Research *Forward*

Cincinnati Children's

A Publication from CCRF Research Administration

And Now You Know…The Rest of the Story

We did it!! FDA approval after 25 years!! What an accomplishment in translational research! Drs. Heubi and Setchell began working on this project – genetic defects in bile acid metabolism in the late 1980's. They discovered the defects, determined how to diagnose them and then how to treat them successfully with cholic acid. The study started as a compassionate use IND for a rare disease. As the research progressed, it became clear that this was a life-saving treatment and for the future health of these children, it needed to be FDA approved and available after Drs. Heubi and Setchell retired. Hence, as the study evolved, it morphed into a clinical trial – but it was never a typical clinical trial.

And now the "rest of the story" from the clinical research coordinator's perspective. It turned out to be the most challenging but also the most rewarding project of my whole career. My first involvement was in 2010 when I coordinated the "bridging study" – the study that would transition all the participants from the formulation provided by our CCHMC Investigational Pharmacy to the new formulation that would be marketed by the pharmaceutical company. Then it was time to get all the participant files and records in shape for the approval process. YIKES!!!! There were many hurtles. For the first 20 years, there was no coordinator. Drs. Heubi and Setchell and a few of their staff maintained all the documentation. And let's face it, over 25 years, the regulations changed, the documentation requirements changed, the whole regulatory culture changed. Plus, this was never a typical clinical trial yet the challenge was to try to make it fit into that mold.

There were a total of 93 participants from all over the world who had been consented. All the files from both Drs. Heubi and Setchell's offices and lab were compiled and organized – no small feat. Over the years, offices and labs had moved several times and the lab had suffered a few floods. The good news in the monumental task of organizing all these files is that I knew each participant's research file by memory and could recall by ID#. I felt like I knew most of them personally.

One of the best, most rewarding aspects of the study was getting to know the families and developing a relationship with them. I took over communicating with all the active families, processing their refills and maintaining all documentation to regulatory standards. There were about 45 active participants, 16 of whom I had met personally during the bridging study. I developed a caring, trusting relationship with most of them and some of the moms have emailed that they intend to stay in contact and update us on their kids. Additionally, since 95% of the participants were out of town, I got to know their hometown doctors and support staff well. We relied

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IN THIS ISSUE:

Summer 2015

Precision Medicine in Cancer: New Blood Test Helps Guide Treatment for Patients

Identifying the right therapy for the right patient has been an elusive goal for oncologists. In cancer treatment, the stakes are high—intensive chemotherapy regimens can be curative, but they also risk creating life-threatening complications. Despite significant advances in treatment, very little is understood regarding risk factors for side effects or how toxicities can be avoided.

A team of Cincinnati Children's researchers in the Cancer & Blood Diseases Institute and Division of Biomedical Informatics are tackling this question. The BMI/CBDI team has developed a rapid and inexpensive blood test that combines DNA genotyping data on the genetic variants an individual possesses with other data to help identify the best course of treatment for patients with Hodgkin Lymphoma.

(from left) William Seibel, Bruce Aronow, Rebekah Karns, John Perentesis, Mayur Sarangdhar, and Mitali Basu

The test uses genetic biomarkers and can quickly identify a key subset of patients at 40 times higher risk for severe chronic lung damage from specific chemotherapy drugs. This finding will potentially allow physicians to direct their treatment course to an alternate, equally effective treatment that does not use these drugs and minimizes the risks for late side effects.

The BMI/CBDI team was led by Bruce Aronow and John Perentesis and included Mayur Sarangdhar, Rebekah Karns, and Mitali Basu. This work also highlights the importance and strong value of prospectively incorporating hypotheses and research on biomarkers of toxicity and outcome in clinical cancer treatment trials. Perentesis leads the molecular biomarkers research on the recently completed NCI-supported national cooperative cancer treatment study of over 1,700 patients with intermediate-risk Hodgkin lymphoma

Hodgkin lymphoma is the most common cancer in young adults. It is a malignancy of marrow-derived B-cells usually presenting with enlarged lymph nodes and a mediastinal mass. Even in advanced stage disease, Hodgkin lymphoma is generally highly curable with regimens of chemotherapy, and often, radiotherapy. Clinicians currently use four different platforms of chemotherapy drug combinations—each equally effective for curing Hodgkin lymphoma— offering the opportunity to use genome-guided personalization of chemotherapy platforms and dosing.

