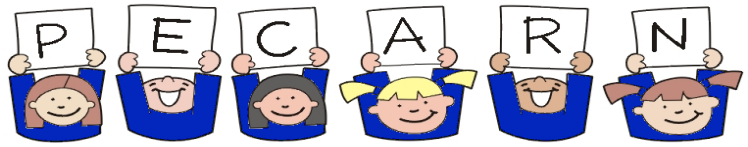
Fall 2012



In a nutshell

Efficacy in EFIC:

Operationalizing the exception from informed consent regulation in PECARN

Kate Shreve, MPH and James Chamberlain, MD

The *Lorazepam for the Treatment of Pediatric Status Epilepticus RCT*, "The Seizure Study" is coming to a close and new studies are being introduced into PECARN that may necessitate the use of the FDA exception from informed consent (EFIC) regulation (21 CFR 50.24). We wanted to briefly provide an overview of EFIC and address two broad issues raised by these regulations. One issue is the fundamental ethical conundrum of doing research in the context of the emergency department where standard informed consent is often not possible. The second is the challenge of implementing the community consultation and public disclosure requirement of the EFIC guidelines. These guidelines are ambiguous and provide no clear guidance regarding what constitutes "community," and they are intentionally vague about what adequate community consultation should look like. Both of these issues are fundamental to pediatric emergency medicine research and both demonstrate the critical role a national network such as PECARN can have in identifying and standardizing clinical trials operating under the EFIC guidelines.

The Exception from Informed Consent

Before 1996, much of what was learned about best practices in emergency medicine was derived from natural experiments on the battlefield. There was no provision in federal regulations for an exception from informed consent for greater than minimal risk research. The need to obtain prospective voluntary consent placed significant limitations on emergency medicine research. The EFIC regulations address these limitations and narrowly define conditions under which informed consent may be waived:

1. The emergent condition must be "life-threatening."
2. Informed consent is not feasible because of the therapeutic window.
3. There may be direct benefit to research subjects.
4. The research could not be performed without a consent waiver.

Additionally, the Rule mandates further protections through community consultation and public disclosure (CC/PD) before and after the study, and mandates study oversight by an independent data safety monitoring committee.

The Ethics of EFIC: Balancing Patient Autonomy with Discovering Optimal Care

The basis for the EFIC regulation is balancing safeguarding patient autonomy with providing optimal care. In many cases, optimal care may not be the same as accepted standard of care or optimal care may be unknown. In cases where clinical equipoise exists (i.e. in which there is no evidence to support one treatment as being "better" than another), there is a strong ethical case to support EFIC research. PECARN testified to the FDA in 2006: "neither the regulation itself, nor the [2006] Guidance recognize the personal loss of autonomy that is inherent in every emergency encounter…well conducted emergency research itself poses no additional loss of autonomy beyond that of standard of care. What such research does is ensure that we can improve the care of patients to the maximum extent possible."

Implementing the EFIC Rule

While the need for EFIC research is clear, the wording of the exception guidelines is ambiguous in several areas, but particularly in their definition of "community consultation." This ambiguity has likely been a deterrent to conducting EFIC research. There has been a decrease in the number of resuscitation research studies following the implementation of the EFIC rule, that some attribute to the Rule itself. Whether or not this is the case, it is indisputable that implementing an EFIC study is labor intensive and expensive and, given the unclear nature of the guidelines, highly variable depending on the site and risk profile of the study. We found tremendous variability in IRB requirements for community consultation and public disclosure in the Lorazepam study.

In order to effectively conduct EFIC trials and to ensure adherence to the ethical intent of the regulations, the guidelines should be operationalized in a more standardized manner. As the only network with experience in pediatric EFIC trials, PECARN is in a unique position to advance EFIC research by identifying best practices for CC/PD for pediatric trials. For example, the Lorazepam study found that small group or individual formats, such as focus groups and clinic-based interviews, were more effective in eliciting critical feedback from parents/providers than large community meetings. Most importantly, operational challenges required by the regulations should not dissuade investigators from performing EFIC research when it is scientifically indicated. In many cases, it is ethically preferable to pursue an EFIC trial rather than extend the therapeutic window, for example, and thus reduce the chance of demonstrating an important clinical benefit by altering the science. Standardization would reduce one important barrier to EFIC research.

