

## upcoming meetings

The PECARN Steering Committee Meeting is scheduled for Wednesday, September 14, and Thursday, September 15, 2005 in Chicago, Illinois. The PECARN meeting will begin at 7:30 AM on Wednesday and will adjourn at 6:00 PM. On Thursday the meeting will be from 7:30 AM to 5:00 PM. It is recommended that those outside of the Chicago area arrive on Tuesday, September 13, in the afternoon or evening.

The PECARN Steering Committee Meeting will be combined with one study training session, for the Bronchiolitis Study. The training session will take place on Tuesday, September 13, 2005 from 9:00 AM to 3:00 PM.

The PECARN Steering Committee Meeting and the study training session will be held at the Hilton Garden Inn Chicago.

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10 East Grand Avenue  
Chicago, IL 60611  
Phone: (312) 595-0000  
Fax: (312) 527-1989

# Site Monitoring: Records Access Bronchiolitis Study

A majority of sites have granted records access during site monitoring visits. However, there have been some occasions in which record access has been problematic. If the site monitor cannot access records during the site visit, data quality and compliance cannot be appraised. For example, if the site monitor is not allowed access to the complete drug inventory records for a randomized control trial, he/she is unable to confirm that drug vials are being dispensed appropriately at that site.

In this article, I will focus in on record access for the PECARN Bronchiolitis protocol.



RITA GERARD, BS, CCRP  
SITE MONITOR

## Records Request:

At least two weeks before a site monitoring visit, an announcement letter is sent to the site which includes a request for records access. An excerpt, taken from the Season 2 close out visit announcement is below:

During my visit I will review the following documentation:

- Season One Consent forms for each study participant
- Essential Document Binder documents including:
  - Curriculum Vitae, Medical License (s)
  - Documentation of GCP training (Participating Physician Agreements)
  - IRB Approval Letter (s)
  - IRB Correspondence
  - IRB Membership Roster & FWA # (Available through your IRB Office)
  - Case Report Forms & Source document files
  - Complete Patient Medical Records
  - Study Drug: all records and drug vials
  - Manual of Operations
  - Any other applicable study documentation

## Obstacles:

There is often confusion about which documents are required on the day of the visit. Secondly, the site may have some restriction on access due to HIPAA or IRB practices. In both of these cases it is important for the site to communicate with the site monitor to clarify records needed for review and confer regarding any applicable record access restrictions.

## Three Areas of Access Difficulty:

### 1. Research Drug Inventory:

It is the site's responsibility to track each vial of study

drug. Each vial should be accounted for. This includes documentation of receipt, dispensing and destruction of drug. At each of my visits, I confirm drug inventory tracking documentation. Drug inventory control is extremely important in a randomized controlled trial.

### 2. Regulatory Documents:

The Essential Documents Binder, also known as the Investigator Study Files, consists of all regulatory records and materials at the participating site pertaining to the study. These documents comprise the Investigator's portion of what FDA

and GCP terms "Essential Documents" for the conduct of a clinical study. When combined with the sponsor's documentation, they permit evaluation of regulation compliance, conduct of the study and the quality of the data produced. All regulatory documents should be available at the time of the visit. For instance, all original IRB correspondence, submissions, and attachments should be provided. Review of these items should provide clear documentation of consent revisions, protocol amendments and any correspondence with the IRB or any other regulatory body.

### 3. Medical records:

For the Bronchiolitis study, access to the complete, original, medical record at the site is required. The monitor will review records from the participant's birth to full resolution of any recorded AE/SAE which occurred within 10 days of receiving study drug.

It is imperative that sites confirm that there are not inappropriate HIPAA or IRB restrictions to site monitor access.

## Conclusion:

It is essential that all requested records are easily accessible during a site visit. Data quality and compliance cannot be confirmed in areas where documentation and records are not provided for review.

## nodalnews

### CDMCC

• We would like to congratulate Brooke Millar on the arrival of her new baby girl! She was born on August 2, at 8:42 pm. Her name is McKenzie Brooke Millar. She was 6 lbs 6 ozs 20 inches long. We are so excited for Brooke and wish her the best in the future. Brooke and her husband also recently moved to California to attend graduate school at Stanford. Brooke has been a valuable asset to the CDMCC as well as the TBI Study. She will be greatly missed.