While the survival rate of Hodgkin patients is high (~85%), major delayed life-threating complications often occur in the decades after treatment. Hodgkin lymphoma patients exhibit significantly increased death rates from late side effects including lung fibrosis and heart failure due to damage from chemotherapeutic agents. Among toxicities, lung damage may not become evident until many years after treatment, but often results in significant morbidity and mortality.

This study population includes the largest Hodgkin cohort of its kind. All patients are children or young adults, with uniform staging, therapy, and data capture. Within this cohort, the team investigated the impact of common polymorphisms in drug metabolism genes on a wide range of therapy-induced toxicities, and combined that data with baseline, routinely-collected demographic and clinical information.

In this study, patients were uniformly treated and underwent consistent objective regular monitoring for acute lung toxicities (abnormal DLCO, FEV1, hypoxia, dyspnea) as surrogate markers of late-effect toxicities such as fibrosis. Previous studies have demonstrated the predictive value of these measures. In parallel, peripheral blood mononuclear cells were collected on the patients and analyzed in Perentesis' laboratory with germline genotyping of over 1,900 single nucleotide polymorphisms to identify variations in 231 genes involved in drug metabolism and distribution, excretion, and transport.

For the total cohort, lung toxicity was observed in 2.5% of patients. The BMI/CBDI team discovered that for one genotypically-defined subgroup of patients (based on just three single nucleotide polymorphisms), nearly 40% developed lung toxicities. The genotype test they developed identifies which patients are in that high-risk versus the low-risk patient group, which has only a 1% risk. Since alternate chemotherapy regimens do not include the drugs that mediate the lung toxicity and are less likely to induce pulmonary injury, the blood test can help doctors identify the best course of treatment for patients as soon as within a few hours of diagnosis.

The Rest of the Story (*continued from cover*)

on them for frequent follow up growth and lab data.

THIS IS IMPORTANT – ORCRA audited our study twice and it was our saving grace. The audits included a review of 21 years of data. I won't say that it was always pleasant but it was very educational and prepared us well for our European Medicines Agency (EMA) and FDA inspections. Tom Asplan, Melissa Schneider and Carla Hanekamp deserve kudos. They were always pleasant, professional (and humorous) – I was the one who got frustrated at times. Our first report was 23 pages, our second report was 12 pages. The responses had deadlines that were stressful for that amount of work and there were no extensions. But, it made me get it done! I wrote more Notes to File than I care to admit. These were the tools that explained any deficiencies, violations, deviations, missing documents, missing data, you name it – a note to file could explain it. I really can't emphasize enough how beneficial these audits were in preparing us for the inspections.

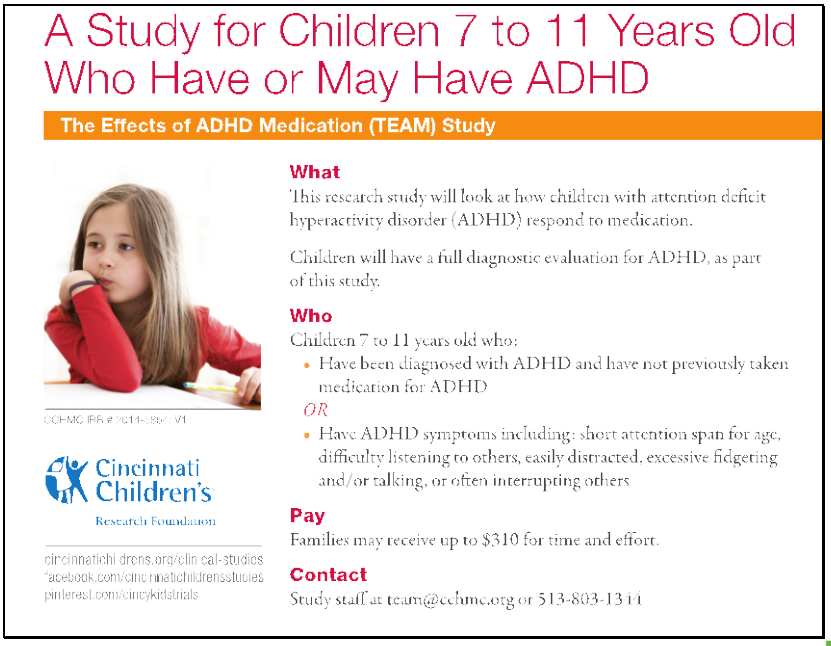
There was a small pharmaceutical company that was formed specifically to take this study product through the approval process. They developed CRFs and began monitoring in 2010. They applied for approval first in Europe, so the EMA inspection occurred first. Tensions were high and tempers flared – by everyone involved. They were the sponsor and I knew that they called the shots. However, they not infrequently overstepped their bounds and were unreasonable. I learned with time that I had the right to push back and challenge them when appropriate. I am grateful to say that Dr. Heubi backed me every step of the way. Additionally, Dawn Lowe-Gooden, Research Compliance Manager from ORCRA, was incredibly supportive and would step in on our behalf when necessary.

