Winter 2017

PECARN In a nutshell

INSIDE

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Spreadsheets, Checklists, and Quality Assurance. How Do They All Fit Together?

Submitted by
Nicole McClanahan
Nodal Administrator, HOMERUN Node

Monitoring is a large part of any research study. It can be incredibly scary as a new Research Coordinator (RC) to receive notice of an impending monitoring visit or quality review of their studies. Luckily there are many things in place for RCs to help prepare.

In the Hospitals of Midwest Emergency Research Node (HOMERUN) we have developed a quality assurance checklist that helps us review Regulatory Binders and Research Files alike. The checklist covers protocol adherence, regulatory requirements, informed consent and eligibility to name a few. The RCs use the checklist to make sure that they've enrolled the appropriate participant, used the correct copy of the informed consent form, have all the staff listed with their IRBs, and followed the approved protocol at the time of enrollment.

This checklist, while helpful did not always make the potential research errors obvious. As an example, when reviewing an informed consent form, it can be challenging to remember the last amendment, the last version number and just when the continuing review was approved. Looking merely at the version dates doesn't help because a consent form may not be expired but that doesn't mean it is the correct version that should be used.

In order to make these intricate details more visually present, we created an Excel file for each new study that included multiple spreadsheets, and each one corresponded to the sections of the quality assurance checklist we used for our HOMERUN reviews. The tab for amendments has notes so the RC can write in what changes to the consent occurred with the amendment. The tab for informed consent has the approval date and the corresponding stamp dates from the local IRB. We did this so when reviewing participants to prepare for a monitoring visit, we can have all the necessary information in one place. We can review 15 participants and quickly determine if the proper version of the consent form was used without having to go back to the amendments and continuing review tabs in our regulatory binders or the sections in our electronic IRB platforms.

Because we also do reviews about every quarter, the spreadsheet is updated as a part of the review. If there are participants who we used the incorrect consent version to enroll, we can find this out much sooner than a study monitoring visit or nodal visit.

Another benefit of the spreadsheet is to help keep up with the addition and removal of study staff. Other nodes have also used spreadsheets to track their study staff and Human Subject research (HSR) training. The spreadsheet is also useful because not only is it used for tracking expiration dates for training but it can also be used to ensure that we have added new staff and removed the previous staff who have left. Probably the best part of using this type of spreadsheet is the fact that it can and is tailored to not only every study but to every site.

There are institutional differences in things such as requirements for who is listed as study staff, who completes study trainings, how frequently staff have to complete CITI or another HSR protection training, but allowing each site to tailor the view of the spreadsheet is incredibly helpful.

Cont. on next page...

This project is supported in part by the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Emergency Medical Services for Children (EMSC) Network Development Demonstration Program under cooperative agreements U03MC00008, U03MC00003, U03MC22684, U03MC00007, U03MC00001, U03MC28845, U03MC00006, and H3MC26201. *This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.* MCHB/HRSA Contact: Elizabeth Edgerton, MD eedgerton@hrsa.gov

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An example of this would be when there are studies that require physicians to be listed with the IRB as study staff, each of those staff members may be required to be listed on the Delegation of Authority Log. This, on top of the research team, can mean upwards of 40 or 50 individuals must have all those documents collected and maintained over the life of the study. Having a centralized location to list each staff member and what documentation they have can help ease the burden for the RC in tracking down staff for signatures.

Also, because this tool is updated more frequently, we can anticipate CITI expirations in the near future or a continuing review coming up.

The downside to spreadsheets is that they need to be maintained and reviewed but it isn't a lot of work when you are first getting a new study up and running. Any inconvenience of maintaining these spreadsheets can be alleviated by working the spreadsheet into a quality assurance or monitoring plan. We use the spreadsheet as a guide when completing our quality assurance checklists.

