Research *Forward*

Cincinnati Children's

A Publication from CCRF Research Administration

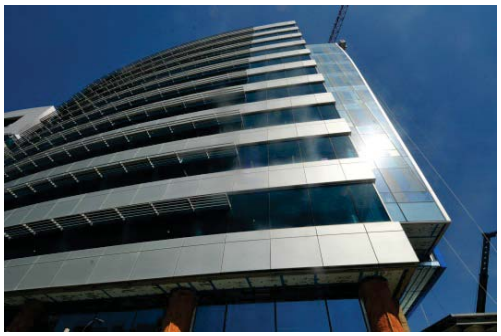
T is for Translation

Location T is getting ready for its debut in June of 2015. Already you can see wall colors and furniture through the windows on several floors. With 25,000 cubic yards of concrete, and nearly 100,000 square feet of exterior glass, it adds just over 400,000 square feet to campus. Messer Construction and their partners have ensured the building is of the highest quality. And with more than 150 researchers involved in its design, Location T is certain to be an excellent facility in which to do translational research.

It is no accident that Location T, also known as the "Clinical Sciences Building" is located between hospital and research buildings, providing both a geographic center for and a symbol of what Cincinnati Children's does so well: collaborative science that improves the outcomes in pediatric medicine.

The new building will house several divisions of the CCRF along with a family-oriented Research Clinic. Floors 1-3 are dedicated to clinical research and two public elevators allow for research subjects and families to access only those floors. The remaining floors are dedicated wet lab and office suites.

Location T under construction, November 2014



Location T exterior, October 2014

Some major design elements are:

- Daylight penetration – the laboratory floors have full height glass walls and the office areas have an open floor plan to maximize employee access to daylight.
- Special food markets with novelty foods – the "beehive" at the junction between Locations T and S is meant increase the likelihood of inter-actions; several floors will market popcorn, ice cream, and other foods to draw people to those areas.
- Open stair – a glass-encased stair spans all 14 stories to encourage movement between floors and enhance connections among colleagues.

The addition of Location T allows programming of the entire R-S-T complex in an effort to bring together divisions that are currently fragmented (e.g., Behavioral Medicine and Clinical Psychology, now in eight locations), and to optimize physical connections (where possible) among divisions who routinely collaborate. In addition, while R-S-T planning is complex and has been a very large undertaking, it will help us to better manage future growth of the CCRF. Shifting entire divisions will require some time and we will be rolling out a move schedule in the next few weeks. Our goal is to have all division moves to occur from July 1 through October of 2015. More information will be posted on the Research Tab of CenterLink.

IN THIS ISSUE:

Architect's rendering of the Research Clinic on T1

Winter 2014

Innovation Showcase Taking Place January 6

Cincinnati Children's is hosting its first ever Innovation Showcase on January 6 in S1.203. The event is focused on bringing our research community and innovators timely and information with an emphasis on innovation, internal/external collaboration and moving discoveries from the bench to the bedside.

The day kicks off with commercialization-focused grand rounds in Sabin Auditorium and then all events for the rest of the day will be in S1.203.

You'll hear from local, regional and national thought leaders including several of our senior leaders and innovative faculty through interactive sessions and networking, all focused on elevating our scientific impact. The CTC will also be launching new funding rounds for two of its programs as well as announcing a new partnership and funding opportunity with Alexion Pharmaceuticals that is focused in the rare disease space.

You can find more information about the event and register for the sessions that are of interest to you by going to www.cincinnatichildrens.org/innovation-showcase. Here is a snapshot of the day:

	Tue, Jan 6	Location
8am	**Grand Rounds| Beyond the Shark Tank: Innovation CCHMC-Style** *John Rice, CincyTech | Mike Venerable, CincyTech* *Dr. Tracy Glauser | Dr. Punam Malik | Dr. Hector Wong*	**Sabin Auditorium**
9am	**Coffee & Networking** (No RSVP needed)	**S1.203 Pre-Function Area**
930am	**Innovation: Our Lifeblood** *Michael Fisher & Dr. Margaret Hostetter*	**S1.203**
10am	**Going Full Circle: The Rotarix Story** *Niki Robinson, Phd, AVP, Center for Technology Commercialization*	**S1.203**
1030am	**Bench to Bedside Champions & Rising Star Program Launch** *Dr. Tracy Glauser*	**S1.203**
11am	**Early Stage Innovation – Starting & Embracing the Journey** *Dr. Michael Jordan | Dr. Ardythe Morrow | Dr. Lee Grimes* *Moderator: Niki Robinson, PhD, AVP, Center for Technology Commercialization*	**S1.203**
12pm	**Our Startups & the CEO/Investigator Experience** **Assurex Health** – *Gina Drosos, CEO & Dr. Tracy Glauser* **Airway Therapeutics –** *Marc Salzberg, CEO & Dr. Jeffrey Whitsett* **Enable Injections –** *Mike Hooven, CEO & Dr. Eric Wall (tentative)* *Moderator: David Wilbrand, JD, Partner, Thompson Hine*	**S1.203 Lunch in Pre-Function Area**
1pm	**Medical Device Innovation & BG3C: A Collaborative Model for Success** *Dr. Daniel von Allmen | Dr. Richard Azizkhan | Chris Stahl* *Moderator: Mark Low, Managing Director, Global Cardiovascular Innovation Center*	**S1.203**
2pm	**Innovation Fund: A New Round, A New Opportunity** *Dr. Hermine Brunner | Dr. Peter Margolis |Dr. Yi Zheng* *Moderator: Jan Rosenbaum, PhD, CSO, Airway Therapeutics*	**S1.203**
3pm	**Alexion Rare Disease Innovation Award: A New Model for Academic-Industry Collaboration** *Dr. Steve Uden, SVP Research, Alexion Pharmaceuticals*	**S1.203**
430pm	**Networking Reception**	**S1.203 Pre-Function Area**

Progressive People: Pete White

Pete White, PhD in his S10 office

Joining Cincinnati Children's in mid-2014, Pete White, PhD, serves as Director and Chair of the Division of Biomedical Informatics. Pete came here after spending 20 years at Children's Hospital of Philadelphia (CHOP), citing the cooperative and collaborative nature associated with our institution as a key driver in his decision to move. This same collaborative nature has also been emphasized by other "transplants" as what makes CCHMC unique and such a great place to do research.

Capitalizing on this collegial spirit, Pete wants to see the institution continue to make data more accessible. He cited an example of the Center for Pediatric Genomics as doing just this…making genomics data available to functional areas that can capitalize on the massive data captured to date. Increasing data accessibility may generate some challenges that are likely more tied to the need for cultural change rather than adoption of new technology. This is definitely not "business as usual".

Pete points to systems biology as being an enabler of these improvements. Key to this is the integration between Hospital Information Technology (IT) and Research IT, with the latter being comprised of the BMI integration services as well as hardware services. One of Pete's long-term initiatives coincides with the industry move to "big data" due to the opportunities and issues presented there. He would like to see more models that capitalize on this data with the net result of improving child health.
Pete points to the collaborative and cooperative nature of our researchers as our greatest competitive advantage. He specifically points to BMI's strong ties with the Epidemiology/Biostatistics division and how they are increasingly integrating with external programs. He hopes to see more such integration.

Pete and his family are enjoying their move to Cincinnati. He and his wife, Lori, a molecular geneticist, have two sons in the Sycamore school district. His older son has cerebral palsy and benefits from the great programs at Cincinnati Children's as well as at his school. The younger son is following mom and dad and is a self-proclaimed "science nerd". Pete likes trail running and ultra marathons. Whenever he gets a chance, he can be found running the trails around East Fork Lake and Mt. Airy Forest.

New Animal Care and Use Training Program for 2015

Beginning in January 2015, the IACUC will be transitioning the electronic portion of the animal care and use training program to the Collaborative Institutional Training Initiative (CITI). CITI is an educational platform that offers a more robust, comprehensive curriculum while providing species-specific training modules. All personnel who work with laboratory animals will begin completing continuing education through CITI every three years and will be able to customize their curriculum, based on the species they are working with. All new personnel working with animals will complete the animal use orientation requirement through CITI as well.

More details about "CITI Curriculum for Animal Care and Use" will be released in late December. The program is targeted to be available January 1, 2015.

OCTR Conference Update

Clinical Research… and All That Regulatory Jazz was a hit! The *2014 Office for Human Research Protection (OHRP) Research Community Forum* held this past May and sponsored by Cincinnati Children's/OCTR, OHRP, UC, Cincinnati VA Medical Center and CCTST was a great day of shared research ideas and learning for 450 participants attending from across the country.