• The CDMCC would like to welcome Gabe Herron as the new PECARN TBI Study Coordinator. We are very happy to have Gabe with us and know that she will be an asset to the Network.

• The CDMCC would like to announce the implementation of their new IRB Tracking System. It can be found on eRoom under Public Resources. There you will be able to view the IRB documents for each study as they are received by the CDMCC. This new tracking system can be an instrumental tool in easing the work load of RAs as they are able to keep constant check on their IRB expiration dates without having to search their own files.

### ACORN

• ACORN welcomes two new Research Assistants this quarter. We welcome Katherine Lamond, who worked doggedly on the head injury study as a student research assistant, and now joins the CHOP team full-time. Katherine's work time will be divided between the Lorazepam study and general PECARN work. Also joining CHOP's research team is Amber Chew. Amber will be primarily responsible for the Bronchiolitis study at CHOP.

### CARN

• Lise Nigrovic welcomes her new son; Gabriel Alexander Nigrovic arrived on July 12th. He was welcomed



to the world by his big brother Ben and big sister Sophie. Everyone is doing well.

• CARN also welcomes several new investigators and research assistants: Corey Atwell: Research Assistant (University of Maryland); Elizabeth Salib: Research Assistant (Johns Hopkins); Dr. Lois Lee: TBI Site PI (Children's Hospital of Boston); Dr. Mark Baskin: Bronchiolitis Site PI (Children's Hospital of Boston); Dr. Getachew Teshome: Bronchiolitis and C-spine Site PI (University of Maryland); Dr. Jen Schuette: C-spine site PI (Johns Hopkins)

## Federal Corner

ISABELLE MELESE-D'HOSPITAL, PH.D.  
EMSC National Resource Center

**N**ew EMSC "Targeted Issues" Grant Awards Nine new Targeted Issue awards totaling almost \$1.8 million were made for FY 2006 to improve the quality of pediatric emergency medical care. The goal of this type of grant is to develop an innovative product/resource or demonstrate the effectiveness of a model system component or service which is of national value. The 9 projects are:

- Predicting Cervical Spine Injury (CSI) in Children (new PECARN study!)
- Evidence-based Secondary Prevention of Traumatic Stress: Practical Tools to Help Parents Help their Children.
- Implementing Adolescent Depression Screening (ADS) in the Emergency Department

- Enhancement of Pediatric Emergency curricula in Physician Assistant (PA) Education
- Michigan's First Simulation, Training, & Evaluation of Paramedics in Pediatrics
- Development and Validation of a Simulator-based Pediatric Emergency Medicine Curriculum for Emergency Care Providers.
- Improving the Care of Acutely Ill and Injured Children in Rural Emergency Departments with Telemedicine
- Evaluation of the Emergency Severity Index for Pediatric Triage
- Preparing for the National Trauma Registry for Children: Assuring Data Quality

### Collaborations

In May, the EMSC Partnership for Children Stakeholders Group met to review and update the most current EMSC Five-Year Plan 2001-2005. The Stakeholders Group consists of representatives of national health-related organizations, EMSC grantees, and federal programs who assist the EMSC Pro-

gram in promoting and achieving its goal of reducing pediatric death and disability due to severe illness and injury.

In June, EMSC Program staff attended two AHRQ-sponsored meetings in Washington, D.C., one on patient safety and one on health information technology (IT).

The federal government is enthusiastic about the increased use of IT at all levels of health care, not only to improve patient safety but also to achieve cost savings. Both meetings provided useful information for researchers in the area of pediatric emergency care, which was shared on the eRoom and on the EMSC Research Listserv. For conference proceedings and more, go to: <http://healthit.ahrq.gov/home/index.html> and <http://www.ahrq.gov/qual/errorsix.htm#confer>.

## pecarnupdate

### Psych Working Group:

Referral Patterns and Resource Utilization for Pediatric Emergency Department Patients Presenting with a Psychiatric or Mental Health Problem: This study is closed to further enrollment. The Central Data Management and Coordinating Center is currently generating queries to participating sites in order to fill in some of the missing data elements.