We frequently find new things we can add to the spreadsheets or we adapt them as needed. This process makes the spreadsheet tailored to each of the sites while still supplying the information needed to complete quality reviews. ■

Good Clinical Practice Tip

What You Need to Know About the ICH GCP E6 (R2) Addendum

Submitted by
Michelle Robinson
PECARN Project Manager, DCC

Since its adoption in 1996, the ICH E6 Guideline for Good Clinical Practice has been the standard in facilitating the design, conduct, oversite, recording and reporting of international clinical trials involving human subjects. Over the last 20 years, clinical trials have changed dramatically due to the continued growth, and their complexity in management and design. To ensure the quality and integrity of data in clinical trials an update was needed. The ICH has added an Addendum to the current E6 Guideline for Good Clinical Practice. Rather than revise the guideline, the ICH chose to add an Integrated Addendum throughout several sections of the Guideline. The addendum will provide additional information, and encourage more efficient approaches to clinical trials in the areas of design, conduct, oversight, recording and reporting.

Amended Sections	Section # and Addendum
INTRODUCTION	NA
GLOSSARY	1.63 Certified Copy 1.64 Monitoring Plan 1.65 Validation of Computerized Systems
THE PRINCIPLES OF ICH GCP	2.10 Clinical Trial information 2.13 Systems
INVESTIGATOR	4.2.5, 4.2.6 Adequate Resources 4.9.0 Records and Reports
SPONSOR	5.0 Quality Management 5.0.1 Critical Process and Data Identification 5.0.2 Risk Identification 5.0.3 Risk Evaluation 5.0.4 Risk Control 5.0.5 Risk Communication 5.0.6 Risk Review 5.0.7 Risk Reporting 5.2.2 Contract Research Organization (CRO) 5.5.3 (a), (b), (h), Trial Management, Data Handling, & Record Keeping 5.18.3 Extent and Nature of Monitoring 5.18.6 (e) Monitoring Report 5.18.7 Monitoring Plan 5.20.1 Non Compliance
ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL	8.1 Introduction

Table 1: The breakdown of the Integrated Addendum in each section of the Guideline

Table 1 breaks down the amended sections throughout the ICH GCP E6 (R2). The Addendum updates the responsibilities of the investigator and Sponsor in trial management, data integrity, validation of systems and resources, and minimizes risk throughout each stage of a clinical trial. This update has added more monitoring responsibilities for the investigators to help maintain the quality of data that is captured and reported.

To learn more about the ICH E6 (R2) Guideline, you can download a PDF copy at:
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

To learn more about ICH, harmonization for better health, visit www.ich.org. ■

EMSC Program Updates

EMSC New Performance Measures

In fall of 2016, the EMSC Program launched three new Performance Measures for the EMSC State Partnership program. Baseline data collection is set to begin in March 2017. HRSA Emergency Medical Services for Children and the National EMSC Data Analysis Resource Center began the process for developing the new measures in 2013. The iterative process involved research, interviews, and input from an advisory committee of subject matter experts, and went through a public comment process…

The new measures are:

- **NEMSIS (National EMS Information System) V3 QI Data:** The degree to which EMS agencies submit NEMSIS compliant version 3.x data to the State EMS Office for submission to NEMSIS Technical Assistance Center (TAC). The goal is that by 2021, 90% of EMS agencies in the state/territory submit NEMSIS compliant version 3.x or higher data to the state EMS office for all 911 initiated EMS activations.
- **EMS Pediatric Emergency Care Coordinator (PECC):** The percentage of EMS agencies in the state/territory that have designated individual who coordinates pediatric emergency care. The goal is that by 2026, 90% of EMS agencies will have a PECC.
- **EMS Skills Check:** Their goal is by 2026 is that 90% of EMS agencies will have a process that requires their EMS providers to physically demonstrate the correct use of pediatric-specific equipment.

More info is available via the HRSA recorded webinar (http:/hrsa.connectsolutions.com/p4cbobi4c7b/?launcher=false&fcsContent=true& pbMode=normal). NEDARC Technical Assistance is available to help EMSC program managers in collecting data on the measures and offers related tools.

EMSC Strategic Plan Update

HRSA EMSC is working with a contractor (Atlas Group–Deloitte) to help the EMSC program with Strategic planning. They are continuing interviews with national and federal partners for the EMSC Strategic Plan as well as framework for the hospital-based performance measures for the EMSC SP Program.

