CTC’s Innovation Fund Ensures Six Projects Move Closer to Market Readiness

The Center for Technology Commercialization (CTC) recently awarded $500,000 to six Cincinnati Children’s research teams to accelerate specific research projects through the commercialization process. The Innovation Fund, created to advance the development of CHMC technologies toward the commercial market, marks a game-changing move by Children’s leadership.

While the CTC has and will continue to provide its suite of services (identify, protect and commercialize intellectual property), the direct funding of these projects represents tremendous opportunity for Cincinnati Children’s. At a stage in the development process when NIH and traditional funding methods tend to not apply, the CTC can step in with Innovation Funds to ensure the project continues and moves to the next level.

The ultimate goal of the CTC and Innovation Fund are to see innovative technologies reach the marketplace and improve patient lives. Each of the six projects recently funded are in the process of determining their optimal path to commercialization. They are likely to go down one of two paths: licensing to an industry partner or creating a new start-up company.

Following are brief descriptions of each project and an overview of how the Innovation Funds will be used to move the project closer to the market:

**Margaret Hostetter, MD**, is working to prevent central line infections by developing a vaccine to combat the potentially deadly problem. Hostetter’s research has shown that line infections often begin when a biofilm forms on the inside of the line, caused when heparin binds to proteins in the yeast Candida albicans. She developed an antibody which shows a significant reduction in the yeast’s ability to bind.

The Innovation Fund will be used to test the antibody in vivo to see if it prevents or reduces the biofilm formation. With in vivo confirmation, Hostetter will be able to move to human studies of peptide immunogenicity and antibody efficacy.

*(continued next page)*
**Michael Seid, PhD and Peter Margolis, MD, PhD,** are working on a technology platform that drastically improves quality of support and communication physicians can provide patients suffering from gastrointestinal diseases. It works by allowing patients to track and record their actions and symptoms on a mobile device and then interact in real time with their doctor. The technology is a true decision support tool, synthesizing the self-reported data with clinical data to ensure doctors prescribe the most accurate and effective treatment possible.

The Innovation Fund will support development and integration of the technology with sleep monitoring devices, fitness trackers and other data sources. Further research is also likely to be done showing the technology’s capability to assist with additional disease areas, broadening its market appeal.

**John Pestion, PhD,** is utilizing years of research working with suicide notes to develop a natural language processing technology. This technology allows physicians to analyze the speech and words of suicidal patients based on a short series of questions, determining their likelihood of a repeated suicide attempt. Pestion has already completed a clinical trial of the technology with 60 patients, proving 90 percent accuracy in predicting a repeated attempt.

The Innovation Fund will support an expanded study of the technology throughout medical centers nationwide and ultimately, improve the technology’s market readiness.

**Yi Zheng, PhD and Marie-Dominique Filippi, PhD,** are focused on the development of a new therapy to reduce inflammation that can damage tissues around the heart, brain or lung after injury, and help subdue cancers. The inhibitors have been shown to work on humans and mouse cells, but further development is still needed.

The Innovation Fund will be used to support further development and improvement of the therapeutic before any human testing. Zheng and Filippi also plan to build mouse models to test the inhibitors against inflammation from brain injury and stroke.

**Hector Wong, MD,** is working to improve care to patients in septic shock. His technology is a group of biomarkers that can be used to quickly provide treatment to individual patients and administer clinical trials to those likely to have the best outcomes. Wong is continuing to improve the test and its speed prior to expanding his studies to other hospitals.

The Innovation Fund will assist with the development of a similar model for adults with septic shock, a much larger market than pediatric septic shock. This expansion of the technology is likely to make it more attractive to a larger commercial market.

**John Perentesis, MD,** is dedicated to bringing more potential treatments for cancer and other diseases to the market more effectively and efficiently. His platform technology automates complex and time-consuming aspects of clinical trials, drastically reducing time and cost. Perentesis’ initial focus is on clinical trials for pediatric cancer but could also be applied to the adult market and even beyond clinical trials.

The Innovation Fund will be used to develop advanced algorithms to read old clinical trial records and determine if the technology performs accurately. The market potential for this type of game-changing technology is strong and is sure to improve with the help of this funding.

