PECARN Pediatric Emergency Care Applied Research Network

PECARN In a nutshell

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PECARN Progress in Pediatric EMS Research

By Mollie Marr, Research Coordinator, Bellevue Hospital Center & Marci Fjelstad, Research Coordinator, Central Data Management and Coordinating Center

The Emergency Medical Services for Children (EMSC) program and the PECARN are dedicated to improving the quality and quantity of pediatric research in emergency medical services (EMS). Recently, PECARN has initiated specific projects focusing on prehospital pediatric research.

PECARN has initiated a study to evaluate the network's ability to collect EMS data. E. Brooke Lerner, PhD, George Foltin, MD, Peter Dayan, MD, MSc and PECARN have teamed up with EMS agencies to collect and analyze prehospital pediatric data. This study called "Development of Research Partnerships with EMS Agencies and Descriptive Study of EMS Pediatric Population within PECARN" (or the "Prehospital Infrastructure Study" for short), aims to demonstrate that pediatric data transmission from EMS agencies to the PECARN data center is feasible. PECARN hospital sites have partnered with a local EMS agency willing to help develop a research infrastructure for conducting pediatric EMS research. Once partnered, each site works with the agency to transmit annual pediatric EMS data to the Central Data Management and Coordinating Center (CDMCC). The data will be used to describe the population of pediatric patients as well as identify barriers and successes of EMS data submission. This will provide the groundwork for further EMS research.

In addition to the Prehospital Infrastructure study, PECARN hosted an EMS Summit to discuss research collaboration of PECARN and EMS agencies and to identify obstacles to and enablers of conducting research in the prehospital setting. The participants of this two-day meeting, held in September 2007, included representatives of EMS agencies from all over the nation and PECARN and EMS researchers. Participants reviewed and updated priorities for pediatric prehospital research and learned more about the structure and organization of PECARN. Participants discussed how EMS research can be conducted and facilitated by the PECARN. Participants also discussed obstacles in gathering EMS system data and brainstormed ways to overcome these barriers. During the Summit, participants developed new study ideas and began to create concept proposals.

The Prehospital Infrastructure study is steadily moving forward. All PECARN sites have identified and partnered with an EMS agency and most sites have IRB approval for transmission of data. The EMS agencies have completed a descriptive survey of agency characteristics, 25 common data elements have been identified, and agencies are in the process of data submission to the CDMCC. To date, three complete data sets (totaling 40,000 pediatric hospital EMS runs) and one test file have been uploaded to the CDMCC. We thank AMR Research who partnered with DeVos Children's Hospital; Huron Valley Ambulance who partnered with University of Michigan; Rural Metro Medical Services who partnered with University of Rochester Medical Center; and Milwaukee County EMS who partnered with Medical College of Wisconsin for their data submissions.

Our sixteen partner EMS agencies have made huge contributions to building a prehospital research infrastructure within PECARN. Without their commitment to improving pediatric emergency care this project would not have been possible. We look forward to collecting the remaining data, and being able to provide descriptive information about the pediatric prehospital population at the PECARN sites. This is a very exciting time in EMSC research!

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Kappa BASICS: What is a Kappa and how do we use it in PECARN Studies?

By Richard Holubkov PhD, CDMCC Biostatistician

The PECARN study Childhood Head Trauma: A Neuroimaging Decision Rule, referred to in PECARN as the TBI study, is complete and manuscripts are in progress. One of the first reports from the study will be an assessment of agreement between clinicians about various clinical factors evaluated in kids with blunt head trauma. This agreement manuscript, authored by Marc Gorelick, MD, MSCE will be making extensive use of a statistic called "kappa". As applied in the TBI clinical setting, kappa (Greek letter κ) is a single number used to summarize how much agreement there is between two clinicians with respect to making a diagnosis (such as presence vs. absence of headache, or number of vomiting episodes). The kappa statistic works a bit like the correlation you may be familiar with, in that a kappa of zero means the two clinicians don't agree any more than would be expected by chance, a value closer to 1 means the two clinicians are agreeing to some extent, while a negative kappa means the clinicians are actually disagreeing.