Hot Topic

EMSC is looking for feedback on a 2017 Hot Topic EMSC should focus on with assistance of our contractor Atlas who will be developing a White Paper. Send suggestions to HRSAEMSC@hrsa.gov

MCHB Research Network Planning Meeting

The Maternal and Child Health Bureau (MCHB) is planning a July meeting of PIs from all MCHB research networks to explore the future of research in MCHB. Two PECARN PIs will attend. ■

HRSA Welcomes Three New EMSC Program Staff

Lorah Ludwig

Lorah joins EMSC as a Public Health Analyst from the U.S. Peace Corps where she served as a Community Health Specialist. She lived and integrated at the community level in Peru to successfully collaborate with local, regional and national institutions to design, plan, manage, and evaluate two principle programs addressing community health priorities. Lorah will work with the State Partnership Regionalization of Care grantees.

Catherine Dooley

Cathy joins EMSC as a Program Analyst. Cathy joins MCHB from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) – GMB, Office of Financial Management. Her most recent appointment with NIH was as a Grants Management Specialist.

Sarah O'Donnell

Sarah joins the EMS for Children Program from the Assistant Secretary for Preparedness and Response, Office of Policy and Planning, Division of International Health Security. Sarah also developed public health preparedness policies and frameworks, including a bilateral framework with Canada for the provision of mutual public health assistance in an emergency. Sarah will work with the State Partnership grantees.

Upcoming Events

General info will be posted on the EMSC Innovation & Improvement Center (EIIC) website (https://emscimprovement.center/).

Introducing Stop the Bleed to the EMSC Community—A webinar presentation by Dr. Mary Fallat, Dr. Lenworth Jacobs, and Rick Patrick of U.S. Department of Homeland Security. 3/29/2017, 3-4pm ET. Registration information is not available yet.

2017 American Academy of Pediatrics Section on Emergency Medicine/Section on Hospital Medicine, Leadership Development Conference. 4/7/2017 in St. Petersburg, FL; registration now open (https://shop.aap.org/2017-leadership-development-conference/).

2017 Pediatric Academic Societies' Annual Meeting. 5/6/2017 in San Francisco, CA; registration now open (https://www.pas-meeting.org/).

EMSC All Grantee Program Meeting will be 8/15/2017 in Arlington, VA. Nodal PIS and nodal administrators are expected to attend. Agenda to be provided shortly.

NEDARC's Scientific Grant Writing Workshop will be held 8/23/17 in Chicago, IL. Designed for pediatric emergency medicine clinicians and researchers interested in applying to the NIH. Each section of the NIH proposal is discussed with ample time for writing and review/feedback from NEDARC faculty. ■

Federal Corner cont. on page 4...

(Federal Corner continued from page 3)

Federal Partners Update

EMS Compass®

EMS Compass is a collaboration between the National Highway Traffic Safety Administration (NHTSA) Office of EMS and National Association of State EMS Officials (NASEMSO). It's goal is to help EMS systems measure and improve quality of care at local, regional, state and national levels.

EMS Compass is releasing newly adopted candidate measures for implementation in the electronic patient care or analytic software. These 14 measures represent the best efforts by over 60 volunteers to develop a set of measures that can be used nationwide to improve care and safety.

Your help is needed to test the newly developed measures to assure their reliability and validity with the newly implemented NEMSIS version 3 standard data. EMS Compass team want to know how impactful these measures are for your agency and how easy they are to use and understand. If you are using NEMSIS v3 and are interested in measuring and improving the performance of your system, you can participate at http://emscompass.org/ems-compass-measures/ .