For questions about the CTC or Innovation Fund, please contact the CTC at ctc@cchmc.org or 636-4285.
Registration Open for Human Subject Protection Conference

This annual event hosted by CCHMC, UC, UK, and Schulman Associates IRB will be held at the Northern Kentucky Convention Center on October 5, 2012.

For more information about this year’s event, including the list of topics and speakers, please view the conference brochure. To register, please visit www.cincinnatichildrens.org/cme and click the link to Register for Continuing Education Events in the orange CME Central box. Then click the October tab. Please be sure to use the "CCHMC" discount code to receive the discounted employee rate. Please note: Online registration for this conference is required. Each registrant must use a unique email address to register. Space is limited – Please register early!

Informed Consent Role Play
Tuesday, September 11, 9:00am - 11:00am;
ELM Registration

PRIM&R Webinar: Research Ethics Beyond Respect, Beneficence, and Justice
Wednesday, September 12, 1-2pm; S1.203;
ELM Registration; no CEUs

Core Clinical Research Training
Tuesday - Thursday, October 2-4, 8:00am - Noon;
ELM Registration; up to 10.5 CMEs

ACRP Webinar: Study Withdrawals-Follow the Reason to Find the Solution
Wednesday, October 31, Noon-1:30pm; S1.203;
ELM Registration; no CEUs

Clinical Research Boot Camp: Clinical Research Orientation
Monday-Tuesday, November 5-6, 8:00am - Noon;
ELM Registration

Clinical Research Boot Camp: EPIC for Research
Wednesday, November 7, 8:00am – 2:00pm;
ELM Registration

Clinical Research Boot Camp: Clinical Research Skills Training
Thursday, November 8, 8:00am
ELM Registration

Clinical Research Boot Camp: Clinical Research Phlebotomy & Shipping
Thursday, November 8, 1:00pm – 5:00pm;
ELM Registration

Clinical Research Boot Camp: ePAS for IRB Submissions
Friday, November 9, 8:00am - Noon;
ELM Registration

Informed Consent Role Play
Tuesday, December 11, 9:00am - 11:00am;
ELM Registration
Data Management: Jumping to the Front Seat

A great deal of attention has been given lately to the growing need for data management to be recognized as a critical component in the research process. The Data Management Initiative was created to foster the development of a new data management infrastructure at CCHMC, which included expanding the Data Management Center (DMC), launching learning modules within the Cincinnati Children’s Hospital Medical Center (CCHMC) Enterprise Learning Management system (ELM), as well as standardizing procedures across the institution. Concurrently, it was recognized that forming a community of data management personnel to collaborate and network would strongly benefit both those who perform data management tasks and CCHMC as an institution.

This “grassroots” initiative for this community began to take shape when Cyndie Baker, in the Data Management Center (DMC), and Amita Mirani, in the Heart Institute Research Core (HIRC), began discussing the idea with Dr. Eileen King, Interim Director of the DMC, early in 2011. The goals were to create a group here at CCHMC who would represent, promote and sponsor data management activities, provide a forum for sharing ideas and best practices, and advance data management knowledge across the institution. Perhaps most importantly, the community would encourage communication and networking among those involved in data management.

In April of this year, a core team was established to lead the development of this new community. Eleven data management professionals comprise the Leadership Committee of the newly formed Data Management Professionals Community (DMPC), under the guidance of two advisors, Dr. King and Rachel Akers, Manager of Data Coordination for the DMC. This Leadership Committee represents many different divisions here at CCHMC. The Committee members are:

- Cyndie Baker, DMC – co-chair
- Amita Mirani, HIRC – co-chair
- Michael Kuhlmann, Office for Clinical & Translational Research
- Jennifer Nobbe, DMC, supporting The Anderson Center
- Lynn Mullins, Emergency Medicine
- Jason Stock, DMC, supporting The Anderson Center
- Dan Jeffers, DMC, supporting The Anderson Center
- Justin Bates, DMC, supporting Adolescent Medicine
- Marilyn Rice, Division of Infectious Diseases
- Carolyn Powers, DMC, supporting Bariatric Surgery
- RicJunette Addie-Carson, Gastroenterology, Hepatology & Nutrition

Says Cyndie Baker, “Knowing what goals we want to achieve, we established Vision and Mission statements that communicate these ideas. Our Vision statement reads “To be the leader in advancing clinical data management in academic research”. Our Mission statement says “To foster data integrity by creating awareness of data management principles, promoting use of data management best practices and procedures, providing educational resources and strengthening communication among data management professionals across the academic health center.”