### Prehospital Working Group:

The EMS survey has been distributed to all sites. The EMS survey will characterize the EMS systems serving PECARN HEDA sites. If you would like to be a part of the prehospital, please contact Tasmeen Singh at [tsingh@cnmc.org](mailto:tsingh@cnmc.org).

### Bronchiolitis Study:

Season 2 site monitoring closeout visits are in progress and will be completed before the PECARN Steering Committee Meeting in September. A training session for sites participating in Season 3 will be held at the Steering Committee Meeting as well. Dr. Corneli will review the study for all participating investigators during the Steering Committee meeting. Sites are beginning to submit IRB renewals and will receive changes for the amendment in the coming month. We have introduced an alternative method for obtaining informed consent called the short form. Sites will be submitting this option to their IRBs. The tentative start date for Season 3 is November 1, 2005.

### Hypothermia Study:

Thanks to the hard work of the data abstractors and study PIs, the Hypothermia study officially enrolled

489 patients. Congratulations to the team at Children's Hospital of Philadelphia, our highest enrolling site at 100 patients! The second round of queries went out in August and we anticipate sending out one more round, so please maintain your IRB approvals. We anticipate submitting the R34 application for the November 1st deadline. Thanks again to everyone who worked so hard to make this study a success!

### C-Spine Study:

Sites are currently in the process of obtaining IRB approval and scheduling their IT conference calls. Sites will begin abstracting data this Fall.

### PECARN Core Data Project:

The ongoing annual collection (2003-2007) of PCDP electronic data is now in progress. Sites should have already submitted IRB renewals or addendums in this regard. The deadline for the initial submission of 2003 electronic data to the CDMCC was March 15, 2005. Please direct any questions regarding this process to Dr. Libby Alpern at [alpern@email.chop.edu](mailto:alpern@email.chop.edu).

### Seizure:

The Lorazepam seizure meeting has 26 completed patients. The goal is to enroll 60 patients. The contract has been extended to December 2005. The next few months will be spent planning for the safety and efficacy study.

Use of Lorazepam for Pediatric Status Epilepticus: Use of Lorazepam for Pediatric Status Epilepticus: A Double-blinded Randomized Diazepam Controlled Clinical Trial: The NIH issued a request for proposals (RFP NICHHD-2003-10) under the Better Pharmaceuticals for Children Act

(BPCA) for a contract to study the pharmacokinetics and efficacy of lorazepam for the treatment of pediatric status epilepticus. Lorazepam is a commonly used drug for pediatric seizures but is not FDA-approved for children under 18 years of age. The BPCA has a congressionally mandated list of such drugs that require pediatric study. The objective of this contract is to determine the pharmacokinetics and optimal dosing of lorazepam for pediatric use and to conduct a randomized controlled trial of lorazepam with a diazepam control arm for the treatment of status epilepticus. The lorazepam study is the first in a series of RFPs that will be issued by NICHD under the BPCA. The contract was funded September 30, 2004 and has 11 participating PECARN sites.

The contract is divided into a pharmacokinetic (PK) study and a efficacy study comparing Lorazepam and Diazepam. The efficacy study will be awarded after successful completion of the PK study. Thus far, progress has included submission of an Investigational New Drug (IND) application to the FDA, formation of the Pediatric Off Patent Drug Study (PODS) steering committee, and submission of the protocol at all 11 IRBs.

### Bioterrorism Surveillance:

Historical data has been sent to Children's Hospital of Boston from Children's National Medical Center and real time data transfer has begun. Additional PECARN sites are getting IRB approval or are in the early planning phases.



eRoom

PECARN Core Data Project: <https://www.nedarcssl.org/eRoom/nddp/PECARNCoreDataProject>  
 Hypothermia: <https://www.nedarcssl.org/eRoom/nddp/Study-HypothermiaPlanningGrant>  
 Bioterrorism Surveillance: <https://www.nedarcssl.org/eRoom/nddp/Biosurveillance>  
 Effectiveness of Oral Dexamethasone in Acute Bronchiolitis: A Multicenter Randomized Control  
 Clinical Decision Rules for Identifying Children at Low and High Risk for Traumatic Brain Injuries