Three pediatric specific measures approved by EMS Compass include:

- The frequency that weight or length-based estimates of weight are documented in kg in the patient care record
- Documentation that a respiratory assessment (oxygen saturation and respiratory rate) occurred
- Administration of beta agonist for pediatric asthma

The EMS Agenda for the Future

Twenty years ago, pioneers and leaders in the EMS industry described a vision of data driven and evidence-based EMS systems in the *EMS Agenda for the Future* (https://www.ems.gov/pdf/2010/EMSAgendaWeb_7-06-10.pdf). Since then, the profession has worked tirelessly to fulfill the vision set out in that landmark document. The *EMS Agenda for the Future* led to EMS system improvements across the nation such as the NEMSIS, the "EMS Education Agenda for the Future: A Systems Approach," universal wireless 9-1-1, and the recognition of EMS as a physician subspecialty.

The NHTSA Office of EMS, with colleagues from the HHS, Health Resources and Services Administration, EMS for Children; Office of the Assistant Secretary for Preparedness and Response and the Office of Health Affairs within the Department of Homeland Security are pleased to announce joint funding of the NHTSA-awarded contract to support the process to create a new *Agenda for the Future*. The process is anticipated to take about 2 years. In Sept., the NHTSA Office of EMS awarded a contract to Redhorse to oversee the project and they are now soliciting for liaison appointments from national organizations and will soon release a call for applications to form a Technical Expert Panel.

A National Trauma Care System. Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury Report

The Departments of Defense, Homeland Security and Transportation were the three Federal sponsors for the report "A National Trauma Care System. Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury," published in June by the *National Academies of Sciences, Engineering, and Medicine (NASEM).* In early Nov. NASEM used funding from this project to hold an Implementation Workshop, attended by invited leaders in trauma care, including representatives from NHTSA's Office of EMS, ASPR, DHS-OHA, HRSA-EMSC and many representatives from the DOD. NHTSA's Office of EMS is partnering with the American College of Surgeons to support a conference to more widely disseminate the NASEM report and to support collaboration among stakeholder organizations to implement the recommendations. The conference will be held in the Spring at the NIH's Natcher Center with additional support from the DOD. ■

PECARN Study Updates

FLUID

The DKA FLUID study has completed enrollment of approximately 1400 children with DKA, and 400 children with Type 1 diabetes with no history of DKA at 13 PECARN centers! We have had two manuscripts published in *Pediatric Diabetes* as well as several abstracts presented at national meetings. There are approximately a dozen manuscripts which are being prepared. The abstract for the main manuscript has been submitted for the 2017 PAS meeting. We are very excited to see study enrollment completed and analysis begun. We really appreciate the collaboration from so many people!

PROBIOTICS

Probiotics is a randomized-controlled trial of LGG vs. placebo in children, aged 3-48 months with Acute Gastroenteritis (AGE). There are 10 PECARN sites participating. To date, 750 patients have been enrolled with a follow-up rate of 89-94% across all time points. In January, the final DSMB meeting occurred, recommending we increase sample size to 970 (from 900) and take the study to the finish line! This is expected this summer. Additionally, Manuscript Analysis Plans (MAPs) continue to be developed from the 16 Manuscript Analysis Request Forms (MARFs) submitted by the study team.

ED-STARS

ED-STARS is continuing to enroll at the Whiteriver site with 44 youth enrolled so far! The Survey Research Center has finished the 3-month follow-up, and they are continuing their work with the 6-month follow-ups. The Study PIs and the team at the DCC continue to work on Study 1 data cleaning, manuscript development, and preparations for Study 2. The Computerized Adaptive Screen is still in development, and the stats group is currently putting together the DSMB report for review at next month's NIMH DSMB meeting. Study 2 is anticipated to begin enrollment mid-summer with sites beginning IRB submissions in the spring.

PECARN Study Updates cont. on page 5...

(PECARN Study Updates continued from page 4)

PECARN Core Data Project

The PCDP is an observational descriptive study to identify basic epidemiological info on all ED visits from each participating hospital in PECARN. This data has been instrumental in hypothesis generation and grant acquisition for PECARN. The PCDP database has complete data for 2002-2015.

Upcoming 2016 data submission deadline is April 14, 2017. Fourteen of eighteen sites submitted in XML format last year. We are working with sites to try to achieve 100% XML submission for 2016 data. Data specs for submission can be found on the wiki (https://wiki.utahdcc.org/confluence/display/PCDP/PECARN+Core+Data+Project).