Here's some made-up data to show different levels of kappa, where Doctor A and Doctor B are reporting their judgment regarding "stomachache" in 100 kids in the ED. Let's say the data look like this:

	Doctor A says Stomachache	Doctor A says NO Stomachache
Doctor B says Stomachache	25	25
Doctor B says NO Stomachache	25	25

Each doctor is reporting that 50 kids have a stomachache. But, a child that Doctor A says has a stomachache is equally likely to be classified as having a stomachache or not having a stomachache by Doctor B. The same holds in reverse for Doctor B. In other words, Doctor A's assessment and Doctor B's assessment don't correspond to each other. The numbers in the above table have a kappa of zero, reflecting the two doctors don't agree with each other, any more than would be expected by chance.
Now look at this table:

	Doctor A says Stomachache	Doctor A says NO Stomachache
Doctor B says Stomachache	40	10
Doctor B says NO Stomachache	10	40

The two doctors now agree on 80 of the 100 children's stomachache status. A child that Doctor A says has a stomachache has an 80% chance of also being called "stomachache" by Doctor B, and vice versa. This data has a kappa of 0.6, which is typically termed moderate to strong agreement. If the doctors agreed perfectly on all 100 kids, the kappa statistic would be 1.

Traditionally used cutpoints for "strength of observed kappa" (from Landis and Koch, 1977) are as follows:

Kappa	Strength of agreement
0	None
0.01-0.20	Poor
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81-1.00	Almost perfect

The PECARN TBI study is using these cutpoints, mandating that only clinical factors for which we're 95% sure the kappa is over 0.40 (that is, factors for which there is at least moderate agreement between two clinicians) will be used in the reported decision rules.

The actual formula for kappa is actually pretty messy in general, though I can show you the idea using the second Doctor A and Doctor B table above. We first calculate the percent agreement, which is 80/100 kids, or 80%. We then have to subtract off the agreement we'd expect between the two doctors just by chance, which would be 50% since each doctor classifies half of all kids as having stomachache. For technical reasons (to make the kappa statistic interpretable sort of the same way for all possible tables), this difference of 30% then has to be divided by (100%-percent agreement expected by chance), which here is 50%. This gives us the kappa of 0.6. Some fun, huh?

Kappa generalizes to the case where there are more than two categories of the clinical factor being evaluated. Suppose we had ordered categories (for example, if the diagnosis is "no stomachache", "mild stomachache", or "severe stomachache"), we would consider Doctor A saying "No stomachache" and Doctor B saying "severe stomachache" for the same child to be worse disagreement than Doctor A saying "No stomachache" and Doctor B reporting "mild stomachache". Fortunately, your statistical colleagues have come up with "weighted" kappas that take this ordering into account when reporting degree of agreement for ordered factors. We make use of these in the TBI agreement analysis when appropriate.

These are the very basics of the kappa statistic and agreement analysis – as always, your friendly PECARN statisticians will be happy to tell you more!

Federal Corner

EMSC Reauthorization

In March, the House Committee on Energy and Commerce approved HR 2464, the Wakefield Act, by a voice vote. The bill, introduced by Congressman Jim Matheson (UT), would reauthorize the EMSC Program for five years, from fiscal year 2009 through fiscal year 2013. The bill currently has 75 co-sponsors. To see a list of co-sponsors, visit: http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR02464:@@@P. The House of Representatives must now consider the measure.

You may recall that in order for a reauthorization bill, such as HR 2464, to become law, both the House and the Senate must vote on, and pass, their respective versions of the bill. To date, no action has occurred on S 60, the Senate version of the Wakefield Act.

EMSC Appropriations

The EMSC Program is funded at $19.454 million in Fiscal Year (FY) 2008 (October 1, 2007 to September 30, 2008). This is a reduction of $346,000 over FY 2007. Looking forward, the Bush Administration budget for FY 2009 (October 1, 2008 to September 30, 2009) does not request funding for the EMSC Program. This is the fourth year in a row the Program has been eliminated from the Administration's budget.

Next, Congress begins the appropriations process, providing funding for Federal agencies and programs for a fiscal year. Both the House and the Senate pass their own versions of each appropriations bill, including the bill funding the Departments of Labor, Health and Human Services, and Education, which contains the EMSC Program. Either chamber may choose to fund Federal programs that were eliminated in the President's budget. If the House and Senate have passed different versions of the bill, each chamber appoints members to a conference committee. The conference committee works out the differences between the two versions of the bill, and both chambers vote on the compromise bill.