As you can see, the DMPC is on track to make a huge impact on the data management profession and our research community. Come join us in the front seat! Learn more about the DMPC at the first outreach event being scheduled in October – details to come. If you’d like to be a part of our data management community or have any questions, please contact us at DMPC@cchmc.org.
# NIH Grant Deadlines through April 2013 (CYCLE I)

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** Effective May 25, 2011, the U01 Activity Code will be used for SINGLE RESEARCH PROJECT Cooperative Agreements ONLY

*** Deadlines Falling on weekends or holidays move to the next business day
Applications for Digestive Health Center Pilot and Feasibility Applications Due December 3

Applications are solicited for pilot projects to conduct basic, translational, and patient based or outcomes research broadly relating to pediatric digestive disease.

Funds will support highly focused projects from individual investigators and are intended to provide support to collect preliminary data sufficient to support an application for independent research through traditional NIH mechanisms. Current membership in the Digestive Health Center is not required.

The deadline for submission is Monday December 3, 2012 at 5:00 pm. The guidelines and forms for submission are available on the Digestive Health Center web site.

Questions should be sent to either Aaron Zorn, PhD (Pilot and Feasibility Program Director) at aaron.zorn@chmc.org or Cynthia Wetzel, PhD (Digestive Health Center Program Manager) at cynthia.wetzel@chmc.org.

Applications for PROCTOR SCHOLAR AWARDS and TRUSTEE GRANT AWARDS due November 5

The Trustee Award and Procter Scholar (TAPS) Program is soliciting proposals for Procter Scholar Awards and Trustee Grant Awards.

Procter Scholar Awards will support the development of highly skilled pediatricians with a strong commitment to pursuing a career in academic research. Funds will support highly skilled MD or MD, PhD Pediatric fellows who are transitioning to a faculty appointment, with the goal to enable the transition to a National Institutes of Health K-level award or K-level equivalent awards from foundations.

Trustee Grant Awards will support faculty who are within the first 4 years of initial appointment to conduct basic, translational, and patient-based research. Funds will support highly focused projects from individual investigators, with the goal to enable the acquisition of additional preliminary data for highly competitive applications for R01 grants from the National Institutes of Health or R01-equivalent awards from foundations or industry.

The deadline for submission for either funding opportunity is Monday November 5, 2012 at 5:00 pm. The guidelines and forms for submission are available on the Procter Scholar web site or the Trustee Award web site.

Questions should be sent to either Jorge Bezerra, MD (TAPS Program Director) at jorge.bezerra@chmc.org or Cynthia Wetzel, PhD (TAPS Program Manager) at cynthia.wetzel@chmc.org.

Trivia Corner

If you were freeze-dried (like coffee), 90% of your weight would be the "real you."

Your fingernails grow four times as fast as your toenails.

Romans used urine as a tooth cleaner (it contains ammonia).

A beard grows an average of 14cm per year.

The skin of the armpits can harbor up to 516,000 bacteria per square inch, while drier areas, such as the forearm, have only about 13,000 bacteria per square inch.

There are an average of 500 hairs in one eyebrow.
People to Watch - Jenny Kaplan, MD

**Jenny Kaplan, MD** is a young translational investigator in Critical Care Medicine who exemplifies “promises kept.” She is a staff pediatric intensivist, basic science researcher, and mother of two young children who is also passionate about finding more answers for gravely ill children with infections. She started on her path to improve outcomes for critically ill children by adding an extra year to her fellowship and completing an MS in molecular epidemiology on a T32 grant. For her, the reward for this extra investment of time was an ideal opportunity here at CCHMC. It allowed her to limit some of her clinical time in order to pursue basic and clinical research.

She credits Dr. Wong for continuing to hold the door wide open for her when it was time for her to make the transition from fellow to faculty. Dr. Kaplan reports that the support and guidance she received here from her peers and mentors fostered many ideas and directions for her future work in sepsis.