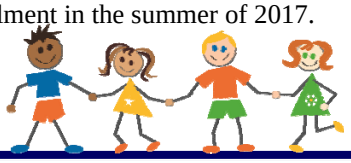
The DCC is offering one-on-one training webinars to any site interested.

Arginine

Two abstracts ("Pediatric Emergency Department Use of Intranasal Fentanyl to Treat Pain in Children with Sickle Cell Disease and Its Impact on Discharge Rates: A Multicenter Perspective" and "Pediatric ED Adherence to the 2014 NHLBI Guidelines Targeting Analgesic Therapy in the Management of Vaso-Occlusive Pain Episodes in Children with Sickle Cell Disease: A Multicenter Perspective") were presented at the American Society of Hematology meeting in Dec. 2016. Two additional abstracts were submitted to PAS 2017. Manuscript writing is now underway. A total of 5/21 patients have been randomized into the Arginine PK Study at Emory University. Grant writing for the phase III clinical trial will begin later this year.

TIC-TOC

The Traumatic Injury Clinical Trial Evaluating Tranexamic Acid (TXA) in Children (TIC-TOC) study has been approved for funding by NHLBI. The TIC-TOC trial is a multicenter, pilot randomized controlled trial to evaluate the feasibility of randomizing severely injured children to one of 3 arms (2 TXA dose arms or a placebo arm). We are awaiting FDA approval for our IND application, and we anticipate patient enrollment in the summer of 2017.



PECARN Registry

The Registry project has developed an emergency care visit registry from EHR data for pediatric patients at participating sites. The Registry currently contains data from all ED visits from the sites for calendar years 2012 through 2016. Each site transmits data to the DCC 4 weeks after completion of the calendar month to allow for data maturation.

The Registry is currently being used to directly populate stakeholder endorsed pediatric emergency medicine quality of care performance measures and has derived achievable benchmarks. Ongoing data validation with chart review containing spot and systematic checks are being done at each site for every performance measure. Each month we distribute over 475 provider-level and site level report cards. Data are currently being analyzed to determine the effect of the report cards on variations of care. The Registry Expansion project is on-boarding 3 new sites with projected production beginning in early 2017.

ASSESS

Three year follow-up is currently underway by the team at Hasbro Children's Hospital. As of early January, follow-up rates were 70% (n=1583) and 98% (n=294) for 2 and 3 year follow-up, respectively (includes only participants who have completed their follow-up window). We anticipate that follow-up efforts will end when all 3-year follow-up calls have been completed. No additional follow-up will be conducted on study participants. The ASSESS Methodology manuscript was accepted by *Pediatric Emergency Care*, while the Primary Aims manuscript titled, "Reliability and Validity of a Two-Question Alcohol Screen in the Pediatric Emergency Department," was published in the December issue of *Pediatrics*. Two additional manuscripts have been submitted to journals and are awaiting acceptance. Three additional manuscripts are being written by the study PIs and analyses conducted by the DCC.

THAPCA

The In-Hospital THAPCA Trial paper was published online in The New England Journal of Medicine on Jan. 4, 2017. Thank you to everyone in PECARN who helped over the years.

PECARN PED SCREEN

This project addresses the need to improve pediatric sepsis outcomes by developing methods to accurately identify at-risk children presenting for emergency care. The project captures EHR data to create a multicenter registry with the ultimate goal of improving the detection and treatment of pediatric sepsis in the ED setting. We automated the determination of organ dysfunction in children with sepsis directly from structured and narrative data in a multicenter EHR patient registry. This data will be used to derive and validate a prediction model of pediatric sepsis that predicts subsequent organ dysfunction within 48 hours using ED EHR data from the first 4 hours of care. Deliverables from this project include the existence of a broad and rich EHR registry, and automated process of outcome determination, and a prediction model of sepsis risk. The protocol is being finalized and will be released shortly.

ESETT

ESETT continues to enroll at an on-target pace. We are about 1/3 of the way to completion. About 40% of enrollees are children (GO PECARN!). An investigator retraining meeting will be held in Baltimore on March 22.