Upcoming National Meetings

EMSC Annual Grantee Meeting, June 25-27, 2008, Bethesda, MD

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PECARN Study UPDATE

C-Spine Injury in Children

Case-control analysis: We have completed abstraction on 539 cases and 2,868 controls. All cases were reviewed by the Principal Investigator and a C-Spine Consultant to determine eligibility. We are completing the verification of control eligibility. Additional data cleaning, the preliminary analysis, and the comparative analysis to identify pediatric specific risk factors of CSI are underway. Four abstracts have been accepted for presentation at the spring academic meetings: two at the PAS meeting and two at the SAEM meeting.

C-Spine 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 at limiting immobilization to those children who are at non-negligible risk for C-spine injury. Six sites have undergone IRB review and approval. The first focus groups and focused interviews were completed in St. Louis, Milwaukee, and Salt Lake City. We will continue in Washington, DC and New York during the summer.

Diagnostic Grouping System

The ICD-Based diagnosis grouping system for child ED visits is now available on the PECARN website at www.pecarn.org/tools.

The diagnosis grouping system is based on ICD-9 codes and groups these codes into clinically sensible, comprehensive, parsimonious categories.

The instructions for this system and the actual grouping system program are available on our website .

This is the culmination of several years work and is an excellent tool for categorizing pediatric ED visits. Please visit the website to view this new tool!

Bronchiolitis Study

The secondary analysis of the Bronchiolitis data, identifying infants with prolonged lengths of stay, is underway. Fifteen sites have obtained IRB approval and completed abstraction. The remaining two sites are awaiting IRB approval. We hope to receive IRB approval at all sites and have all data abstracted by early April. An abstract for this secondary analysis has been accepted for presentation at the PAS meeting in May.

Traumatic Brain Injury

Patient enrollment ended in September, 2006 after successful enrollment of 34,000 patients for the derivation phase of the study and an additional 9,000 patients for the validation phase. Data cleaning and query resolution continued through 2007, and is essentially finished (until we have more!). Three abstracts have been presented (Inter-rater Reliability and the Decision Rule) at the 2007 PAS and SAEM, and Parental Presence at the 2007 ACEP). Two manuscripts are ready for submission (Inter-rater Reliability and Parental Presence), and the Decision Rule manuscript is getting close to submission. Five more abstracts have been accepted for the 2008 PAS in Hawaii (still awaiting news from the SAEM). One of them (Isolated LOC and TBI) was selected for the Presidential Plenary session out of all abstracts submitted to the PAS. We will be submitting four more abstracts for the 2008 AAP meeting. We anticipate turning many of these abstracts into manuscripts over the coming year, and continuing to work on subanalyses throughout 2008. Next grant: knowledge translation to implement the decision rule!

Intra-abdominal Injury

The first anniversary of IAI enrollment is fast approaching. To date, over 4,600 patients have been enrolled and we have study wide capture rate of 76%. The site monitors have completed visits to 63% of the sites and are expected to complete all visits by the end of May. The monitors have reported being thoroughly impressed with the dedication of the investigators and research coordinators. Findings from the monitoring visits have been helpful in identifying ways to improve the study procedures and data.

PECARN Core Data Project

All sites now have final 2006 data, and the cubes have been updated. The deadline for submission of 2007 data was April 1, 2008. We will be happy to help in any way possible to streamline the submission process to the CDMCC. The PCDP working group is also developing the "Registry" project that will link PCDP to electronic medical record data as endorsed by the Steering Committee in September 2007. For preliminary analysis of PCDP data, you can either use the cubes or complete a data request form. The cubes can be accessed at http://reports.pecarn.org/reportportal. Contact

andrew.demarco@hsc.utah.edu to obtain or reset your cube login and password. The data request form can be found at https://www.nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0_a670. For any questions, please contact Libby Alpern at alpern@email.chop.edu.