The EMSC-DCC is funded by the Health Resources and Services Administration, Maternal and Child Health Bureau, Emergency Medical Services for Children Program through grant number U03MC00008

Language Translation and Interpretation in Clinical Research

Ann Johnson, MPH, CIP, University of Utah Institutional Review Board
Sally Jo Zuspan, RN MSN, PECARN DCC Director

Note: Ann Johnson is enrolled in the PhD program at the U of U. As an IRB administrator and a doctoral candidate, she has a keen interest in language and translation as a barrier to enrollment in clinical trials.

The United States population is growing more diverse. Currently, 13% of the US population is Hispanic and will grow to 21% by 2050[1]. With the increasing diversity, the number of people for whom English is not a primary language may grow. This presents difficulties in clinical care, but may present even greater challenges in conducting clinical research. The 2011 PECARN Core Data Project Emergency Department visit data shows that 21% of PECARN patients are Hispanic; this is higher than the overall US Hispanic population. Even though 61% of Latino adults surveyed state that they can read and speak English "very well" or "pretty well", proficiency in first generation Latinos is much lower.[1] Given the diversity of patients seen in PECARN EDs PECARN researchers may encounter non-English speaking patients or family members when enrolling subjects for PECARN research studies.

The Regulations. Research regulations require that non-English speaking patients be provided with language translation and interpretation services. This means that important documents must be translated into appropriate languages. This also means that an interpreter is needed for oral communication, ideally one that is familiar with the research project. When a researcher enrolls subjects who do not speak English, the subject, or their legal guardian, must be provided with both a written parental permission form in a language understandable to them, and an interpreter fluent in both English and the subject's spoken language. [2] Having both written translation and oral interpretation is important because patients and parents/guardians must be able to understand the risks, benefits and non-English speakers should have equal access to research opportunities.

Barriers. Enrolling children who do not speak English poses unique challenges. Researchers may be overwhelmed trying to provide language translation services for every subject. They may believe that it is not important to try to reach every subject, or may feel like translation efforts add difficulty and even risk to the consent process especially in the ED. Even when documents are available in the other language, comprehensibility can be less than ideal. [2,3] If assent is required, a translator must be available to discuss the study with both child and parent. Some research studies use patient surveys or instruments that are only validated in English or one other language. Investigators may feel it is easier simply to avoid enrolling non-English speaking subjects.

So why enroll non-English speakers? Enrollment of non-English speakers is important to avoid bias and improve generalizability. What if a PECARN study only enrolled Caucasian children? Would those results be applicable to all children? In addition, it is not ethically justifiable to routinely exclude potential subjects solely on the basis of language spoken, nor is it ethically justifiable to obtain consent of subjects who do not have a clear understanding of the consent form.

PECARN progress. PECARN has had significant experience in its ten years of research. Sites have successfully translated consent and parental permission documents into languages suited to the populations that frequent their emergency departments. In the Biosignatures Study, for example, 12 of the 19 sites have translated the parental permission form into Spanish. A few sites have access to phone-based translation systems. Some PECARN sites use 'short form' consents available in multiple languages. Several sites have bilingual research coordinators and physicians (Spanish or other languages) or use hospital translation services; at one site, an RC obtained certification as an official Spanish interpreter.

Yet, PECARN sites have encountered difficulties enrolling non-English speaking subjects. The availability of translators may vary among sites especially after hours. The presence of a third party translator is helpful, but sites report that the consent process simply takes longer when translation is required. Different dialects may make translation difficult even with a translator available. Document translation can be costly and is required for both original documents and subsequent modifications. Turnover of bilingual staff is also a problem, making permanent availability of translators a challenge. PECARN sites have also reported difficulties accessing translators who are comfortable and competent in the informed consent process. Finally, some studies have procedures that must be accomplished within a specific time period making translation and explanation of documents difficult to achieve before a patient becomes ineligible.