## newfaces

### Phil Chaffee, RA



I am the new research assistant for Head Injury and C-spine at Primary Children's/University of Utah. I have been in Utah for 2 years now, having previously worked in California as an EMS educator for 10 years. I have just finished my undergraduate program in Health Promotion and Education with an emphasis in EMS and Disaster Preparedness. I began my research experience in the fall of 2004 through the University of Utah

working as a research assistant in the bronchiolitis study. The R.A. position was a great way to complete an internship requirement for my bachelor's degree at the University of Utah. Kammy Jacobsen is responsible for recruiting me and the bronchiolitis team this past year. During the study Kammy asked if I would be interested in further research employment in the childhood head trauma study. I was excited for the opportunity to further work in research and gain more insight and understanding as to how PECARN and research in general works. I have learned a great deal in childhood head trauma research and look forward to further studies in the future.

### Amber Chew, RA



Amber Chew joined ACORN in August as a Research Assistant at CHOP. Amber has a B.S. in Psychology from the University of Georgia. She has impressive experience as a Peace Corps Volunteer in Paraguay for more than 2 years, and as a Disaster Relief Caseworker/National Rapid Response Corps member for the American Red Cross. Amber is a wonderful new addition to our team.

### Katherine Lamond, RA



Although she is not new to PECARN Katherine "Katie" Lamond was recently hired as a full-time Research Assistant at CHOP. Katie received her B.S. degree in the Biological Bases of Behavior at the University of Pennsylvania in spring of 2005. During her last two years as an undergraduate, Katie worked as a student research assistant primarily dedicated to PECARN studies. She was invaluable to the early implementation of the Traumatic Brain Injury study at CHOP

and will undoubtedly contribute greatly to her current projects (the Lorazepam study, primarily). Katie is a Rhode Island native and a medical school hopeful. Katie enjoys bumming around Philadelphia with her friends, reading, and watching reruns of the PBS remake of *Pride and Prejudice* (starring Colin Firth).

### Andrew C Wong, RA



Having just finished my third year of medical school at the University of Michigan, I am spending this year to gain experience in clinical research. Ultimately, I plan on a career in emergency medicine. Prior to medical school, I taught English in Taiwan. My outside interests include classical piano and serving in the church.

### Jeffery A. Trytko, MS



I am privileged to work with Drs. Hoyle and Denenberg at Spectrum Health DeVos Children's Hospital. I started with a BA in Biology and Art and completed a MS in Policy and Leadership Studies at DePaul University. I recently moved to Michigan from Colorado with my wife, Glenda, and our two kids, Dominick (2 years), and Makenna (7 months, Head Trauma Study pt. #10-916). During downtime, I enjoy mountain biking and creating art work.

### Alissa Genthon, RA

I am the new Research Assistant for the TBI study at Children's Memorial Hospital in Chicago. I recently completed my undergraduate degree at Northwestern University where I majored in Biology and Psychology. I am considering medical school and am taking the MCAT this fall. After participating in bench research for most of my undergraduate career, I am glad to now be a part of a clinical research group. Though I have lived in Chicago for 5 years, Texas is where I call home. There, I had a strong background in athletics and continue to pursue that interest now, especially volleyball. After living in a town called "The Woodlands," I quickly learned to love the outdoors and the animals that surrounded me. I even spent time in the rain forest in Costa Rica, which only strengthened my love for the outdoors.

### Gabrielle Herron, TBI Coordinator



As an IRB Coordinator I realized I enjoyed research and have been involved ever since, most recently coordinating a lung cancer screening study. I am originally from Las Vegas, and 5 years of living in Utah has not helped to adjust me to winter. So, I hibernate when the snow falls, because I can't seem to master walking on ice and snow. I can always count on a couple of good wipe-outs each winter.

## PCDP Abstracts

The first manuscript, "Availability of Pediatric Emergency Visit Data From Existing Data Sources", based on the original PCDP data has been accepted to the journal *Academic Emergency Medicine* for publication. Another manuscript, "Epidemiology of a Pediatric Emergency Medicine Research Network: The Pediatric Emergency Care Applied Research Core Data Project" has been submitted for review. Two additional manuscripts are currently in preparation. In addition, six abstracts were presented at the Pediatric Academic Society Annual Meeting (2 oral presentations and 4 poster presentations) and one at the SAEM Annual Meeting this year.