The Inspections!! Wow – talk about intense!! The EMA was here for one week with two inspectors and a high level FDA attorney in attendance to observe. The FDA came 1½ years later with three inspectors for a whole month. They inspected everything over 25 years associated with the study – IRB, regulatory, participant files, laboratory, pharmacy, shipping, etc. Again, ORCRA was supportive every step of the way. Dawn attended every session with me. We both took minutes and noted the tone and body language of the inspectors each day. We made copious copies for them, generated spreadsheets and provided documents that they requested. Dawn coached the whole team on how to act, how to respond, what not to say, etc. She clued us in on their techniques and when to be concerned and when to relax. We met every morning to prepare for the day and again after the inspectors left to debrief. We escorted them everywhere they went (except the bathroom, of course) and made sure they wore their "surveyor badges". It was rigorous, intimidating, exhausting and sometimes humorous. The whole team bonded surviving such an experience together and we have some funny memories that bring laughs now. The FDA returned unannounced last summer to further inspect Dr. Setchell's laboratory. By then, we had survived…bring it on!

So, here I am now…two months after approval and still busy transitioning participants from study drug to commercial product. It is bittersweet: I'm glad to have it behind me…but sad that it's over. I will so miss my families. I learned more during my five years on this project than I think in my entire career. I had the pleasure of working with and really bonding with every member of the research team. What an exceptional experience! I am just so proud and grateful to have the opportunity to be part of a project that so profoundly affects the lives of "my research participants". Thanks to the pioneering work of Drs. Heubi, Setchell and their team, these children and those diagnosed in the future with serious/fatal liver defects will go on to live normal lives!

Contributed by Donna Buckley, Senior CRC

Now Enrolling



Dates & Deadlines

NIH Grant Deadlines SEPTEMBER 25, 2015 through DECEMBER 13, 2015 (CYCLE III)

Activity Code	Program Description	SPO Due Date	CYCLE III Due Date
P Series *New, renewal, resubmission, revision*	**Program Project Grants and Center Grants**	September 18	September 25
R18/U18 R25 *New, renewal, resubmission, revision*	**Research Demonstration Education Projects**	September 18	September 25
C06/UC6 *New, renewal, resubmission, revision*	**Construction Grants**	September 18	September 25
G07, G08, G11, G13, G20, S11, S21, S22, SC1, SC2, SC3 *New, renewal, resubmission, revision*	**Other Activity Codes**	September 18	September 25
T Series **D Series** *New, renewal, resubmission, revision*	***Institutional*** **National Research Service Awards Other Training Grants**	September 18	September 25
R01 *New*	**Research Grants**	September 28	October 5
U01 *New*	**Research Grants – Cooperative Agreements**	September 28	October 5
K Series *New*	**Research Career Development**	October 5	October 12
R03, R21, R33, R21/R33, R34, R36 *New*	**Other Research Grants**	October 9	October 16
R01 *renewal, resubmission, revision*	**Research Grants**	October 29	November 5
U01 *renewal, resubmission, revision*	**Research Grants – Cooperative Agreements**	October 29	November 5
K Series *renewal, resubmission, revision*	**Research Career Development**	November 5	November 12
R03, R21, R33, R21/R33, R34, R36 *renewal, resubmission, revision*	**Other Research Grants**	November 9	November 16
R41, R42 R43, R44, U43, U44 *New, renewal, resubmission, revision*	**Small Business Technology Transfer (STTR) Small Business Innovation Research (SBIR)**	November 30	December 5
F Series Fellowships *New, renewal, resubmission*	***Individual*** **National Research Service Awards (Standard)**	December 1	December 8
R13, U13 *New, renewal, resubmission, revision*	**Conference Grants and Conference Cooperative Agreements**	December 7	December 14
F31 Diversity Fellowships *New, renewal, resubmission*	***Individual*** **Predoctoral (F31) Fellowships to Promote Diversity in Health-Related Research**	December 7	December 14