The “promise” was an offer from her boss and mentor, Hector Wong, MD. A promise to give her the time needed to develop new strategies through her lab work focused on sepsis. The promise was repaid with pioneering work in the role of PPAR gamma in pediatric sepsis and the inflammatory response in obesity. This was an extension of work performed in collaboration with her mentor, Basilia Zingarelli, MD, PhD...

Kaplan states that the research grants and awards she has received would never have been possible without the collaboration she encountered here. Her TRI grant and NIH funding helped her to develop some unique therapeutic interventions for children with sepsis.

As part of “promises kept,” Dr. Kaplan is the first intensivist here to pursue an Investigational New Drug application (IND) to support her work in critical care. While the regulatory work that is required for an IND can seem daunting to most investigators, Dr. Kaplan said that after an initial meeting with Sheri Selk, Clinical and Regulatory Affairs Manager of the Office for Clinical and Translational Research (OCTR), she was on her way. Her fears about “...Not knowing what she didn’t know...” were calmed when she was assigned to a regulatory expert, Christina Canter, Clinical Research Project Manager in the OCTR. Ms. Canter helped her develop her first clinical trial protocol, prepare, organize and complete her FDA pre-IND meeting along with OCTR’s Marianne Brunner, and develop and submit her FDA IND application. Dr. Kaplan credits OCTR with a shortened timeline for the entire process from idea to IND approval. She also credits investigational pharmacy with novel developments for drug dosing methodologies that enable her study to move forward safely.

From this initial start as a clinician-scientist, Dr. Kaplan has developed enough clinical trials acumen to develop adverse event reporting relevant to critically ill children. She just sees this as part of the continuum of her interests: intensivist-wife- mother-scientist. So if the adverse events review takes another 12 hour day, it’s just part of the plan. She credits her research nurse with preparation of these and Chris Canter with most of the heavy lifting with the FDA reports. For her, exciting next steps will be a study of efficacy of a novel drug in critically ill adolescents with sepsis. If there are going to be better results for children with sepsis, Jenny Kaplan wants to be sure that it happens on her watch.

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**Consent Corner**

Short form templates for several foreign languages are now available on the Research WaterCooler. When you click the “Informed Consent” link on the Human Subjects Researchers tab, you’ll find these short forms along with the corresponding certification document.

Languages currently available include:

- Arabic
- Chinese
- French
- Japanese
- Korean
- Nepali
- Spanish

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NIH News

More Compounds Available

The June 2012 ResearchForward contained an article stating that three pharmaceutical companies were making available compounds that had undergone preliminary study, but were no longer being evaluated. Five more companies have since joined this effort and $20 million will be available in fiscal 2013 for research proposals using these compounds. NIH is requesting formal requests for applications using these compounds through its National Center for Advancing Translational Sciences.

New Programs Available through the NIH Common Fund

New programs for understanding undiagnosed diseases are among the latest priorities for the NIH Common Fund. Approximately 6 percent of the U.S. population suffers from a rare disorder. The Common Fund Undiagnosed Diseases Program (UDP) will promote the use of genomic data in diagnosing diseases. Additionally, the UDP will engage basic science researchers to identify underlying mechanisms so that therapies can more rapidly be identified.

The program will also provide training to clinicians on using contemporary genomic approaches so that these methods can be utilized to fight other diseases. This program is expected to receive approximately $145 million in NIH Common Fund support. The goal is to spawn new medical discoveries as well as accelerate clinical investigations.

All About Grants NIH Podcasts

Designed for investigators, fellows, students, research administrators and others, the NIH presents podcasts (conversations with NIH staff members) to provide insights on grant topics from those who live and breathe the information. These can be accessed at: http://grants.nih.gov/podcasts/All_About_Grants/

A recent podcast covers strategies for pre-doctoral or postdoctoral fellowship applications. One of the ways these differ from research applications is the emphasis on the applicant, their mentor, and the proposed training plan. The NIH Report can help you identify fellow researchers who might present opportunities.

FDA News

Over the last ten years, the number of FDA-approved new products has dropped to almost half of what was realized the previous decade. This is surprising in that it occurred despite unprecedented investments.
Ohio Research Institutions Form Statewide IRB Collaboration

The three Clinical and Translational Science Award (CTSA) institutions in Ohio—the University of Cincinnati (UC), Case Western Reserve University and The Ohio State University—and their partnering institutions (including CCHMC) have established a statewide collaborative agreement allowing a single organization’s Institutional Review Board (IRB) to assume IRB responsibilities on behalf of multiple institutions when conducting multicenter studies.