Abstract	Objective	Conclusions	Author
1. Epidemiology of Pediatric Emergency Department Recurrent Visits	To describe the epidemiology of pediatric patients with recurrent ED visits.	A large number of pediatric ED visits are accounted for by a minority of patients with recurrent ED visits. Young children, those with public insurance, and some minority populations who visit the ED are at an increased risk for recurrent visits. Future evaluation of how these factors influence high ED utilization may improve patient care.	Elizabeth Alpern
2. Use of Geographic Information Systems (GIS) to Locate High Risk Areas for Injury Prevention	To determine whether there are high-risk census tracts for injuries requiring ED visits.	GIS mapping of readily available electronic data from hospital computer systems can be used to identify high-risk census tracts for community injury prevention efforts.	Jim Chamberlain
3. Disagreement in Pediatric Emergency Visit Diagnosis Information From Administrative and Clinical Data Sources	To determine the agreement on final diagnoses between two sources, electronic administrative sources and manually abstracted medical records, for ED visits in the nationwide Pediatric Emergency Care Applied Research Network (PECARN).	ED diagnoses retrieved from electronic administrative sources and manual chart review frequently disagree, even if similar diagnosis codes are grouped together. Agreement varies by institution and by diagnosis. Further work is needed to improve the accuracy of diagnosis coding; development of an EMSC-specific grouping system may be beneficial.	Marc Gorelick
4. Descriptive Analysis of Psychiatric Related Illnesses in PECARN	To describe emergency department visits for psychiatric related illness (PRI) in PECARN.	The PECARN data is consistent with national data indicating that PRI visits account for a significant proportion of ED visits and adversely impact resource utilization.	Prashant Mahajan
5. Variations in Diagnostic Testing in the ED for Pediatric Non-urgent Illnesses	To demonstrate variations in diagnostic testing in ED patients with non-urgent diagnoses.	Institutional practices may be more important than provider training, staffing models or hospital characteristics in determining diagnostic testing rates in children with non-urgent illnesses. Potential areas for future research include benchmarking diagnostic testing in well-defined risk groups and adherence to accepted testing guidelines.	Rachel Stanley
6. The Epidemiology of Children With and Without Health Insurance Seeking Emergency Care in the Pediatric Emergency Care Applied Research Network	To describe and compare the subset of patients identified as lacking health insurance to insured children in the PCDP.	Uninsured children were more likely to use the ED for non-urgent problems and to have ED diagnoses related to lack of access to non-ED care. Children with chronic diseases presenting to EDs were more likely to be insured. Further study of uninsured children seeking care in EDs may provide additional information and insight into this vulnerable population of children.	James Tsung

### Good Clinical Practice Tip

Q) Must an investigator gain IRB approval before implementing EVERY type of research change?

A) An investigator must assure that he or she "... will not make any changes in research without IRB approval, except where necessary to eliminate immediate hazards to human subjects." However, IRBs may employ expedited review procedures to assess "minor" changes.

Reference: Good Clinical Practice: A Question and Answer Reference Guide. June 2003. Douglas Mackintosh, Dr.PH, MBA, MS Hyg, GCPA, Inc. Vernetta J. Molloy, MBA, RN, GCPA, Inc. and Mark P. Mathieu.

# Professional Organizations for Clinical Researchers continued...

Re-certification is required every three years. CE units can be achieved by attending a variety of educational meetings, including: workshops or pharmaceutical company meetings, programs developed for SoCRA, seminars that contribute to professional advancement within clinical research, college courses relevant to clinical research, grand rounds and IRB meetings.

## WHAT IS ACRP?

The Association of Clinical Research Professionals (ACRP) was founded in 1976 to address the distinct educational and networking needs of research nurses and others who supported the work of clinical investigations. With the development of its own professional society came the recognition of a new distinctive profession; that of the clinical researcher. The purpose of ACRP is to provide global leadership for the clinical research profession by promoting and advancing the highest ethical standards and practices. ACRP is the primary resource for clinical research professionals in the pharmaceutical, biotechnology, and medical device industries, as well as those in hospital, academic medical centers, and physician office settings. ACRP is an international association comprised of more than 17,000 individuals dedicated to clinical research and development.