So what is an investigator or research coordinator to do? First, consult your IRB. The IRB can often help with assessment of the local patient population, translator availability and may make recommendations on the translation process. Find out if IRB has approved a 'short form'. A **short form written consent** document states that the elements of informed consent have been presented **orally** (in the subject's language) to the subject or the subject's legally authorized representative[4]. However, regulations imply that the short form should be used for a non-English speaking subject that is 'unexpectedly encountered'. Most IRBs stipulate that consent forms be translated for a patient population that is anticipated to make up 5% of the total site enrollment and allow the 'short form' to be used for a patient whose language was not anticipated. IRBs also have specific requirements about when and how short forms can be used, so it is wise to investigate. Finally, determine if your IRB will accept documents translated at another site so that repeated translations can be avoided.

The lead PECARN investigator can provide information on the demographics of the disease; for a disease that is rarely seen in Asian children, it may not be necessary to translate documents into corresponding languages. The lead investigator can also identify whether survey instruments are available in multiple languages. The DCC can help with regulatory interpretation and best practices among PECARN sites. Nodal leaders can help identify barriers to enrolling non-English speakers and assist investigators in resolving issues. During the study start up, sites should include adequate time to assess availability of translation services. Sites may also consider contacting translators in advance to explain the study and to increase the likelihood that the consent process will be conducted comprehensively.

Some "Dos & Don'ts" in translation.

- Do make an effort to enroll non-English speakers in clinical research
- Do consult your IRB for all language and translation issues
- Do have access to an experienced translator who understands research
- Do have IRB approved translated consent documents available
- Do not allow a child to translate the consent document to the parent
- Do not use the 'short form' without discussing the process with your IRB

Research at U of Utah - Ann Johnson is conducting a "Language Translation and Interpretation of Clinical Research Survey" to capture information about barriers, benefits, and expectations that research teams experience when accommodating non-English research subjects. Participants can complete an on-line survey and/ or be interviewed by Ann Johnson. To participate in this non-PECARN research, contact Ann ann.johnson@hsc.utah.edu.

1. Pew Research Center www.pewhispanic.org
2. Readability of informed consent forms for subjects participating in biomedical research: updating is required. Paris et.al. Presse Med. 2005 Jan 15;34(1):13-8.
3. Assessing the Readability of Non-English-Language Consent Forms: The Case of Kiswahili for Research Conducted in Kenya. Kithinji, C., Kass, NE. IRB. 2010 Jul-Aug; 32(4): 10–15.
4. Office of Clinical Research Protection (OHRP) http://www.hhs.gov/ohrp/policy/consent/index.html

NIH Releases Program Announcement on EMS for Children Research

The NIH has released a multi-agency Program Announcement for Research on EMS for Children through the National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH). The purpose is to improve the quality and quantity of research related to EMS for Children, with the goal of reducing morbidity and mortality in children through improved care delivery. The announcements will close on May 7, 2015. For more information on the EMS for Children PA, please go to www.grants.gov and search for funding opportunity PA-12-141 (R01) and PA-12-142 (R21).

Three EMSC Advocates Appointed to the National EMS Advisory Council

In June, the U.S. Department of Transportation (DOT) appointed 25 leaders in the EMS field to serve on the National EMS Advisory Council (NEMSAC). NEMSAC serves as an advisory body to DOT's National Highway Traffic Safety Administration (NHTSA) and is responsible for providing advice and making consensus recommendations concerning the Department's EMS activities. Appointees included three members of the EMS for Children community: Katrina Altenhofen, MPH, Arthur Cooper, MD, and Joseph Wright, MD, MPH.

HRSA Launches New Technical Assistance Website

In June, HRSA launched a new Grants section on the HRSA.gov website that provides an array of useful technical assistance information and resources that will be invaluable to those interested in federal assistance. It includes: webcasts, videos, guidance about application registration and submission requirements, funding opportunity announcement structure and content, tips for writing grant proposals, and more.