That said, the planning committee has begun exploring partnerships and sponsors to conduct the next enriching and fun research learning experience. The next OCTR/Research Foundation sponsored symposium is being planned for 2016. There will not be an OCTR/ Research Foundation sponsored conference in 2015.

If you relied on the annual research conference/symposium for your continuing education credits, please watch for and attend other instructional research opportunities around the academic health center and region. Some of these include the annual fall Human Research Protection conference at the Northern Kentucky Convention Center, monthly CRP presentations, CCTST presentations, as well as other educational sessions being offered around the center for coordinators who need to meet certification requirements (every three years).

While we will miss you in 2015, we look forward to offering you a diverse and interesting program again in 2016 for a day of research instruction and fun. See you in 2016!

Consent and the Autonomy of Human Subjects

by Elisa A. Hurley, PhD, PRIM&R Executive Director

We all know that designing a mechanism for obtaining valid informed consent is a perennial challenge, but it seems to be receiving special and renewed interest lately.

The United States Food and Drug Administration (FDA) recently released a draft guidance, *Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors*, for public comment. The draft is intended to replace the FDA's previous, and much briefer, guidance on informed consent, which dates from 1998. Throughout the new draft guidance, the FDA emphasizes that informed consent involves more than a form, and encourages investigators, IRBs, and sponsors to think of informed consent as a dynamic process that can be adapted to reflect the unique needs of potential subjects, as well as local context.

The introduction to the FDA draft states it plainly:

> *To many, the term informed consent is mistakenly viewed as synonymous with obtaining a subject's signature on the consent form. FDA believes that obtaining a subject's oral or written informed consent is only part of the consent process. Informed consent involves providing a potential subject with adequate information to allow for an informed decision about participation in the clinical investigation, facilitating the potential subject's comprehension of the information, providing adequate opportunity for the potential subject to ask questions and to consider whether to participate, obtaining the potential subject's voluntary agreement to participate, and continuing to provide information as the clinical investigation progresses or as the subject or situation requires. To be effective, the process must provide sufficient opportunity for the subject to consider whether to participate.*

Additionally, the Secretary's Advisory Committee on Human Research Protections (SACHRP), the body charged with making recommendations to the Secretary of Health and Human Services regarding human subjects protections issues, devoted a full quarter of its July 2014 meeting agenda to a discussion of the informed consent process, in a session aptly titled, *Informing Informed Consent: Defining and Validating Comprehension*.

There is a common thread between these two examples—a renewed emphasis on the role and importance of subject understanding in the consent process.

The FDA draft guidance focuses on the importance of consent documents being written in language understandable to subjects, and includes expanded sections on informed consent with respect to non-English speakers. The SACHRP session concentrated on barriers to subject comprehension, including the fact that therapeutic misconception persists despite increasingly well-informed efforts to educate potential subjects about the purposes of research.

These points are well taken: empirical research dating back to the 1980s consistently shows that research subjects have limited understanding of study information (Falagas et al., 2009; King and Heubi, 2014), and that consent forms are often to blame. Long, dense, and technically written consent documents do a better job of legally protecting research institutions than enabling potential subjects to make informed decisions about research participation. And while legal protection is important for both the subject and the institution housing the research, the focus on avoiding future litigation puts the interests of the institution above the interests of individuals who are being asked to take on sometimes significant risks for the sake of, at least primarily, generating scientific knowledge. Without subject comprehension, consent can't meet its intended goal: to afford potential research subjects the opportunity to autonomously agree to participate in a research study, with full and well-considered knowledge of all that participation entails.

None of this is news, of course. And valiant efforts are being made to offer empirically grounded recommendations about how to improve both consent forms and processes, precisely to increase subject comprehension (Nishimura et al., 2013; Koyfman et al., 2009; Stunkel et al., 2010; Kass et al., 2011). But attending the SACHRP meeting and then shortly afterward working on PRIM&R's comments on the FDA guidance, got me thinking about the tenacity of the problems around subject comprehension in informed consent. This led me to reflect on another practice around consent I've noticed and always objected to: the use of "consenting" as a transitive verb – as in, "we consented the subject into the study…." This may seem like a minor detail; in fact you hear it all the time. But I think this way of speaking reflects the same general attitude toward

(continued next page)