The agreement will serve to accelerate research by streamlining human subject protection processes when participating institutions are partnering on research projects requiring IRB approvals. Until now, collaborations across participating institutions required redundant review at each individual institution—a multi-step process that could impede multicenter studies essential to developing new treatments and therapies to improve human health.

Developed through statewide discussions that included the UC Center for Clinical and Translational Science and Training (CCTST), this is the first reciprocity agreement among multiple CTSA organizations and encompasses eight legally separate institutions in Ohio. In addition to UC, CWRU and OSU, they are: CCHMC, Nationwide Children’s Hospital (Columbus), Cleveland Clinic, MetroHealth Medical Center, and University Hospitals Case Medical Center. Click here to learn more.

CCTST Preparing for CTSA Competitive Renewal

Time flies— with about 18 months of funding remaining in the UC Academic Health Center’s initial 5 year NIH Clinical and Translational Science Award (CTSA), the Center for Clinical and Translational Science and Training (CCTST) is preparing for its competitive renewal. The CTSA currently provides about $4.5 million annually to support pilot funding, methodology consultation, training programs and other resources which accelerate and improve clinical and translational research. The next funding cycle may accommodate a modest increase, if funds are available.

The CCTST is currently collecting and reviewing one-page summaries of accomplishments and future plans from leaders of each of its core service areas. This fall, a new and improved CCTST website, including an updated dashboard of core service statistics, will be up and running. In December 2012, a detailed outline and rough draft of the renewal application will be presented to the CCTST’s External Advisory Committee for review and comment. Early next year, a revised application draft will be prepared, with completion/submission to follow in the second or third quarter, depending on the announced due date. For more information on the CTSA renewal process, please contact CCTST co-director Dr. James Heubi.

Considering Certification?

The Academy of Physicians in Clinical Research (APCR) offers a certification program for investigators. The next testing period is February 28-March 16, 2013. Applications to sit for the certification exam are being accepted October 2012 through mid-January 2013. Those passing would earn the CPI designation as a Certified Physician Investigator.

A physician investigator is a physician (MD or equivalent degree) who serves as the primary, sub-, or co-investigator; or monitors, supervises, or designs clinical trials; and accepts responsibility for the safe and ethical conduct of a clinical trial, herein defined as a systematic experiment designed to evaluate the pharmacokinetics, pharmacodynamics, pharmacoeconomics, safety; efficacy and effectiveness of a drug, biological, medical device (therapeutic or diagnostic), procedure; or other intervention involving human participants.

For details about the certification program and for registration details: http://apcrnet.org/MainMenuCategory/Certification.aspx

While not mandatory, the APCR is recommending that the FDA consider PI certification as a means of ensuring investigator qualifications.

Similarly, there are certifications for other research staff including:
Certified Clinical Research Coordinator (ACRP)
Certified Clinical Research Professional (SoCRA)

Funding Opportunity

Started in 2010, PCORI (The Patient-Centered Outcomes Research Institute) is authorized by Congress to conduct research to provide information about the best available evidence to help patients and health care providers make better-informed health care decisions. PCORI’s research is intended to give patients a better understanding of the prevention, treatment and care options available, and the science that supports those options.

Since 2010, they have already funded over $30 Million in research and announced another $120 million slated for comparative effectiveness research. Their web site contains full details: http://www.pcori.org/funding-opportunities/
CTSA Pediatric Regional Collaborative Grant Program Offered

Administered locally by the Center for Clinical and Translational Science and Training (CCTST), this program was established to promote translational research collaborations between investigators at multiple Clinical & Translational Science Award (CTSA) institutions and regional partners that bring together expertise, scientific resources, patient populations, and/or community resources not all readily available at a single site. Participants include CCHMC, Nationwide Children’s Hospital (Columbus), Rainbow Babies Hospital (Cleveland), Riley Children’s Hospital (Indianapolis) and University of Kentucky Medical Center (Lexington). Interdisciplinary collaborations which include both clinicians and basic scientists are preferred.