EMS for Children Resource Centers Funded through HRSA-MCHB

HRSA has awarded the EMS for Children National Resource Center (NRC) cooperative agreement to Children's National Medical Center under PI Joseph Wright, MD, MPH and interim executive director, Elena Yureneva, MD, MHA. Additionally, HRSA awarded the EMS for Children Data Coordinating Center (DCC) cooperative agreement to the University of Utah, which includes the functions of both the National EMS for Children Data Analysis Resource Center (NEDARC) and the PECARN DCC, under PI Mike Dean, MD, MBA and Lenora Olson, PhD. Both the NRC and the EMS for Children DCC are excited about the opportunity to continue to support EMS for Children stakeholders and grantees.

The National Pediatric Readiness Project

The National Pediatric Readiness Project (www.pediatricreadiness.org) is a multi-phase quality improvement initiative to ensure that all US emergency departments have the essential guidelines and resources in place to provide effective emergency care to children. The first phase of Peds Ready is a national assessment of EDs' readiness to care for children. The national assessment will begin in January 2013, following a field test in Maryland, Minnesota, and Guam launching in November 2012.

NIH Creates Office of Emergency Care Research

The NIH has created an Office of Emergency Care Research (OECR) to help improve health outcomes and patients who require emergency care. OECR will focus on basic, clinical, and translational emergency care research and training across NIH and will be housed in the National Institute of General Medical Sciences (NIGMS). OECR will not fund grants; however, it will foster innovation and improvement in emergency care and in the training of future researchers in this field. More information is available at http://www.nigms.nih.gov/About/Overview/OECR/.

EMS for Children Hosts TI Webcasts

In summer 2012, EMS for Children hosted four Targeted Issues webcasts highlighting nine grantees and their projects. The webcast titles were:

- Innovations in EMS Care Through Research – April 16, 2012
- On the Road to Injury Prevention – May 24, 2012
- Kids in Disasters: Facing Our Challenges – June 20, 2012
- High Volume, High Impact Pediatric Patient Populations in the Emergency Department – July 16, 2012

Each of these webcasts has been archived and is available at the MC Learning Website: http://learning.mchb.hrsa.gov.

Winter 2013 Teleconference
Wednesday, January 9, 2013 11AM—5PM ET

Summer 2013 Teleconference
Wednesday, June 12, 2013 11AM—5 PM ET

NEXT PECARN STEERING COMMITTEE MEETING:
Spring 2013 March 6-8
San Francisco

MAGiC

The MAGiC trial is moving full steam ahead with all eight sites actively enrolling. We recently reached a milestone with the 100th patient enrolled in mid-October and passed the halfway point for enrollment! Additionally, we are pleased to announce the recent DSMB meeting recommended the study continue without modification. We also received an administrative supplement from NICHD to fund the extended time for enrollment and to increase the number of sites required for study completion. Thanks to everyone for their efforts on the project!

PECARN REGISTRY

We are completing the first year of this RO1 grant from AHRQ. This project is establishing a data registry from electronic health records at four PECARN sites (CHOP, CCHMC, CNMC, Children's Hospital Colorado) to collect and report quality measures of emergency care provided to children. Measurable benchmarks will be established and a clinician feedback intervention will be implemented to improve performance. The project will allow systematic and widespread collection and reporting of performance and outcomes and is critical to allow clinicians and emergency care stakeholders to improve care beyond the local level.

TBI-KT

The overall goal of the study is to promote the appropriate use of cranial CT for children with blunt head trauma by creating a generalizable model to translate the PECARN TBI prediction rules into clinical practice. In December 2011, we initiated the clinical trial and data collection using the electronic health record blunt head injury data collection tool. We have now fully developed the clinical decision support (CDS) and will implement the CDS in the upcoming months. Subsequently, we will assess whether there is a change in the use of CT for children with minor blunt head injury after CDS implementation.

Biosignatures Study

In its fifth year of enrollment, the Biosignatures study has now collected approximately 4,000 Biosignature samples and 1,400 PCT samples across all sites. Sites are collecting samples at an astounding rate of about 100 per month! The total enrollment goal has been increased to 4,800 and enrollment is planned to continue through May 2013. Two papers are currently in progress.