**Standard due date falls on weekend or federal holiday. Deadline extended to next business day.

Trivia Column

When asked why they participate in clinical trials, two-thirds of study volunteers identified to "advance medicine" or "improve the lives of others."

During the 2013 fiscal year, 19.3% of NIH grant applicants received funding.

In the U.S., Hispanics make up 16% of the population, yet only 1% participate in clinical research. African Americans comprise 12% of the population, yet only 5% participate in clinical research.

Over 50% of clinical research studies fail to take adequate steps to reduce biases.

CCTST Research Central Consultation Changes

On April 1, 2015, the CCTST introduced a new system for providing support for study design, data management and analysis. Up to this point, 10 hours of research support were provided each grant year (April 1–March 31) to all members of the CCTST. In the new system, free methodologic consultation and advice are provided to CCTST members for up to one hour, but direct support for study design and statistical analysis is granted via vouchers.

The system allows the CCTST to focus its efforts and invest resources on promising projects that may need and deserve even more than 10 hours of support. Other functions, such as data management via REDCap and simple cohort size identification via i2b2, will continue to be processed at no cost to investigators through the CCTST's Research Central portal and will not be subject to the voucher system. **CCTST membership** is free of charge. For more information, **read the new policy here** or email **CCTST@uc.edu**.

CCTST | Center for Clinical & Translational Science & Training

By JoVE! Pratt Library keeps you up on science research!

Pratt Library now subscribes to the innovative Journal of Visualized Experiments (JoVE), the world's first peer reviewed scientific video journal. JoVE helps accelerate the progress of biological, medical, chemical and physical research.

Established in 2006, JoVE publishes scientific research in a visual format that improves reproducibility of experiments, and makes it easier to learn new experimental techniques.

JoVE has published thousands of video articles from top research institutions around the world. The format allows authors to dynamically present their methods, data analyses and results clearly, accurately, and professionally with the guidance of JoVE's professional videographers and editors. All JoVE articles are indexed in subject-relevant indexing sites, including PubMed/MEDLINE, SciFinder and Scopus.

How to access JoVE

- You can access JoVe from any computer on any CCHMC campus at jove.com or through the Pratt Library website at prattlibrary.cchmc.org.
- You can also download the JoVE app from Google Play or the App Store and register using your CCHMC.org email address for mobile access!

Professional Development

PRIM&R Webinar – Maximizing Benefits to Research with Human Subjects Through Data Sharing Tuesday, June 23rd; 1:00-2:00pm; ELM registration

- -

Core Clinical Research Training
Tuesday, August 25th - Thursday, August 27th; 8:00am – 12:30pm; ELM Registration

- -

Informed Consent Role Play
Thursday, September 3rd; 9:00am – 11:30; ELM Registration

- -

Clinical Research Orientation
Monday, September 14th - Tuesday, September 15th; 8:00am – Noon; ELM Registration

- -

Clinical Research Skills Training
Thursday, September 17th; 8:00am – Noon; ELM Registration

- -

Clinical Research Phlebotomy Training
Thursday, September 17th; 12:30pm – 5:00pm; ELM Registration

- -

EPIC Research Registration
Friday, September 18th; 8:00am – 2:00pm; ELM Registration

Make a splash with joyful enthusiasm this summer!