Eligible collaborative translational research projects may include “T1” research that seeks to apply clinical or basic research knowledge in an identifiable pathway towards the development of trials and studies in humans; “T2” research to validate T1 research in phase 2 and 3 clinical trials; or “T3” research aimed at enhancing the adoption of best practices in the community. This may include methods or design for new or improved elements of health care, whether intended for internal use or use by others outside of the respective institutions.

Each collaborating site will contribute $10,000 of support. Thus, the maximum allowable budget (direct costs) is $50,000 if all 5 institutions participate. New proposals may request one year of support. Competing renewal applications may request one additional year of support. The number of awardees will be determined by the quality of the proposals, the total amounts of the requested budgets of sufficiently meritorious proposals, and available funds.

Applications will be accepted from any faculty member with an appointment of 80% FTE or greater at any of the participating institutions or affiliated universities. Eligible applicants include basic scientists, physicians, nurses, and other health care faculty with advanced degrees (MD, PhD, MD-PhD, or equivalent). Clusters of investigators spanning disciplines and programs made up of basic and clinical faculty are strongly encouraged.

There are no specific deadlines. Applications may be made at any time during the grant year of July 1, 2012-June 30, 2013. For additional details, please see the program description and application guidelines/forms linked below. Questions may be directed to CCTST Co-Director James E. Heubi, MD at james.heubi@cchmc.org or (513) 636-8046.

Research with Pediatrics

Did you know that children bear nearly 60% of the burden of ten major global diseases, while only 12% of the clinical trials on those diseases include children! These “top ten” diseases include migraine headaches, asthma, and depression, among others. While some research has been done on adults and pediatrics of all ten of these, the discrepancy is most notable in diseases most prevalent in mid-to-low income countries including: lower-respiratory infections, diarrhea, and HIV.

They also found that adult trials are more likely to be conducted collaboratively across multiple institutions. This analysis, conducted out of Boston Children’s Hospital, finds that this discrepancy is likely related to a relative lack of industry funding and corresponding support for clinical studies among pediatrics. The majority of adult trials are industry funded while the majority of pediatric clinical trials is government/non-profit funded.

ePAS News: UC implements ePAS

As some of you are aware, the ePAS IS team and members of UC and CCHMC IRB have been working to bring UC on board with using ePAS. The hard work has paid off and UC is now accessing ePAS.

Since both UC and CCHMC will be sharing the same system, investigators that have studies requiring the review and approval and/or reliance of either UC or CCHMC will be required to submit only one submission. Both UC and CCHMC will have the capability to access the submission and either process it, or acknowledge reliance. This means that when there will be one submission required for amendments, continuing reviews, and problem reports. If need be, the relying institution will be able to have access to those submissions. During continuing review for example, both institutions will be able to view the one submission for continuing review.

A group of key people at Cincinnati Children’s is trying to make consent documents easier for families to read and understand. The goal is to have better consent documents that more children and families can understand, share with family and friends, and use to ask additional questions.

(see additional article on ePAS...next page)
Our epic (intentionally lowercase) ePAS Journey

As many of you are aware, Cincinnati Children’s has been on a journey that started back in 2007. The journey is the development, implementation and roll out of the Click Commerce, Inc. research management software solution. Here at Cincinnati Children’s, we have named our application of this software “ePAS” (electronic Proposal Administration System). Admittedly, we were not very flashy with our name… and probably could have used some support from our marketing and communication colleagues. Nonetheless, we are preparing to reach a major milestone in our ePAS journey. To be sure, the ePAS journey is not quite the journey that EPIC has been for the hospital, but here in Research Administration, we think that it is pretty a big deal.

Our upcoming milestone is the release of the ePAS IACUC module, which will occur during the week of October 24, 2012. The release of the IACUC module represents the final piece of our original ePAS implementation project that began back in 2007 with the development and eventual launch of the ePAS IRB module (in 2008). Once we launch ePAS IACUC, we will have the following ePAS modules live – IRB, IACUC, IBC, Sponsored Programs, and COI. This is truly a major accomplishment for Cincinnati Children’s and is a testament to the flexibility and willingness to embrace new technologies that is embodied by our research community. We know that learning and adapting to new systems is challenging. We also know that the process of converting your existing paper records and processes into a paperless, electronic environment is difficult and time consuming. The research community at Cincinnati Children’s continues to be flexible and willing to provide constructive feedback during each step of our ePAS journey. With the launch of the IACUC module and completion of the subsequent conversion process, we hope to move resources that have been dedicated to system development, into an ongoing period of refinement, improvement and aggressively adapting much of the user feedback that we receive into improvements across all five ePAS modules.