IAI

We continue to analyze and prepare abstracts/manuscripts from the IAI database. The primary paper (Prediction Rule for IAI in Children) and the inter-rater reliability paper are currently under review at two different journals. The manuscript describing the rate of IAI in children with normal emergency department abdominal CT scans is currently at GAPS and will be submitted soon. Two additional abstracts were presented at research meetings in May 2012, and these manuscripts are in preparation. Three additional abstracts are in preparation for submission in November 2012. Finally, an additional six more manuscripts are being planned for future submissions.

ASSESS

Project ASSESS (Age Specific Screen for Ethanol and Substance Status) is a new five year research study funded by the National Institute for Alcohol Abuse and Alcoholism (NIAAA). This study, led by CO-PIs Drs. James Linakis and Anthony Spirito, aims to validate the newly developed NIAAA two-question screen for early detection of alcohol use and problems with 12-17 year olds in 15 PECARN pediatric emergency departments. 8,000 youths presenting to participating PECARN pediatric emergency departments will be enrolled over a 3.5-year period and will complete the two-question screen along with an alcohol and other drug and behavior assessment battery. A subset of participants will also complete one week or 12 and 24 month assessments. Study protocols are currently being submitted to institutional IRBs with study enrollment beginning in the spring of 2013. We look forward to working with all involved sites! If you should have any questions feel free to contact the Principal Investigators; Project ASSESS Program Manager, Julie Bromberg; DCC Project Manager, Marci Fjelstad or Hasbro RC, Rosalie Berrios-Candelaria.

EMS

An abstract for this project was published in Prehospital Emergency Care and it was presented at the National Association of EMS Physicians' annual meeting in Tucson, Arizona. Data were reported for 521,239 runs from 14 partner EMS agencies covering the years 2004 to 2006. The manuscript is in preparation.

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials continue to enroll really well! To date 9-6-12, the study has screened a total of 3,637 subjects; 811 were eligible and 444 have been randomized. The participating sites have shown true commitment to the study and we thank everyone for their hard work on the project!

TBI

We continue to aggressively analyze data and publish manuscripts from the TBI project. Since the last newsletter, we have published two more manuscripts (*Risk of TBI in Children with VP shunts, AND Racial and Ethnic Disparities in CT use after Pediatric Head Trauma* – the latter received press in the NY Times*!)*, and have another manuscript submitted and currently under the status of "revise and resubmit" (*the Association of Scalp Hematomas and TBI)*. A manuscript has been submitted for publication and is currently under review (*Risks of Sedation for Children Undergoing CT*), and we are finishing 2 other manuscripts (*Isolated Vomiting and the Risk of TBI, AND Non-traumatic Incidental Findings on CT*). We have approximately 10 more manuscripts near completion. This brings the total productivity of presented abstracts and published manuscripts for this project to well over 20! We hope to have all sub studies submitted for publication by the end of 2012. The TBI Public Use Dataset has been released.

IAF-Appendix

This study's aim was to determine how the adequacy of intra-abdominal fat impacted the ability of radiologists to detect a normal appendix on CT scan. The manuscript is completed and will be submitted for publication shortly.

PECARN Core Data Project

The PECARN Core Data Project (PCDP) is an observational descriptive study to identify basic epidemiological information about all ED visits from each participating hospital within PECARN. This data has been instrumental in hypothesis generation and grant acquisition for PECARN. The PCDP database has recently locked data for years 2009-2011 and has complete data for 2002-2011. The PCDP Demographic Reports have been updated with 2009-2011 data. These reports are now found through the Report Manager tool https://www.utahdcc.org/reports. PCDP data from 2002 – 2011 are currently available in the cubes which can be accessed at https://www.utahdcc.org/reportportal/design/view.aspx. Information about using the cubes, is available in the eRoom at: https://www.nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0_5935. If you need help with access, please contact Marci Fjeldstad. For preliminary analysis of PCDP data, PECARN members can use the cubes or complete a data request form (found in the PCDP eRoom at https://www.nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0_15909). April 15, 2013 will be the deadline for data submission from all sites for 2012 data. For any questions, please contact Libby Alpern at alpern@email.chop.edu.