There is a minor software glitch on the protocol-assist device that sometimes doesn't allow the team to unblind. We are working on a resolution.

Biosignatures I

We have submitted 4 abstracts to the PAS meeting and several manuscripts are being written up based on analyses of the clinical data from this project.

Biosignatures II

This study is actively enrolling patients across all 18 PECARN sites. We currently have 498 confirmed eligible patients to date. We now have 53 patients with sequential samples and we are starting to increase acquisition of sequential samples.

Public Use Datasets

Study data sets can be downloaded directly from the PECARN website at http://www.pecarn.org/studyDatasets/. ■

New Policy on IRB Review: NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Submitted by
Sally Jo Zuspan
Director of Research & Business, DCC

You may have heard discussion surrounding single IRBs and multi-center research in recent months. Here's all you need to know to understand this new policy and how it will affect PECARN research.

Recently, Francis S. Collins, M.D., Ph.D. Director, National Institute of Health (NIH), stated that launching clinical studies in the US simply takes too long. One Factor in this delay may be that too many institutional review boards (IRBs) are reviewing the protocol and consent documents for the same study, often with no added benefit in terms of the protections for research participants. To address this issue, NIH has issued a new policy to streamline the review process for NIH-funded, multi-site clinical research studies in the US. The NIH Policy on the *Use of a Single Institutional Review Board (IRB) for Multi-Site Research* sets the expectation that multi-site studies conducting the same protocol use a single IRB to carry out the ethical review of the proposed research. http://www.nih.gov/about-nih/who-we-are/nih-director/statements/single-irb-policy-streamline-reviews-multi-site-research

This NIH Policy establishes the expectations that all sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH or other federal agencies will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. This policy is intended to enhance and streamline the process of IRB review and reduce inefficiencies. This means that instead of each institution reviewing a research protocol, a single IRB, called the reviewing IRB, would be identified to review the protocol *on behalf of all* participating institutions. The effective date of this policy has been recently extended from May 25th, 2017 to September 25th, 2017. For investigators planning to submit a grant on or after this date, applicants will be expected to include a plan for the use of a sIRB in applications submitted to the NIH. The NIH's acceptance of the submitted plan will be incorporated as a term and condition in the Notice of Award.

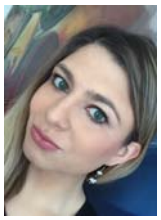
All sites participating in a multi-site study are expected to rely on a single reviewing IRB to carry out the functions required for institutional compliance with IRB review. The Reviewing IRB takes on IRB oversight responsibilities associated with that study throughout its duration. Participating sites are still responsible for meeting other regulatory requirements, such as obtaining informed consent, overseeing the conduct of the protocol, and reporting study progress to the sIRB. The sIRB policy does not prohibit any participating site from duplicating the sIRB, however, NIH funds may not be used to pay for the cost of the duplicate review. Then how does the sIRB accommodate local community issues with a central review process? The answer is that it's essential for participating sites and relying IRBs to communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations. Relying institutions provide key local context information about state law, study team member training and qualifications, and any applicable conflict of interests. Together, relying IRBs and reviewing IRBs from a new alliance to streamline the review of clinical research protocols and ideally, decrease study start up time. For more information, contact the DCC or your local IRB. Source: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html.

PECARN investigators with funded grants affected by this policy will need to plan an approach to establishing a sIRB. There are many ways to set up a sIRB either on a study-by-study basis or network wide. Details on how this will be implemented will be discussed in the future by the Network. Many PECARN institutions are already establishing generic reliance agreements in anticipation of this policy. You may wish to check with your institution to determine if it has signed a reliance agreement with a sIRB. In additional several institutions may already function as a central or single IRB. Thus, PECARN is becoming positioned to meet the requirements of the single IRB policy for upcoming studies. The TXA study has begun to implement as sIRB for the R34 project that will begin in 2017. ■

PECARN New Faces & Nodal News

WBCARN Node

Chris Wanka joins WBCARN/Children's National Medical Center as a new EMSA coordinator working alongside the Prince George's County Fire/EMS Department. Chris works and volunteers as a firefighter & paramedic in the Virginia & Maryland suburbs of DC, as well as serving as a paramedic instructor. He earned his M.S. in Emergency Health Services form the University of Maryland, Baltimore County in May of 2016. Chris lives with his wife, Rachel, and their Labrador Retriever, Lexie, in College Park, MD.