## WHAT DOES ACRP HAVE TO OFFER?

ACRP offers three certification exams leading to CRA (Clinical Research Associate), CRC (Clinical Research Coordinator) and CTI

(Clinical Trials Investigator) certifications. You must qualify to take part in these certification exams. ACRP members can enhance their knowledge of clinical research with skills and expertise gained by attending ACRP seminars, educational sessions, audio conferences, certification programs, and forum activities. These professional development opportunities provide study coordinators, study monitors, project managers, QA/QC auditors, site managers, regulatory affairs professionals, data managers and others with much needed information. ACRP also includes the investigator in the training process and offers Continuing Medical Education (CME) credit hours covering a broad range of Good Clinical Practice (GCP) topics and human subjects protection issues. In addition to providing a monthly email newsletter, ACRP publishes *The Monitor* and *White Papers*. Both ACRP publications give members a forum for publishing articles.

## HOW DO I BECOME CERTIFIED?

To become ACRP certified, you must successfully complete an exam and pay a fee of \$350. Re-certification is required every 2 years. There is also an annual membership fee of \$120.00 to join ACRP, which includes attendance at one forum. Members are encouraged to join the forum that best matches their primary work responsibility, or one representing a particular interest- however, members are permitted to join as many forums as they like. ACRP Forums include:

- Academic Medical Centers
- Clinical Research Associates
- Clinical Research Coordinators
- Clinical Trial Investigators
- Data Management
- Device
- Ethics & Regulatory
- Independent Consultants
- Project Managers
- Quality Assurance
- Research Pharmacists
- Site Managers
- Technology

## What are the differences between SoCRA and ACRP?

SoCRA requires you to meet a list of qualifications to be a member while ACRP requires only that you are working in the research field. The certification term is 3 years for SoCRA and 2 years for ACRP. The cost of membership varies between the two organizations. Both organizations require successful completion of an examination on basic principles of clinical research. SoCRA and ACRP Certification (and recertification) both require the completion of continuing education credits, and each organization offers a variety of training sections, on-line education and publication opportunities.

SoCRA and ACRP are two organizations that offer PECARN research professionals an opportunity to continue education in principals of research, an opportunity to mentor others, and a medium for writing position papers, posters and articles. I encourage everyone to log on to the their websites to learn more about SoCRA (<http://socra.org>) and ACRP (<http://acrpnet.org>).

## FEDERAL CORNER continued...

In July, the EMSC Program participated in an expert meeting on Pediatric Bioterrorism Preparedness convened by AHRQ. Participants discussed developing a research agenda based upon recommendations made to the DHHS Secretary's Office by the National Advisory Committee on Children and Terrorism (NACCT). Initial recommendations from the 2003 report can be downloaded at <http://www.bt.cdc.gov/children/>.

Later in July, EMSC Program staff participated in "Meeting the Challenge of ED Overcrowding/Boarding," a Roundtable Discussion in Washington, D.C. hosted by ACEP and jointly funded by NHTSA and EMSC. Participants offered descriptions of the problem at their own EDs. ACEP will use the results of this Roundtable discussion and consensus to develop formal guidelines and then issue a policy statement.

In August, the EMSC Program attended a pediatric patient safety meeting in North Carolina sponsored by Duke University. This planning meeting, "Setting the Agenda for Pediatric Patient Safety in Emergency Care," con-

tinued a November 2004 interdisciplinary meeting of representatives from multiple organizations for a discussion on pediatric patient safety. This group of pediatric emergency care experts developed an agenda for safety, shared information about current safety initiatives, identified priority safety concerns, and worked on promoting a collaborative approach to the development of risk-reduction strategies. The August 2005 planning meeting included updated reports on the current state of safety in pediatric emergency care and the development of a summary of metrics and goals proposed by the regulatory agencies. These ideas will be further developed into practical tools and guidelines for pediatric patient safety teams.