Consent and Autonomy *(continued)*

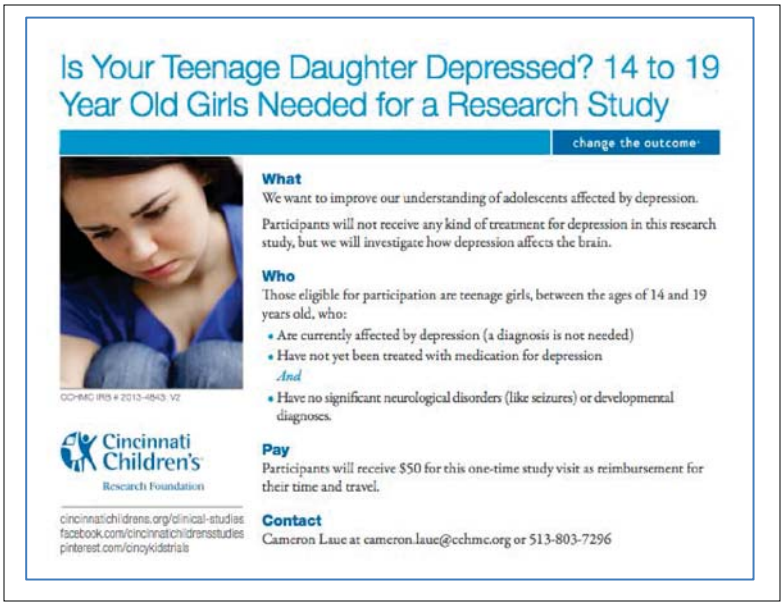
consent that results in overly lengthy, poorly constructed consent forms: that it's something done to subjects so that research can get started.

Thinking this way does real violence to the very idea of what consent is supposed to do: respect, acknowledge, and invoke the agency of potential research subjects as they think about and knowledgeably decide whether they want to participate in research. Again, the phrasing may seem like a small detail, but words matter. They convey an attitude. In this case, it's an attitude reflective of a more general corruption of the spirit of informed consent, namely, that in practice, on the ground, there is not enough regard for its role as our primary mechanism for respecting the autonomous, informed choices of individuals to participate in this important endeavor we call research.

* * *

Elisa Hurley is the Executive Director of Public Responsibility in Medicine and Research (PRIM&R). PRIM&R's highest priority is providing those responsible for ensuring research protections, and those involved in the design and implementation of research protocols, with education, practical tools, and cutting-edge strategies to inform and guide their work.
Read Dr. Hurley's bio.
Learn more about PRIM&R.

Now Enrolling



Professional Development

Core Clinical Research Training
Tuesday, January 27th - Thursday, January 29th; 8:00am – 12:30pm; ELM Registration

- -

Informed Consent Role-Play
Thursday, February 5th; 9:00am – 11:30; ELM Registration

- -

Clinical Research Orientation *(Part of Clinical Research Boot Camp)*
Monday, February 9th - Tuesday, February 10th; 8:00am – Noon; ELM Registration

- -

ePAS – IRB Submissions *(Part of Clinical Research Boot Camp)*
Wednesday, February 11th; 8:00am – Noon; ELM Registration

- -

Clinical Research Skills Training *(Part of Clinical Research Boot Camp)*
Thursday, February 12th; 8:00am – Noon; ELM Registration

- -

Clinical Research Phlebotomy Training *(Optional Part of Clinical Research Boot Camp)*
Thursday, February 12th; 12:30pm – 5:00pm; ELM Registration

- -

EPIC Research Registration *(Part of Clinical Research Boot Camp)*
Friday, February 13th; 8:00am – 2:00pm; ELM Registration

- -

Core Clinical Research Training
Tuesday, April 21st - Thursday, April 23rd; 8:00am – 12:30pm; ELM Registration

- -

Informed Consent Role-Play
Thursday, May 7th; 9:00am – 11:30; ELM Registration

- -

Clinical Research Orientation *(Part of Clinical Research Boot Camp)*
Monday, May 11th - Tuesday, May 12th; 8:00am – Noon; ELM Registration

The Radiology Protocol Submission Form

Radiology has restructured their process for researchers needing to use services in the department of Radiology during their research studies. The Radiology Protocol Submission Form (PSF) will be required for all new studies requesting research imaging procedures in Radiology (e.g. MRI's, CT's, ultrasound, x-ray and nuclear medicine). The form will be used to request services and costs from Radiology for these research imaging procedures and can be found on Centerlink under the Research tab, Research Information tab, in the Clinical Research Menu.