PECARN Study UPDATE

EMS Populations

Thanks to all the hard work of the PECARN investigators and research coordinators, the EMS study is well underway. All but one site has IRB approval (pending a BAA with the agency). Each agency has received a letter of explanation and an individualized request for their electronic data. We are tracking each agency's progress towards data submission and have set up eRoom accounts for agencies that are nearing submission. Two EMS agencies have successfully uploaded their electronic data to the secure eRoom, with 25,000+ rows of data! Two others have uploaded trial files and are close to uploading their complete data. Twelve other agencies are close to submission. We continue to work with sites and agencies to work out existing obstacles to data submission. The CDMCC will work to clean these data and report back to agencies and sites as necessary.

Patient Safety

The transmission of incident reports to the CDMCC has been successful. From July to December 2007 the CDMCC has received a total of 1,221 incident reports from 18 participating sites. We submitted a Targeted Issues Grant in March 2008 and submitted three abstracts for the PAS meetings: 1) Staff perceptions of safety in pediatric EDs; 2) Benchmarking patient safety characteristics in pediatric EDs: and 3) Incident reports and medical errors in pediatric EDs. All three abstracts were accepted for posters. Reports on climate of safety results by site and incident reporting rates per 1000 patient visits have been posted on the Patient Safety eRoom.

Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA)

The THAPCA Trials application was submitted to NHLBI for the Feb 5, 2008 cycle. A Scientific Application (Frank Moler PI) and a DCC Application (Mike Dean PI) were submitted as a cluster for THAPCA. If funded, 30 sites will enroll pediatric patients who have had recent cardiac arrest in order to determine the efficacy of therapeutic hypothermia to improve neurobehavioral outcome in in-hospital and out of hospital settings (2 RCTs).

Seizure

Four of eleven sites have received IRB approval to begin patient enrollment, 4 of 4 have conducted site initiation visits and 2 of 4 have received study drug and are actively screening patients. Several patients have been pre-consented for the study, three patients have been enrolled to date. One site has received contingent IRB approval to begin enrollment and expects to initiate the study in early to mid-April. Sites are speaking to their Neurology Departments concerning pre-consenting video EEG patients for the study. Dr. Pam Okada and Children's Medical Center Dallas have agreed to participate in the study replacing the University of Rochester. Community consultation and public disclosure is ongoing at all remaining sites.

Quality Performance Measures

The PEM Performance Measure project will hold its first meeting on Tuesday, April 8th. During this meeting, expert panel members from general and pediatric emergency medicine, quality improvement and outcomes research will work together to generate a preliminary list of candidate PEM performance measures. Each measure will be categorized with respect to Donabedian's structure, process, outcome designation as well as whether it relates to a specific condition or cuts across multiple conditions. Next steps include 1 or 2 conference calls over the summer to rate candidate measures with respect to importance to PEM and ability to be influenced by best practices.

Biosignatures

The study training session took place on January 29, 2008 in New Orleans. Sixteen of the twenty sites have received IRB approval and most sites have obtained their specimen handling training. We are in the process of finalizing the manual of operations, TrialDB and other study details. Children's Hospital of Michigan received their study tubes and has enrolled the first patient. All other sites should begin receiving the study tubes immediately following the PECARN Steering Committee Meeting.

Pediatric Sedation Pilot Study

A 5 week pilot study has been conducted within PECARN at the end of 2007. We are currently compiling and analyzing the data but preliminarily over 600 patients were enrolled at 20 sites. The study was undertaken to address NIH feedback regarding feasibility of conducting the study as we have designed it as well as to gather data from the network which will allow us to make better estimates about resources required to conduct the study as well as to refine our data analysis plan. The pilot study has successfully met our goals. We are in the process of drafting a revised RO1 grant proposal to be submitted to NICHD in July, 2008. Thank you to all who have participated in the pilot and have supported the Sedation Safety Study through this process; much appreciated.

Informed Consent Review Process

By: Kym Call and Heather Gramse

Research Coordinators, CDMCC

Why does the CDMCC conduct a review of the informed consent documents prior to IRB submission?