Eight new Maternal and Child Health (MCH) research awards totaling \$1.6 million will be initiated on September 1, 2005 to improve health care and services for MCH populations. For more information on these new projects, visit the MCHB Research website: <http://www.mchb.hrsa.gov/research>. Additional awards totaling approximately \$1.5 million will be awarded in

January 2006. A new 5-year grant was awarded to the ACOG for its MCH Research Network on Pregnancy-Related Care: The Collaborative Ambulatory Research Network (CARN). This network will conduct survey studies to inform and evaluate the College's efforts to provide guidance on clinical practice to its Fellows by tracking obstetrician-gynecologists' knowledge and practices on a wide range of clinical issues and comparing existing practices with that supported by evidence-based guidelines.

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### TBI Corner: Recent Bits of Information

In total, we have now enrolled more than 22,000 patients- about 2/3 of the 31,000-32,000 patients we now plan to enroll. Our overall self-reported capture rate has remained steady at 79%. This summer, we've lost a few smaller sites, however, we have added a couple of bigger sites. Chicago Memorial has now completed the run-in period and is providing real data. Also, Boston Children's has completed their run-in period and should be providing read data very soon, pending the resolution of a couple of issues. With these changes, we still expect to meet our enrollment goal by March, 2006 as we stated in the grant.

In the next few months, we will likely need to let our IRBs know that we will continue enrolling past the

25,000 patients we initially estimated.

We've continued to perform site monitoring visits this summer, and have uncovered then resolved some important data quality issues. In particular, we found that one site was enrolling a disproportionately low number of patients hospitalized through the trauma service. This prompted a query of all participating trauma centers, to verify that the problem is not wide spread. Of note, we have now intervened at this site and they are performing very well. However, addressing these data quality issues now, rather than leaving them for the end of the study, has motivated us to produce quite a few new data queries lately.

continued on page 11...

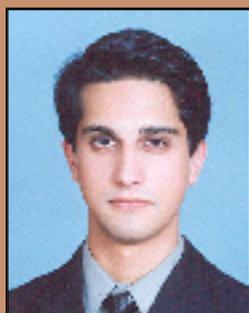
## spotlights

### COREY ATWELL (CARN)



I am very excited to be the new RA at the University of Maryland. I graduated from RPI in 2004, where I pole vaulted and studied biology and psychology. I miss upstate New York but am enjoying being back home in DC after living in Texas for a year. I am also enjoying fixing up my new house and planning my wedding which will be this April! I hope one day (not too long from now) to be a pediatric oncologist. In the mean time, GOOOOOOOO CARN!!!

### OSMAN FAROOQ (PED-NET)



Osman Farooq, Site Coordinator for Lorazepam Study at Children's Buffalo. I am very glad to be a part of the Clinical Research team at the Women and Children's Hospital of Buffalo. Having been born and raised in Buffalo, NY, and going abroad to study medicine, was an amazing learning experience. Participating in clinical research has

only broadened my outlook that much further. I am in the process of applying for residency programs starting July 2006, and look forward to future research projects as a practicing doctor. In my spare time, I enjoy photography, music, and collecting musical instruments from around the world. I also play the drums, guitar, and bass guitar.

### ELIZABETH POWELL, MD, MPH (CARN)



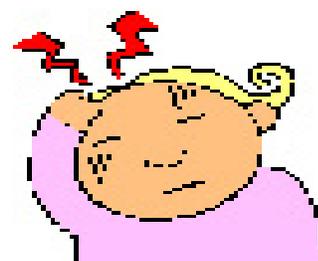
Elizabeth Powell is the HEDA PI for Children's Memorial Hospital, Chicago, IL. My colleagues and I were quite pleased to join the Great Lakes Node this spring. I am an attending physician in the CMH Emergency Department, and an Associate Professor of Pediatrics at Northwestern University's Feinberg School of medicine. I am also the Pediatric Emergency Medicine

Fellowship Director. I completed a residency in pediatrics and a fellowship in pediatric emergency medicine at Children's Memorial in Chicago, and a Masters in Public Health at the University of Illinois. My research interests include injuries and injury epidemiology and health care delivery. My family includes my husband, and two boys, ages 5 and 7.