Spotlight on Biomedical Informatics Services, Support for Researchers

The second part of a two-part article.

As both the amount of data and the sophistication of technology continue to increase at an accelerated pace, biomedical research is now firmly in the "big data" era. Cincinnati Children's and the University of Cincinnati (UC) Academic Health Center joined forces in 2014 to create a new, cross-institutional Department of Biomedical Informatics (BMI).

Along with its academic research mission, BMI provides a variety of computational resources, services and support to researchers affiliated with both Cincinnati Children's and UC. The goal is to help researchers take full advantage of new data analysis methods and the development and application of novel technologies.

This is the second of two articles outlining several of the biomedical informatics core and collaborative services, with links to further information. Complete details can be found on the Research IT Core Services website.

Application Development & Support

BMI has faculty-supported collaborative service and development groups with expertise in a number of different areas, including:

- Developing customized software applications in a wide variety of programming languages, (e.g., Python, Perl, Java/J2EE, iOS, and .NET)
- Evaluating, hosting and customizing licensed and open-source research software
- Designing and hosting research databases, datamarts, and registries
- Developing customized research web sites and web services compliant with industry and corporate standards
- Hosting content management systems and web portals

Support Staff: Staff members include experts in web- and mobile-based software development, networking, system administration and maintenance, and database programming. Staff are accustomed to working within a unique environment that facilitates realization of complex projects with significant programming and outreach extensions.

Due to high demand, application development provision is prioritized especially for academic collaboration, supported and sustainable projects, and strategic, initiatives.

Data Security and Compliance

In order to facilitate collaboration with external institutions, BMI has built a dedicated research network with separate segments for data storage, data management systems, and applications

BMI closely collaborates with Cincinnati Children's Information Services Department, as well as various Hospital and Research Foundation legal and compliance groups to provide an environment that meets or exceeds all local and federal requirements, including HIPAA (the Health Insurance Portability and Accountability Act), and as needed, 21 CFR Part 11 (U.S. Food and Drug Administration regulations on electronic records and electronic signatures) and FISMA (the Federal Information Security Management Act).

BMI provides consultations for faculty and staff on best IT practices and helps facilitate data use agreements with partner institutions for a wide range of projects. We have developed data use agreements as well as annual System Security Plans as required by a number of regulations.

For complete details, visit BMI's Research IT Core Services website.

Shire and Cincinnati Children's Establish Rare Disease Research Collaboration

The Shire and Cincinnati Children's Research Collaboration is a funding program that is designed to accelerate the development of a rare disease therapeutic. The goal of the collaboration is to discover and develop novel therapies to treat rare diseases with high unmet medical need, combining Shire's development and commercialization capabilities with Cincinnati Children's research expertise. As a nationally ranked hospital, Cincinnati Children's has expertise in many fields of research that align with Shire's therapeutic areas of focus, including rare diseases, gastroenterology, nephrology and neurology. The partnership underscores Shire's long-term commitment to bringing innovative therapies to patients living with rare diseases around the world.

The research collaboration will provide funding and laboratory research support to advance a research project at Cincinnati Children's toward the commercial market. Funding level will be commensurate with the project-specific research design and scope of work, as anticipated by the investigator and approved by the CCHMC/Shire Joint Steering Committee. Following completion of the funded research program, Shire will have an exclusive option to enter into a license agreement for the selected projects / intellectually property. This option will not encumber other work outside of the project and research scope that is funded as part of this research collaboration.

Review of the research proposals will be conducted by a Joint Steering Committee (JSC) composed of members from both Shire and Cincinnati Children's.

Letters of Intent are due by 5PM on June 4, 2015. For more information, visit the Center for Technology Commercialization's (CTC) CenterLink page or search "Shire" on CenterLink.

Genomics and Ethics Conference a Success

Over 100 participants from 13 states, Japan, and Kuwait attended the March 12–13, 2015 conference ***Genomics and Ethics in Research and Medical Decision-Making,*** which featured empirical and conceptual investigations into the ethical aspects of genetics and genomics in diverse research, community, and clinical domains in biomedicine.