With regard to the launch of the ePAS IACUC module, in addition to the October 24th launch date, the following is additional key information:

- October 24, 2012 – system Live
- November 26, 2012 – last day to submit new IACUC studies outside ePAS
- January 2, 2013 – last day to submit 3-year IACUC renewals outside ePAS
- April 30, 2012 – last day to submit annual IACUC updates outside ePAS (requires conversion of existing protocol into ePAS)

Following the launch of ePAS IACUC, training documents and office hours will be available on a regular and ongoing basis to support users in the use of this new module. Stay tuned for email communications and announcements within ePAS regarding these documents.

Technology in Research

An advisory panel of the OHRP is drafting updates to policies governing federally-funded research. One of the areas being updated applies to technology. When the regulations were last updated (in 1991), the internet was largely in its infancy. Think about what has transpired since then with social networking, Facebook, Twitter, and avatars.

Incorporation of this technology in the conduct of your research presents challenges to the researchers themselves, not to mention the institutional review boards that approve those studies.

Some concerns include:
- Whether potential research subjects fully understand the risks before agreeing to participate.
- Whether research subjects may be misrepresenting themselves in order to qualify for studies
- Whether avatars should be granted human subject protections
- Differentiating a public site from a private site (if anyone can join)
- Privacy of data, given the capabilities of today’s search engines.

One thing’s for certain, there’s no going back. Technology is increasingly becoming an integrated part of medicine and research. It’s important to make efforts towards the continued protection of research participants.
Consent Form Readability

A group representative of the IRB, research compliance, researchers and faculty have undertaken an initiative to assess the guidance and templates for developing research consent documents that are provided to research participants at Cincinnati Children’s. This initiative was primarily undertaken because we have the interests and protection of our research participants at heart. Often, there is a disconnect between the participant’s ability to understand and the researcher’s communication of information pertaining to a clinical trial. Consent documents are generally attempting to communicate complex medical material and important information about risks and benefits. If the research participant or his or her parents has difficulty understanding the informed consent document, we are not being fair to them, nor are we meeting our ethical obligation. The document that participants and their parents take home with them must be one which they can understand, share with family and friends, and/or ask questions of others.

Or, this could be stated differently, using simplified language…

In research, consent documents help children and families learn about what it will be like to be in a study. The forms can be long and wordy with lots of detail and difficult language. This causes families to understand less about a study, not more. When this happens, we fail to meet our responsibility to make sure that families are truly informed.

A group of key people at Cincinnati Children’s is trying to make consent documents easier for families to read and understand. The goal is to have better consent documents that more children and families can understand, share with family and friends, and use to ask additional questions.

The above two paragraphs illustrate two approaches to informed consent. Informed consent grows out of respect for people who participate in research. This includes special protections for children and other vulnerable participants. Informed consent is not a formality, nor is its purpose to protect the researcher. The informed consent/assent process must ensure that both older children and parents fully understand the research, understand what they are being asked to do, and understand the risks and benefits of the research for which they are providing consent/assent.

Many people do not read well. Average American reading levels range from 6th – 8th grade. People who are unable to read well often will not admit it, so they say they have read and understood something even if that is not the case. It is not our purpose to add shame to the emotions of an already difficult situation. Another factor to consider, especially for parents, is shock. Parents hearing for the first time that their child may have a serious disease will find it harder to understand complex language.

Health literacy is another aspect of this issue. While someone may be quite literate and able to read and understand complex information, that same person may not be health literate. Many people will not be able to understand the health information needed to make basic decisions and follow instructions for treatment.

While informed consent is a process and not simply a document, the document still must be understood by any person who is asked to sign it. Reading level tools, such as Flesch-Kincaid or Fry are not perfect, but they give a starting point for analyzing readability. Short sentences, words of few syllables, and use of the active voice all serve to make a document easier to read. Simpler and shorter informed consent documents will make the process of obtaining consent easier and more meaningful for everyone.