Seizure

The Pediatric Seizure study (officially titled the Use of Lorazepam for Pediatric Status Epilepticus: A Randomized, Double-Blinded Trial of Lorazepam and Diazepam) reached its target enrollment of 310 patients in March 2012 and is therefore no longer enrolling patients. Closeout visits have been conducted at all sites and the study is currently in the data cleaning phase with data analysis to begin before the end of the year. Post study public disclosure activities will be conducted at each of the participating sites that enrolled patients once preliminary results become available.

Quality of Care

The long term objective of the study is to create a generalizable quality of care instrument that can be used to improve the quality of care provided to children in ED. We will accomplish this by validating and applying a previously developed implicit review instrument that measures quality of care delivered to children in EDs. Data collection at the performance sites is now completed. Physician reviewers are currently conducting quality assessments and assigning scores. The physician review phase of the study is expected to be completed by late fall of 2012. A Nurse Researcher will be hired by April, 2013 and will review records by applying the Gausche-Hill instrument for the purpose of validating the quality of care.

Progesterone

In preparation for a future clinical trial, the Progesterone study has completed a prospective yield study to pilot the inclusion/exclusion criteria, as well as test accrual feasibility. We enrolled 295 patients at 16 sites. We presented a poster at the National Neurotrauma Society annual meeting in July 2012 and the manuscript is being prepared. Concurrently, there is ongoing work at two laboratories (AT Emory University and Boston Children's) involving preclinical testing of progesterone In juvenile rats and mice. The preclinical work and the prospective yield study are important to inform a future large grant application for a clinical trial of Progesterone for head-injured children.

FLUID

FLUID, a prospective randomized clinical trial using a factorial design, will determine whether variations in the rate of administration and sodium content of rehydration fluids during pediatric DKA treatment are associated with differences in neurological outcomes. The NICHD-funded study will enroll 1,510 DKA patients and 400 non-DKA patients over five years at (now) 13 PECARN centers. Three new centers have been added since we initiated the study. The funding has been changed to a capitated model, to ensure sufficient funding until we have enrolled all necessary patients, and we have also applied for an administrative supplement. We have enrolled 338 DKA patients to date. 1 of the 3 new sites is enrolling patients, and the other 2 new sites are about to start enrolling. We have also enrolled 43 "non-DKA" comparison patients – children with type 1 diabetes who have never had DKA. We continue to hold regular webinars for RCs and PIs, and the study leadership is communicating on a weekly basis. We are also having monthly calls with all site PIs and site RCs. Finally, we have drafted a "Methods Manuscript" that is circulating among the investigators. The study is going well, the team is great, and we are anticipating enhanced enrollment with the three new sites!

Patient Safety

The Patient Safety study has collected over 29,000 incident reports from 19 sites participating in the study, since July 2007. Data collection for the study ended on June 30th, 2012. We are currently analyzing the data and writing multiple manuscripts about errors in Emergency Departments. A manuscript on medication errors has been accepted to the "Emergency Medicine Journal". A manuscript on the infrastructure and methodology of the study has been accepted to "Pediatrics Emergency Care".

C-Spine Injury (CSI) in Children

Case-control analysis: We published the results of our primary analysis in Annals of Emergency Medicine. The manuscripts for the utility of plain films in the diagnosis of CSI in children and for the method of spinal immobilization in children less than 2 years old at risk for CSI were/will be published in Pediatric Emergency Care. Two manuscripts are under peer review: outcomes of children with CSI stabilized at outlying hospitals and SCIWORA. Five other manuscripts are in development: age stratification analysis, description of CSI patterns in children, inter-observer agreement, AARS, and sports-related cervical spine injury.

EMS Focus Group: This aspect of the study aims to use focused interview and focus group methodology to identify the barriers and facilitators to EMS participation in research aimed to limit immobilization to children who are at non-negligible risk for C-spine Injury. Focus groups and focused interviews with all echelons of EMS leadership were completed in St. Louis, Milwaukee, Salt Lake City, Buffalo, Rochester, DC and Baltimore. All transcripts were reviewed and comments were categorized into topics such as qualities, beliefs, barriers, motivators and suggestions. Manuscript was expedited for publication in the February 2012 issue of Academic Emergency Medicine.