Conference co-chair Rick Ittenbach, PhD, professor, biostatistics and epidemiology, CCHMC (left), welcomes Jusaku Minari, PhD, assistant professor, biomedical ethics

Held at the UC Kingsgate Marriott Conference Center, the event provided a forum for discussing the intersection of genetics/genomics and ethics, including genomic medicine, community engagement, return of research and clinical results, challenges of biobanks in research, commercialization of genomics research, and consent in medical research and clinical settings.

Keynote speakers were Gail Jarvik, MD, PhD, head of the division of medical genetics at the University of Washington School of Medicine, and Barbara Koenig, PhD, professor, Institute for Health & Aging, University of California, San Francisco. Dr. Jarvik holds The Arno G. Motulsky Endowed Chair in Medicine and is joint professor of medicine and genome sciences. Dr. Koenig is co-principal investigator of the Translational Genomics & Ethics Center at UCSF.

A late-breaking session on genomic data security and compliance by Angel Pizarro, MSE, of the Scientific and Research Computing division of Amazon Web Services, was presented on Day 2. Event co-sponsors were the UC CCTST and Ethics Center of CCHMC.

For more information, follow the links below or contact conference co-chair Rick Ittenbach, PhD.

- **Download Conference agenda**
- **View Conference photos**
- **View Presenters' slides**

Electronic Options Ease Paper Burden

The fact that many divisions are inundated with paper is not news at Cincinnati Children's Hospital Medical Center (CCHMC) and the institution is working diligently to address the need for innovative, space-saving solutions. Tours of office spaces conducted in late 2014, along with interviews conducted with more than 30 divisions confirmed that there is great concern for diminishing space and reducing the overwhelming burden of paper. The interviews also revealed a wide range of perceptions regarding the appropriate criteria and procedures of electronic documentation storage. Therefore, viable tools, guidelines, and educational materials have been created by a workgroup of experts from ORCRA, OCTR and CBDI that are now being provided to help in this transition. This effort has been supported by a taskforce of senior leadership and researchers from various divisions who have provided guidance and continue to serve as key stakeholders as the scale-up of these efforts continue.

The electronic storage of documents is in congruence with the hospital's desire to find more space for our researchers, to reduce costs, and to be innovative in our use of available technology. Importantly, maintaining research documents in electronic format is also in compliance with Food & Drug Administration (FDA), Health and Human Services (HHS), and Office for Human Research Protection (OHRP) guidelines and regulations.

There are divisions within CCHMC who are already utilizing electronic storage processes, who have worked with ORCRA to ensure compliance in these practices, and who are eager to help you get started. A team of these individuals have developed instructional Standard Operating Procedures (SOPs) that include: SOP 41-1.12 Electronic Maintenance of Regulatory Binder (which includes: eREG Quick Guide Template to help structure folders for electronic storage); and SOP 41-1.13 Converting Paper Records to Electronic Format for Storage. These SOPs have been approved by ORCRA and are available in Compliance 360. *(Please note that your division cannot amend the 41 series SOP since it is created for all of research. However, your division can create its own SOPs though, you must meet the minimum requirements in the 41 series SOPs).*

A first phase of implementation is focused on converting paper regulatory binders to electronic binders. While ePAS is considered the electronic record source for many components of the regulatory binder, some departments also keep the information saved in PDF format within a structured framework of files. This eases monitor visits and ensures that a complete "electronic binder" is available for review at all times. To do this, divisions in CCHMC have tested and have been utilizing an extensively tested file format for their study Regulatory Binders (provided in SOP 41-1.12 Quick Guide). Their experiences with this format have been overwhelmingly positive. These divisions and others are also starting to convert regulatory binders of ongoing studies into electronic files, since ongoing regulatory documents may be converted to electronic format once approved.

The conversion process of existing paper to electronic storage involves some planning and logistics, including a detailed review of SOP 41-1.13 to ensure that all applicable approvals are in place. Currently, each division will be responsible for acquiring resources to aid in conversion. All electronic files are to be stored on the secured CCHMC network drive. The level of access is defined by the department and/or division. To establish a storage folder drive and/or secure a flash drive, CCHMC employees can contact the Division of Biomedical Informatics https://bmi.cchmc.org/.