After you have submitted the completed PSF to Lisa Ulland (Business Director of Radiology), you will need to schedule a study start-up meeting that will include the study PI, study CRC/RN, Lisa Ulland, and the appropriate procedure contact (listed on the PSF). This meeting will cover the imaging procedure process for individual studies including:

- Anticipated start date and duration of project
- Who to contact when a participant is coming (Radiology and Anesthesia)
- How to schedule (contacts below)
- Billing and registration/PEFs
- Protocol(s)

** Please note that this process pertains to imaging procedures completed in the department of Radiology, and does not pertain to the use of the Imaging Research Center (IRC).

If you have any questions about the new process or PSF, please contact Lisa Ulland at lisa.ulland@cchmc.org.

CCTST Methodologic Research Program

The Center for Clinical and Translational Science and Training (CCTST) Methodologic Research Program requests applications to advance methodologic research in biostatistics, epidemiology, bioinformatics and related disciplines in order to enhance the capacity to conduct and analyze data from clinical and translational studies. The Program will support promising innovations with potentially important applications that may enhance research validity, efficiency, and causal inference. Relevance for clinical and translational research is a key evaluation criterion, and coordination with ongoing CCTST-supported research is encouraged. **The next application deadline is Monday, January 26, 2015 by midnight.**

Up to $10,000 may be requested for a one year, non-renewable award. Appropriate topics include, but are not limited to, novel statistical methods development for design and analysis of clinical and translational studies; novel methods of subject enrollment, retention, and data or sample collection and management; and validation of novel scales or predictive models using existing datasets to address important clinical and translational research needs, e.g., quality of life, attitudes, and prediction of key behaviors or critical health outcomes.

The Program anticipates making 2 to 3 awards, based upon the merit of applications. Criteria for evaluation include scholarly merit of the proposed activities, innovation and application of the proposed research program to address important methodological issues in clinical and translational research, capabilities of the principal investigators, and potential for future extramural funding. All 80% or greater FTE faculty members based at UC, Cincinnati Children's or the Cincinnati VA Medical Center are eligible to apply. Applicants must be CCTST members (**join here free of charge**).

The request for applications (RFA) is **available here**. For more information, visit the **CCTST website**, email **Sandy Geideman** or call (513) 636-9776.

Trivia Corner

According to data published by CISCRP (the Center for Information and Study on Clinical Research Participation):

1) The industry has seen what drop in participant enrollment rates since 2000?

2) How much Is spent annually to try to remedy the problem of decreasing enrollment rates?

3) What percentage of study volunteers report having difficulty understanding the Informed consent form?

Answers

1) Twenty percent

2) One billion dollars

3) Thirty-three percent

Dates and Deadlines

NIH Grant Deadlines January 25, 2015 through April 13, 2015 (CYCLE I)

Activity Code	Program Description	SPO Due Date	CYCLE I Due Date
P Series *New, renewal, resubmission, revision*	**Program Project Grants and Center Grants**	January 19	January 25
G07, G08, G11, G12, G13, G20, R10, R24, S06, S11, S21, S22, SC1, SC2, SC3, UG1, U10, S06, U19, U2C, U41, U42, U45, U54, U56 *New, renewal, resubmission, revision*	**Other Activity Codes**	January 19	January 25
R18/U18 **R25** *New, renewal, resubmission, revision*	**Research Demonstration Education Projects**	January 19	January 25
C06/UC6 *New, renewal, resubmission, revision*	**Construction Grants**	January 19	January 25
T Series **D Series** *New, renewal, resubmission, revision*	***Institutional*** **National Research Service Awards** **Other Training Grants**	January 19	January 25
R01 *New*	**Research Grants**	January 29	February 5
U01 *New*	**Research Grants – Cooperative Agreements**	January 29	February 5
K Series *New*	**Research Career Development**	February 5	February 12
R03, R21, R33, R21/R33, R34, R36 *New*	**Other Research Grants**	February 9	February 16
R15 *New, renewal, resubmission, revision*	**Academic Research Enhancement Award (AREA)**	February 18	February 25
R01 *renewal, resubmission, revision*	**Research Grants**	February 26	March 5
U01 *renewal, resubmission, revision*	**Research Grants – Cooperative Agreements**	February 26	March 5
K Series *renewal, resubmission, revision*	**Research Career Development**	March 5	March 12
R03, R21, R33, R21/R33, R34, R36 *renewal, resubmission, revision*	**Other Research Grants**	March 9	March 16
R41, R42 **R43, R44, U43, U44** *New, renewal, resubmission, revision*	**Small Business Technology Transfer (STTR)** **Small Business Innovation Research (SBIR)**	March 30	April 5
F Series Fellowships *New, renewal, resubmission*	***Individual*** **National Research Service Awards (Standard)**	April 1	April 8
R13, U13 *New, renewal, resubmission, revision*	**Conference Grants and Conference Cooperative Agreements**	April 6	April 12
F31 Diversity Fellowships *New, renewal, resubmission*	***Individual*** **Predoctoral (F31) Fellowships to Promote Diversity in Health-Related Research**	April 6	April 13