Future Directions: An R21 was submitted to the NICHD to fund a HOMERUN pilot aimed at prospectively refining, validating and implementing a Pediatric C-Spine Injury Risk Assessment Tool in the pre-hospital and ED settings. The grant scored at the 14th percentile and either will be funded or undergo revision.

The Research Coordinator (RC) Advisory Committee

The RC Advisory Committee , organized in March 2012, includes all of the RCs in the PECARN network. Mission: To provide a forum for PECARN RCs to apply their expertise in support of network goals and efficient management of research studies through collaboration, investigation of best practices within the network, and providing feedback for implementation of research protocols.
The committee was established to 1) Support PECARN in conducting high-quality research. 2) Augment infrastructure by offering collaborative activities for RCs during SC meetings and conference calls. 3) Provide a 'voice' for RCs in the network by formalizing a structure wherein RC input can be gathered and submitted. 4) Provide opportunities for RC education, mentoring, and professional development.
Some of our initial activities include providing feedback for new protocols, review of the informed consent policy, and a poster display project to be displayed at the November steering committee meeting. Persons wishing to work with the RC Advisory Committee should contact the committee chair, Kammy Jacobsen kammy.jacobsen@hsc.utah.edu .

Good Clinical Practice Tip

Erroneous AE/SAE reporting is one of the top GCP violations reported. Because AE/SAE data are key to the safety profile in many studies, it is not surprising that these data are central to a review by regulatory authorities. Some items to avoid include:

UNDERREPORTING

Missed AEs/SAEs, particularly, SAEs prolonging hospital stay.

INACCURATE/INCOMPLETE

Improper data transcription, inadequate record review (leading to inaccurate data), and lack of complete and thorough source documentation.

IMPROPER TERMINOLOGY

Listing symptoms that can be defined by one diagnosis (e.g. *upper respiratory infection* vs. *runny nose* and *congestion* and *cough* and *sore throat*), listing procedures (e.g. *intubation* vs. *difficulty breathing*), and vague terminology (e.g. *pain* vs. *pain in upper left extremity*).

RESOLUTION

Lack of adequate follow through to AE/SAE resolution/stabilization as well as associated supporting documentation.

TIME

Failure to report SAEs to appropriate study authority as outlined in the protocol.

Source: Pierce, Charles. "Common GCP Violations and Site Mistakes: How to Avoid Them." *The Monitor*. 26.5 (2012): 55-59.

Submitted by: Marie Kay, BA, CCRC

PRIDENET

The PRIDENET Node is proud to announce that it is alive and well, thriving in Biosignature enrollments while beginning to enroll eligible participants in FLUID and MAGiC too! Tara Ketterer and Dr. Jonathan Bennett have already completed 10 successful FLUID enrollments! We are very excited to proceed with all future studies. UPMC has a fantastic new Research Coordinator, Kathy Calabro RN, BSN. Previously she was a charge nurse at Children's Hospital of Pittsburgh, and we are delighted to have her with PECARN! We would like to congratulate Dr. Thomas Chun of Hasbro Children's Hospital for his recent promotion to Assistant Dean of Admissions for the Brown medical school. Everyone at PRIDENET is extremely proud! In other news, Karli Wagers (formerly Carpenter) "tied the knot" on June 2nd to her *very* lucky husband Nathaniel. Karli also recently completed her MBA and is very much looking forward to enjoying married life and of course, working with the phenomenal people of PECARN!

PRIME

The PRIME node would like to congratulate Nate Kuppermann on being named the 16th recipient of the Jim Seidel Distinguished Service Award by the AAP Section on Emergency Medicine (SOEM). The Jim Seidel Distinguished Service Award was established in 1988 to recognize members who have provided exceptional service to the Section and to the field of pediatric emergency care. This award will be presented during the SOEM program at the AAP National Conference & Exhibition in New Orleans.