Carmen Goralski joined Lurie Children's Hospital as a new Clinical Research Coordinator II in the Emergency Medicine Department. Previously, she worked for the Allergy and Immunology Department at Lurie. Carmen received her medical degree from the Medical University of Lublin in Poland. She was involved in research as a student primary in the Neurology Department where she examined rare case studies involving neurological autoimmune diseases. Interest in the Neurology Department led her to shadow a neurologist in the emergency room as a medical student during her free time. Her involvement inspired her to co-organize and lead a workshop for students teaching the Glasgow Coma Scale, and AVPU Scale amongst other neurological assessments in the emergency room. Apart from research, Carmen danced ballet for 12 years, and trained Brazilian Jiu-Jitsu for 2 years. She lives in the Chicago area, and is pursuing residency in the near future.

WBCARN would like to congratulate **Bobbe Thomas** for her promotion to Clinical Research Program Manager! Bobbe has been instrumental in building the research program in the Division of Emergency Medicine at Children's National Medical Center. From starting the clinical research internship and mentorship programs in the ED to promoting both research and clinical QI for the Division and building critical relationships with other departments in the hospital, Bobbe has provided inspiring leadership. What makes ED Research happen at CNMC? A great team, and....."The Bobbe Factor". Congratulations, Bobbe!!

PEM-NEW Node

Kathleen Grice graduated from Metropolitan State College of Denver with a B.A in Health Care Management and a minor in Nutrition. She first joined the Emergency Medicine Research team as a Research Support Assistant 6 years ago. She is very excited to make the transition to PECARN Research Coordinator and looks forward to this new chapter her career. In her spare time she loves listening to music, dancing, playing games, cooking and watching her 5 year old son grow and learn new things.

PEM-NEWS wishes to thank **Kendra Kocher** for her years as PECARN RC at Colorado. She was a smiling face and an enrollment superstar and we'll miss her. We wish her the best of luck in her future endeavors.

PRIME Node

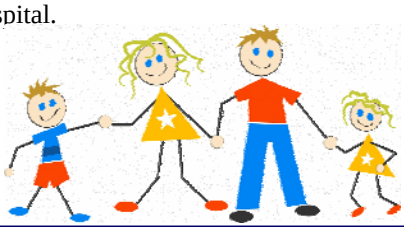
The PRIME node would like to congratulate **Dr. Angie Ellison** (HEDA PI, CHOP) on her recent promotion to Associate Professor of Pediatrics at the University of Pennsylvania. Way to go, Angie!

SW-Node

Isabelle Chea joined the University of Arizona as a Research Coordinator. She recently completed her undergraduate degree this past May in Physiology, with a minor in Biochemistry and Spanish. She is currently applying to medical school, and hopes to pursue pediatric emergency medicine. She is excited to be working with PECARN!

Zachary Chandler joined Oklahoma University's section of Pediatric Emergency Medicine this past October as a Staff and Research Assistant. He graduated from the University of Oklahoma with a Bachelor of Arts in Anthropology in December of 2015. He enjoys riding his road bike, cooking and playing with his cats.

Ginny Stasinski, Nodal Administrator, spent the last few months training for her first marathon! She ran the Rock 'n' Roll event in Phoenix on January 15th. In addition to the training, Ginny worked hard fundraising for the event to support St. Jude Children's Research Hospital.



PECARN New Faces & Nodal News cont. on page 8...

(PECARN New Faces & Nodal News cont. from page 7)

DCC

Benjamin Miller joined the DCC stats team after completing his Master's degree in Biostatistics at Grand Valley State University in Grand Rapids, Michigan. He has experience in consulting with investigators of various disciplines, utilizing statistical methods and software to help answer research questions. He enjoys trying new restaurants, snowboarding, and music production.