The workgroup has researched, developed, and approved SOPs in order to empower divisions to use electronic methods for storing regulatory research documents. In order to emphasize the importance of making this transition in stages, we often remind ourselves and others that, "when eating an elephant, take one bite at time. Research teams and staff are encouraged to use the resources available on the Electronic Document Storage CenterLink page and to get practice-based advice from their colleagues and the members of the taskforce throughout CCHMC.

If you have follow up questions, need more guidance, and/or have tips to share then please send an email to estorage@cchmc.org.

There's an App for that…GCP!

The Association for Clinical Research Professionals (ACRP) has recently announced a new, free app called GCPartner that is now available for download to anyone who needs quick and easy access to the ICH Guidelines for GCP E6 from the International Conference on Harmonization. The app allows users to search, bookmark, and highlight sections of the guideline, as well as to save personal notes for future reference, download resources for on-the-job assistance, and watch videos that put each section into real-world context. Apps available for both Iphone and Droid phones/tablets.

Say It With Pictures

You know the phrase "a picture is worth a thousand words"…. Well, the Center for Professional Excellence Education has released a job aid that may be worth more than a thousand! Their "Patient Education Picture Book Tool" is a compilation of photos that document medical procedures. This is a great tool to supplement your conversation explaining procedures involved in a research study and includes demonstrations including: Pulse Oximeter, Drawing Blood, and EKG administration, among many others.

This link will take you to a PDF version of the book from which select procedures can be printed: http://centerlink.cchmc.org/WorkArea/DownloadAsset.aspx?id=141573

And, IRB approval is not required for you to use pages from this job aid in your consent conversations.

In the News

A recent study shared in the March Centerwatch discussed an industry-wide movement towards patient-centered clinical research. This trend has forced sponsors to re-evaluate their site relationships as they've come to realize that patient experiences in clinical trials will not improve if sponsors are neglecting their relationships with sites. The article mentioned interviews with sponsor senior executives focused on improving clinical trial practices. The article went on to suggest areas for improvement including: being more flexible in modifying protocols and budgets, supporting efforts for sites to build stronger relationships with study volunteers, and by providing protocols requiring fewer amendments. Fingers crossed!!

* * * * *

A partnership between AstraZeneca and PatientsLikeMe allows AZ access to PLM's global network of patient-reported data to shape future medicine development and help improve results across its main therapeutic areas, including: respiratory disease, lupus, diabetes, and oncology.

* * * * *

According to an article in the Journal of Clinical Research Best Practices, the average cost of a screen failure is $1,211 (this is across all therapeutic areas, worldwide). The therapeutic areas with the highest screen failure costs include Genitourinary System, Central Nervous System, Respiratory Syste, and Oncology.

* * * * *

Considering e-consent? The FDA has shared some requirements, including that the potential participant be able to ask questions and receive answers prior to signing the e-consent form, ensuring that data captured in an e-consent form cannot be altered, and that sufficient protections are in place to ensure a participant's privacy and the data's confidentiality.

Save the Date

The 2015 Human Subject Protections: Takin' Care of Business" conference offers a new twist with a second day of programming.

With the event held again at the Northern Kentucky Convention Center, the "traditional" conference will be held October 1 and will feature the following:
Charles Sabine – Emmy Award winning television journalist sharing the patient perspective, personally
Amy Corneli – Scientist and researcher sharing her quantified findings on consent form simplification
John Wilbanks – Chief Commons Officer from Sage Bionetworks sharing on the impact of the Mobile era upon informed consent and data sharing
Michelle Feige –Executive VP of AAHRPP and past OHRP officer, sharing ways to improve your workings and operations with your IRB
Liz Wool – GCP consultant and nurse sharing her experiences and strategies on what it takes to make (and keep!) a site GCP compliant

The second day is more *regulatory* focused with these PRIM&R-provided talks, delivered by **George Gasparis** and **Dean Gallant**:

- Research on Biological Specimens
- Internet Research
- International Research
- Unanticipated Problems & Adverse Events
- Case Studies

Registration will open soon and allow for registration for either or both days…$150 for either day (with early-registration discount offered for Day 1-only registrations); or $250 for both days.