Clinical trials literature suggests that the informed consent review process by IRBs is highly variable and does not guarantee that the consent forms are compliant with the federal regulations and Good Clinical Practice. As a network, it is important for us to be compliant with the regulations, and along with sites, the CDMCC is responsible to help assure regulatory compliance for all PECARN activities. CDMCC routinely assists sites with the IRB submission process, maintains documentation of all IRB approvals, and provides assistance in other aspects of Good Clinical Practice. For the Biosignatures study, we assisted sites preparation of informed consent documents prior to site IRB submission. The purpose was to help ensure that all consent forms met the regulatory requirements and that informed consent documents were reasonably consistent across all sites. It is a difficult yet important task to maintain a balance between individual site IRB differences in consent language yet there is a need for relative consistency in consent documents throughout the network. We were careful in our CDMCC review to focus primarily on regulatory requirements and terminology related to the protocol so as to retain the original language as much as possible.

How was this review conducted for the Biosignatures Study?

Each site was instructed to submit their informed consent form to the CDMCC for review prior to submitting to the IRB. An additional 7 days were added to the 21-day IRB submission deadline to accommodate the review process. Once received at the CDMCC, the review process began and comments were provided back to the site within 2 business days. Each informed consent form was reviewed by two coordinators against a list of basic required elements and additional elements from the Code of Federal Regulations, 21 CFR 50. There are eight basic elements of informed consent that should be included in a consent form and six elements that should be included if they are appropriate to the study. Detailed emails were sent to each site listing any missing basic required elements or additional elements that should be added when appropriate; suggestions for incorporating these elements into their informed consent form and/or instructions for consulting with their IRB were included.

What did we find?

Overall, network consents were quite complete and in most cases contained the required elements. We also found that the majority of the sites used the language from the informed consent template that was provided. We found that the statement explaining that the Food and Drug Administration (FDA) may inspect the study records was often missing. We recognize that the Biosignatures study is not an FDA study but since the specimens are being stored for a period of 10 years and additional research studies may be conducted we asked the sites to include this element in their consent form.

Issues arose about adding a site-specific liability/ compensation statement on the informed consent form. We asked that sites consult with their IRB regarding this element. According to the regulations this statement should be included for studies that are more than minimal risk. Because the consent forms were reviewed prior to IRB submission and, in most cases, level of risk had not yet been determined by the IRB, we recommended that this be included.

Many of the additional elements to be added when appropriate to the study (such as unforeseeable risks, number of subjects, etc.) were missing. In this instance we instructed sites to consult with their IRB to determine the appropriateness of adding these elements based on the protocol of the study. This was also the case for each site's institutional HIPAA authorization language. We learned that the HIPAA authorization information is either found on a separate document, not embedded in the consent form, or missing. Sites were asked to include their institution's required HIPAA language in their consent forms before IRB submission.

Due to the cooperation of the sites, the CDMCC review did not delay the process of IRB submission and provided an extra level of review/ assurance that our PECARN consent documents were complete. The consent document in any study is a crucial piece of the consent process and adding this step to the process is great progress for the network.

Spotlight

Cody Olsen

Statistician at the CDMCC

I have been a PECARN statistician for one year, and am working with the C-Spine and Patient Safety working groups. I really enjoy working with investigators from all over the country on these interesting and important problems, and am very excited about upcoming analyses. I am interested in many statistical methods and topics, including conditional logistic regression which we will be using in the upcoming analysis of the C-Spine data.

I moved back to Utah last April after earning my M.S. in Statistics from Oregon State University. There I had many opportunities as a research assistant to consult on projects ranging from tree rings to fish populations and from cancer research and mice to clinical trials.

I am originally from Utah and am happy to be back in the Rocky Mountains. I earned my B.A. in statistics from Utah State University in 2005. It was there I met my wife Kimberly. We have two great kids: Parker (2 years) and Aiden (4 months).

A Peek into the CDMCC's Data Management Team.

By Rene Enriquez

Being a Clinical Data Manager (CDM), what does it mean?

- The CDM is a core member of the clinical research project team. The CDM interacts with clinicians, research assistants/coordinators, statisticians and project managers on a regular basis.
- The CDM is involved with all aspects of collecting, cleaning and managing patient data.
- The CDM gives input to the design of the protocol - focusing on data elements to be collected and when to collect them.
- The CDM designs the study database and edit checks. The CDM ensures the system meets the data entry, validation and reporting requirements.