Alecia Peterson has recently been promoted to the role of Manager, Clinical Data Management. She has been a CDM at the DCC for the past 8 years and has worked on PECARN studies in the past (MAGiC, Patient Safety). When she is not in the office, she spends every moment she can with the love of her life, her 2 year old son, Gavin.

Cody Wei has recently joined the Clinical Data Management team at the DCC from sunny California where he received a BS in Integrative Biology and Physiology from UCLA and has been working as a Data Manager in the Clinical Research Department at his alma mater. Cody will be providing CDM support for PECARN.

Rebecca Gardner completed her Master's degree in statistics at BYU. Prior to joining the DCC as a biostatistician, she completed an internship at Stanford's Center for Health Policy. One of her long-term goals includes becoming involved in reproductive endocrinology and infertility research. She enjoys writing, experimental music, cooking, and spending time with her family.

Deveree Partridge, a new Project Manager, comes from within the Dept. of Pediatrics at the University of Utah. She has worked for the Division of Hematology and Oncology as a RC for 25 pediatric studies. She also has worked as a CRC for the Orthopedic Center. She has a MS degree in Health Promotion and Education. She brings a wealth of info with retrospective and observational studies and interventional clinical trials. She will be working on the Biosignatures and Probiotics studies.

Joe Wojdula has taken on the role of Director of IT, replacing Rene Enriquez who has transitioned to the Trial Innovation Network inside the DCC. Joe began his role as IT director on January 23.

Michelle Robinson has joined PECARN as a Project manager. She comes to us from the Dept. of Pediatrics at the University of Utah where she was a CRC for the division of Pediatric Cardiology as a site in the Pediatric Heart Network (PHN), a national research network with similarities to PECARN. She has been involved with the PHN for 5 years, and prior to that she was a RA at Intermountain Healthcare and also a study coordinator at the University of Utah. Michelle will contribute substantial pediatric experience. She has taken over the PM role in the ED STARS study.

This month we officially say goodbye to **Marie Kay** as a PECARN PM. Marie has been with the DCC for over 5 years. She has worked on several projects including MAGiC, Biosignatures and ED STARS. She is an extremely hard worker, great communicator, innovator and has been a star Project Manager. We are losing her to another DCC project but thankfully she will still be within reach. Please bid farewell and congratulate Marie on her new position in the Trial Innovation Network inside the DCC at the University of Utah.

Heather Gramse welcomed new baby boy, Miles Henry Gramse, on Saturday, October 22, 2016. Miles was 8 pounds and 19 inches long.

GLEMSCRN Node

Jessica Saunders, GLEMSCRN Nodal Admin., graduated from the Ohio State University with a Masters of Applied Clinical and Preclinical Research.

Kelsey Ryan, RA, at NWCH was accepted to medical school at Ohio State University.

The University of Pittsburgh would like to welcome a new RC, **Richelle Kurtis**, to the research department! Richelle is a pediatric nurse who continues to work casually in the Children's' Hospital of Pittsburgh of UPMC's Emergency Department as she transitions to her new role as a RC. Richelle enjoys yoga, taking walks with her Yorkie Gia, and sticking to her vegetarian diet.

HOMERUN Node

Andrew Funk recently joined CINC and he is from the Chicagoland area. His favorite sports teams include the Chicago Cubs and Green Bay Packers. His favorite pastimes include working out and spending time with friends and family. Andrew is a CRC II in the ED and helps work on the Biosignatures II study at CCHMC.

CHaMP Node

The CHaMP Node was renewed for funding. The CHaMP team is unchanged with **Brooke Lerner**, Nodal PI; **Brittany Farrell**, Nodal Admin.; **Manish I. Shah**, **Jon Studnek**, and **Lorin Browne** as Site PIs. CHaMP's goal is to conduct high-quality pediatric EMS research. We will also continue to lead the PECARN EMSA Consortium. CHaMP is also please to announce that **Manish** has been promoted to Associate Professor at Baylor College of Medicine. ■