WBCARN

On June 9, 2012 our site in Chicago moved from its Lincoln Park location to the new downtown facility. Our site name has since changed from Children's Memorial Hospital to Ann & Robert H. Lurie Children's Hospital of Chicago.

We also welcomed a new RC named Laura Turner to our site in July. She will be working on the Biosignatures, MAGiC, and FLUID studies.

HOMERUN

HOMERUN would like to thank everyone for completing the feasibility questionnaire for Dr. Jackie Grupp-Phelan's STAT-ED proposal. The multi-center PECARN phase of this project has been postponed to spring 2015 due to Dr. Grupp-Phelan's receipt of an R01 award from the CDC. The CDC funds provide support for STAT-ED to be trialed at two sites, Cincinnati and Columbus.

SCIENTIFIC GRANT WRITING WORKSHOP
AUGUST 21-23, 2013
CHICAGO, IL

This is a valuable 2-1/2 day workshop for those who want to improve their skills, receive professional guidance on rigorous research-oriented grant writing, and to learn to:

- Write the specific aims
- Outline the significance, innovation, and the approach section
- Write your biographical sketch
- Plan your budget
- Put your NIH proposal together. At this workshop, attendees will work on each section of their research grant proposal, receive continual feedback from experienced grant writers, and leave with a well-defined draft.

Visit **www.nedarc.org** for online registration.

New Faces to PECARN

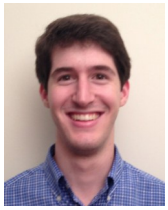
PEM-NEWS NODE

Anita Patel – PECARN RC (CHONY)
Anita has rejoined PECARN as a research coordinator at the Children's Hospital of New York after spending time at the EMSC National Resource Center.

Mimi Goodwin –Research Manager (Children's Hospital CO)
Mimi was the Clinic and Memory Study Manager of the Albert Einstein College of Medicine's, Bronx, NY site of The Women's Health Initiative (WHI). Following WHI, she worked in Advanced Women's Health Research in administrative and hands-on capacities.

Keven Cabrera – RC (CHONY)
Keven recently graduated from Vassar College as a pre-med student with a Bachelor's in Biology and minor in Japanese language. PECARN would like to welcome him as a new research coordinator.

Brittany Kronick – RC (CHONY)
Brittany joins us from Boston where she was the PECARN CRC for the Children's Hospital. Currently, she assists CHONY with neurocognitive follow-ups while being enrolled in Nursing school full time.



Joshua Natbony – RC (CHONY)
PECARN welcomes Josh Natbony as a new Research coordinator. Josh recently graduated from the University of Pennsylvania with a Bachelor's degree in psychology.

Nicole Hirsch – Clinical RC (Children's Hospital CO)
Nicole recently joined the ED in the role of research coordinator. Nicole graduated with a Master of Science degree in Kinesiology and Health and has spent the last ten years working in the clinical setting (cardiac rehab), teaching college science courses, and working on clinical trials at the University of Colorado Denver.

Van (Mimi) Chau – Clinical RC (Children's Hospital CO)
Mimi received her degree in Human Biology and Anthropology from Stanford University. She recently joined Children's Hospital Colorado as a research assistant in the ED.

GLEMSCRN

Erica Baumker— RA (Nationwide Children's Hospital)
Erica graduated with a BS in Human Nutrition and BA in Spanish from The Ohio State University. Before joining the Emergency Department, she conducted human behavioral and policy research with both the College of Public Health and Department of Human Nutrition at Ohio State.

Jr. Faces to PECARN

Heather Gramse had baby girl, Olive on 8/23/12.

Olive was 7 lbs 8 oz and 19 inches

Amy Clark had baby boy Henry Robert on 6/10/12. He weighed 6 lbs 10 oz and was 18 ½ inches long.

Tomo Funai's little girl Althea was born on 8/16/12. She weighed 6 lbs 12 oz and was 18 inches long.

Hai Le's baby boy Mykah Khai was born 9/23/12. He weighed 9 lbs 2 oz and was 23 inches long.

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www.pecarn.org