Profile: Research Participant Advisory Council

Over the last year, a group led by Becca Harper DNP, RN, CTRC Clinical Research Nurse Manager, has been working to establish the first research focused patient and family advisory council, called the Research Participant Advisory Council (RPAC). The council aims to provide a platform for research participants to engage with and advise Cincinnati Children's Hospital Medical Center (CCHMC) administration, faculty, and staff on research and its conduct at the medical center.

Interest in such a program grew following a presentation given by Lorraine Hodsdon, Head of Nursing Clinical Research and CRF Manager, from the *Great Ormond Street Hospital* for children at the International Association of Clinical Research Nurses (IACRN) conference. Emphasis was placed on making patients the driving force in research…"*No research about me without me*."

Last September Lorraine presented as part of a CCTST Special Speaker Forum. Her presentation titled Pediatric Research and Patient Public Involvement encouraged the research community to make patients the driving force behind the work we do. Her presentation can be found here:

The objectives of the CCHMC RPAC group are:

- Partner research participants and families with members of the research community to provide guidance on how to improve research across the academic health center, with a focus on participant experiences and building relationships of trust.
    - Establish best practices and improvement initiatives to implement these changes.
    - Provide a formal referral system for other patient and family advisory councils across the institution looking to engage in research.
- Humanize the face of research at the institution and in the surrounding communities.
- Provide an infrastructure for investigators wishing to include patients and families in their research and study design.

The council has been meeting monthly since January 2015 and has a total of 30 members. The members of the RPAC consist of research participants (pediatric and adult) and parents/guardians of research participants. The RPAC member's ages range from 14-58 years. Additionally, the RPAC has staff representatives from a diverse group of work areas in both research and clinical operations at the medical center. Staff members are from the CTRC, CCTST, ORCRA, OCTR, James M. Anderson Center for Health Systems Excellence, Child Life & Integrative Care, Gamble & Infectious Disease, Asthma Research, and Endocrinology. These staff members act as content experts and group facilitators for focus groups and discussions. The group has been working on exploring the consent and assent process here at the organization. The project is being led by Michelle Dickey, APRN, RN Associate Professor of Pediatrics and Tara Foltz RN III both from Gamble/Infectious Disease and in collaboration with the DAAP program at the University of Cincinnati (UC).

The RPAC is not currently recruiting participants or staff representatives but will begin looking to onboard new member in January 2016. Be on the lookout for future communications and the open recruitment period for the council. Members for the RPAC are selected based on the diversity of background, experience, and strengths that they add to the group. The goal will be for membership to accurately represent the broad spectrum of research participants and families served by Cincinnati Children's Hospital Medical Center (CCHMC).

The CCTST sponsors the RPAC and provides monetary operations support.

Just for FUN

D J P Z C S R T C E S R O L O S Q R T C O N R S T
K R I R O T D E K Y E H G S R R O S O V O Q E T N
V T A H I D N Q S C R Q H O M Y C M K I Q M S C E
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J S M E Y P F S V H L A D I N N G Z X T A E C L N
R S N Q M D E E U E L I N E U U N E O H T H O A E
D T P R V V O M W I R I N Z M A R N R G I J O N S
O K E U N B C R Z L M L R V Q R O S G M S L R O M
Y T X I O K X A E D E W A A E I O S E C T W D I R
D C B Y L E T C A U R N E N T S L F A S I S I T O
G U Q M N I N H Z F F U K N O M T A N V C X N A F
S M A E O F C W Z Y D J E T G I Y I K I S R A G T
J U J N O R T W V L S T K D Z V T B G I A G T I R
R D A T A M A N A G E M E N T D E U N A Y G O T O
B K R E D N I B Y R O T A L U G E R T W T A R S P
K G S C R E E N I N G U H S G I J V H I C O S E E
I E D X Z V R K I Q V H U Z Y D D P J J T J R V R
R B I O M E D I C A L I N F O R M A T I C S O N E
T M D Z Q R J C A I D R P B Z L V Y Y C P X N I S
O E X L N P Z R Y C I K S C M Q D U R G U N W I A
B S E X V S H H X E C N A I L P M O C F X Q V W C

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Send comments, story ideas or questions to:

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Have a great summer!

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