Skills required to be a Clinical Data Manager

- A degree in life sciences, informatics or statistics. A clinical background desired but not essential.
- A problem solver and detail oriented.
- Able to work under pressure and to multitask.

Who's Who

Nathan Kuppermann, MD,MPH
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ACORN Principal Investigator

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Sherry Goldfarb, MPH
GLEMSCRN Administrator

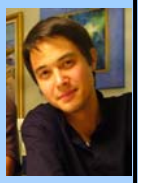
Rachel McDuffie, MPH
GLEMSCRN Project Manager/Monitor

Sally Jo Zuspan, RN, MSN
CDMCC Program Coordinator

New Faces

ACORN: UC Davis would like to welcome **Leah Tzimenatos** as our new HEDA PI. Leah recently finished her fellowship in PEM at Cincinnati Children's Hospital Medical Center. She has been an attending physician at UC Davis for six months. Leah's research interests include procedural sedation and analgesia, as well as medical error reduction and patient safety. In her free time, Leah and her husband enjoy cooking, reading and anything that can be done outdoors (hiking, skiing, cycling, kayaking).

CARN: Hi there. My name is **Alexei (pronounced uh-leks-ay) Ku,** a recently ordained Research Coordinator at Children's National Medical Center. I was raised to like living things, and after graduating university with a degree in Biology, I was a writer for a biotechnology trade journal. I dabbled in healthcare as a volunteer in a hospital in Madagascar, which made me think I might enjoy the American version. I'm thrilled to join this wonderful research team!



Hey Gang! I am **Racheal Townsend** and I am a Research Assistant at CNMC and Howard County General Hospital. Through the influence of medicine, I aspire to be a major contributor in improving medical care for the nation and global community. I am also an aspiring film writer...hopefully I can find a medium between the two interests.

Hello all! I am **Katrina Nathaniel,** the new project assistant here at CNMC. I graduated from University of Maryland, Baltimore County in 2006 with a BS in Psychology conc. Development, minor in Biology; Pre-med. I am currently pulling my hair-out whilst I go through this Med. School application process (sigh) and I am leaning towards Pediatric Neurology.

Bahiyyah Jackson, RC, PECARN Hi! I am the new Research Coordinator at University of Maryland Medical Center. I have a B.S. in Biology from Bowie State University and a Master's Certificate in Medical Coding and Billing from Johns Hopkins University.

CDMCC: Please welcome **Heidi Niitsuma** as a new Secretary. We are excited to have her as a part of our team. Colleen Cummins is not leaving the CDMCC but has accepted a full-time position with NEDARC . The IRBs will continue to be sent to Colleen until announcement to change has been made.

Hi, I'm **Tamara Artz.** Like a lot of Utah natives, I enjoy skiing, cycling, and trail running. I am ecstatic to be part of PECARN. Previously I worked in drug discovery as a synthetic organic chemist. I am assisting Jennie Wade with the Intra-abdominal Injury Study.

Nodal News

GLEMSCRN

Alex Rogers (Heda PI for University of Michigan) along with faculty from Emory and Tampa, recently taught two American Heart Association courses for Pediatric Advanced Life support (PALS) in Honduras.

"It was a challenge since we had to teach in Spanish. This was the first such class given in this region– a town called Santa Rosa de Copan. The class was very well received and we were able to graduate 13 providers. We hope in the future to return and train some instructors, to make a self-sufficient teaching core in Honduras."

PED-NET

PEDNET would like to congratulate CHONY site PI Maria Kwok who welcomed her first baby, Emelia Lan on August 5th, 2007.

Good Clinical Practice Tip

Q:: How long do we need to keep study records in PECARN?

A:: According to regulation 45 CFR 46.115,

Study records (including informed consents, financial records, supporting documents, and data) should be kept and accessible for at least **three years following the completion of the study**. Remember, completion means after manuscripts are published**,** not after enrollment has ended. For our purposes, the time clock has not started on most of our studies because main manuscripts are still being prepared. Therefore, your site should be prepared to keep study records for many years.

If the need arises, you should be able to access the records in a reasonable time and manner. Study sponsors, institutions, or specific regulations may require longer lengths of retention.

Reference:"Code of Federal Regulations" Title 45, Part 46: Protection of Human