## TBI Corner: Recent Bits of Information continued...

**W**e really need the site PIs and RAs to work together on completing these queries in a timely fashion. Some good news: we recently performed an analysis of our triple data entry, and determined that we are not catching a significant enough number of errors through this process to justify continuing it. Currently, we are drafting a letter to the funders to request stopping triple data entry - 99% of discrepancies between double and triple data entry were explained easily by events such as changes/additions to the database that created new data entry options. Finally, we introduced a new protocol amendment this summer (that was in the grant all along, but we forgot to include in the IRB protocol), to let our IRBs know that we will be sending deidentified equivocal CTs and medical records of hospitalized patients to UC Davis for adjudication.

Please be sure that you have submitted this amendment (4.0), and have received approval before sending further images or medical records to UCD. Overall, it's been a very productive and fast-paced summer for the TBI study. Thanks as always for your excellent commitment to the success of this study!



## The Short Form Consent continued...

The short form is codified in 45CFR46.117(c). The goal of the short form is to reduce reliance on a complicated written form and increase the parents' understanding of the study and therefore improve the process of informed consent.

The short form consent process is as follows:

1. The parent or legal guardian is provided with an oral presentation of the required elements of the informed consent. These elements are outlined in a "short form".
2. The "short form" is signed by the parent or legal guardian, and a witness.
3. The witness and consenter also sign an IRB approved "written summary", or script, of what is to be presented to the parent.
4. The parent is provided with a copy of the short form and written summary.

### Short form in PECARN

We suggest sites begin using the short form with the Bronchiolitis protocol in

season 3. The CDMCC will provide a short form template and an example of the written summary (script) to all sites. Each site must review the example forms and revise them as the local IRB requires. Sites should talk directly to their IRB representatives to discuss concerns that the IRB may have about the use of the short form.

Sites will submit an amendment to the IRB for the short form approval. Note: the protocol does not require any changes to use the short form. The amendment to the IRB will involve submission of the short form, and the written script for approval. Application to your IRB for use of the short form should be submitted separately from any other amendment. This will avoid delays in enrollment while the IRB considers the request. The short form amendment approval process does not have to occur before the start of the study. Sites can begin season 3 using the previously approved consent process and enroll patients as they have done in previous years. Once the IRB approves the short form, sites would begin to consent patients using this

process.

The IRB should specify what constitutes an impartial witness. For instance, is a family member or emergency department staff member an acceptable witness? Also, the IRB should specify the witness process. Does the witness need to be present for the full presentation, or can the witness question the parent at some point after the presentation to confirm that the consent elements were covered?

PECARN has a unique opportunity to use the short form to improve how we inform parents about the bronchiolitis study. The short form is designed to enhance the information exchange between the researcher and the parent in the emergency department. Sites should open a dialogue with the local IRB regarding the short form and justifications for its use.

Reference:

1. Dresden GM, Levitt MA. Modifying a Standard Industry Clinical Trial Consent Form Improves Patient Information Retention as Part of the Informed Consent Process. *Academic Emergency Medicine*.2001; 8:246-252.

PECARN On the Road...

Month	Site	Study / Studies
May	Atlantic Health System / Morristown Memorial Hospital	Head Injury Study
	Newark Beth Israel Medical Center	Head Injury Study
	Harlem Hospital Center	Head Injury Study
	Children's Hospital of Philadelphia	Head Injury Study
	Children's Hospital of Wisconsin	Head Injury Study
June	Children's Hospital of Michigan	Bronchiolitis
	Hurley Medical Center	Bronchiolitis
	DeVos Children's Hospital	Bronchiolitis
	Bellevue Hospital Center	Bronchiolitis
	Children's Hospital of New York	Bronchiolitis
	Children's Hospital of Philadelphia	Bronchiolitis
July	Primary Children's Medical Center	Bronchiolitis
	Children's National Medical Center	Bronchiolitis
	University of Rochester Medical Center	Bronchiolitis
	Children's Hospital of Buffalo	Bronchiolitis
	DeVos Children's Hospital	Bronchiolitis
August	Cincinnati Children's Hospital Medical Center	Head Injury Study Bronchiolitis
	Washington University and St. Louis Children's Hospital	Bronchiolitis