*** Deadlines Falling on weekends or holidays move to the next business day*

CCHMC as Central IRB

An increasing number of studies are requesting CCHMC to act as the Central IRB. A checklist was created for what is needed and required for CCHMC to operate as the Central IRB on a protocol.

The following checklist was produced by Jeanie Bailey, Leslie Korbee, Rosie Miller, and Krystal Bradford. We hope that you find the information helpful.

ROLE CALL – ACRONYM DEFINITIONS:

	OCTR – Office for Clinical
	RAP – Reliance Agreement Protocol- also known as "UMBRELLA Protocol" this is the final protocol that includes all Performance Site's info
	DCC – Data Coordinating Center (can be CCC for Clinical or MCC for Medical)
	LPS – Local Performance Site- this is the current IRB approved protocol at CCHMC
	ICF – Informed Consent Form
	PSP – Protocol Signature Page
	DOR – Delegation of Responsibilities
	CV – Curriculum Vitae
	COI – Conflict of Interest
	HPA – Human Protections Analyst
	Master Reliance Agreement – Agreement previously established to allow CCHMC IRB to act as the IRB of Record for study

GETTING STARTED – PRIOR TO CONTACTING THE IRB:

	Review the information on IRB website regarding central IRB.
	Ensure that the research team has adequate expertise and resources to serve as the IRB of record
	Identify which institutions may be willing to rely on CCHMC as the IRB of record.
	For the institutions that will not agree to rely on CCHMC as the IRB of record, provide them with a regulatory packet of items needed to begin the trial/study including templates for 1572, ICF, Asse PSP, DOR, and requests for CV, licensure and COI etc. If CCHMC is managing the DCC portion of this protocol, confirm that these institutions will contribute data to the DCC for this protocol.
	For the institutions that will not rely on CCHMC as the IRB of record, confirm that the sites have the expertise to make regulatory filings to their own institution's IRB. If needed, offer remote training resources to support completion of regulatory packet.

CONTACTING THE IRB:

	Request a consultation with the IRB. This can be via phone or in person. Describe the design of the study; the participating institutions involved; the desire to request consideration to have CCHMC be IRB of Record.
	Initiation of the Reliance packet to the research team this packet may have an existing multi-study reliance agreement. If a reliance agreement is already in place with the institution, CCHMC would like to proceed under the established multi-study agreement. Review the documents to ascertain what is expected for completion.
	Lead research team will obtain appropriate IRB contacts and coordinate with the performance site team to complete the packet. This is important so that the packet can be vetted thru the other institutions necessary departments, i.e. Legal. The lead research team should track the time from receipt of packet at the site to submission to the institution's IRB and then receipt of approval memo. This metric will be important to the funder at the time of grant renewal.

(Continued next page)

CCHMC as Central IRB *(continued)*

CREATING PROTOCOLS IN EPAS:

	Typically there will be 3 different types of protocols included. Please include the acronym in the short title: 1) RAP – Reliance Agreement Protocol 2) DCC – Data Coordinating Center (can be CCC for Clinical or MCC for Medical) 3) LPS – Local Performance Site
	It is recommended to submit all 3 protocols at the same time. It is recommended to have RAP, DCC and LPS protocols open in separate browser windows as you upload documents to submit. This will be beneficial and support the creation of mirror submissions which will save time for the HPA review and reduce errors.
	Addressing the "Funding Information" – on the CCHMC page Question 4 – Needs to reference the other two or three protocols.
	For Funding Information – CCHMC page Question 5 – Needs to have a description of this protocol. (Helps with clarity as the study ages in the system.) RAP - This is the Reliance Agreement Protocol (also referred to as Umbrella Protocol) for the studies. CCHMC is the IRB of Record for the performance sites on this study. DCC / CCC - This is the Data Coordinating Center for the studies. Not all sites may be relying on CCHMC as the IRB of Record on this study. LPS - This is the Local Site for the performance site of the Umbrella Protocol. This typically will have a different PI.
	Study Management – Research Locations page RAP and DCC should choose this option: The PI listed on this application is the lead site on a multi-institutional protocol. Research data collected at the participating sites is submitted to and/or analyzed at CCHMC/UC, including situations where CCHMC/UC is functioning as a Data Coordinating Center. LPS should choose this option: N/A (i.e. the PI is only responsible for the research conducted at their institution).
	Study Management – Performance Sites page This will only appear for the RAP and DCC studies. The RAP should ONLY upload sites that have the Reliance Agreement Packet. The DCC should upload ALL sites. Including the CCHMC LPS. This study is the study that gathers all the data for analysis.
	General Research Plan page The RAP and LPS studies should mirror each other on the documents and how the study is conducted.
	Research Categories page All protocols should be the same here.
	All additional categories that appear will be the result of selections chosen. All the pages should mirror or complement the other studies. Example: The RAP and LPS may say that specimens/data are stored in a repository. The DCC protocol would be the repository that is managing the security of that data, and the choices could be separate.
	Plan Regarding Informed Consent, Assent, and Parental Permission and Recruitment of Participants page. These pages should again mirror or complement the other studies. Example: RAP will have consents for all the Reliance agreement sites. This will allow CCHMC IRB to control the content of the document and merge with approval. The Informed Consent documents will contain all information for both PI's and IRB's and reflect appropriate letterhead of institution. LPS will have only the consent document for this study. The content should match the content provided from the RAP protocol. DCC may only have a template document of the RAP consent or remain blank. Other sites will have their own IRB oversight and will not require a copy of their consent template.

Clincard Process Revisions

We are now a couple of months into the mandatory conversion to the use of the GreenPhire/Clincard system for processing payments to research participants. Over the last two months, the Office of Research Compliance and Regulatory Affairs has been monitoring the conversion process and working closing with the IRB to determine whether improvements in that process can be made in order to further streamline the conversion efforts.

You may recall that the original ORCRA guidance and FAQ that was previously released required revisions to consent forms, revisions to research protocols, revisions to the IRB application, re-consent of existing subjects and IRB review of Clincard-related subject education/information materials. After reviewing our experience over the previous month or so the IRB has determined that revisions to this process are in order. As such, effective Friday, December 12, 2014 the new process for converting existing/ongoing IRB approved studies to Clincard is as follows:

1. Currently active/previously consented research participants may be converted to the Clincard payment system at their next study-related visit, without any interaction/approval from the CCHMC IRB. These individuals should be provided a copy of the patient/subject information sheets that can be found on the Clincard CenterLink site.

2. If your research will be enrolling/consenting new research participants following the conversion to Clincard, a revised consent form should be submitted to and approved by the CCHMC IRB. This revised consent form should include language about the use of the Clincard as well as language regarding the use of the participants Social Security or TaxID Number.

Please note, in contrast to what was originally communicated, the IRB has decided to **no longer** require submission of any additional documents or protocol/IRB application revisions. The consent form revisions described in #2 above are only required in cases when new research participants will be enrolled/consented after the conversion to Clincard. Moving forward, the IRB has begun requiring that all new studies submitted to the IRB include use of the Clincard.

Please note that only the patient/subject information sheet, located on the Clincard CenterLink site may be used without IRB approval. If you wish to develop your own Clincard Information sheet, it must be submitted to and approved by the CCHMC IRB prior to its use. Also, please visit the Clincard CenterLink site for useful information around conversion to Clincard, training, FAQs, and other guidance.

Although the institution has gathered significant experience with use of the Clincard system through the pilot period and a soft launch, we understand that previously unanticipated challenges associated with the use of the Clincard system may arise. While we cannot promise solutions for all challenges, please forward those issues to ORCRA@cchmc.org as you encounter them. This will allow us to centrally collect those issues, assess their magnitude, and attempt to identify solutions.

Drum Roll and Congratulations!

Please join in congratulating Vicki Davis, Sponsored Programs Analyst on her pending retirement. She joined Cincinnati Children's Hospital in 1986 and has spent her entire career in the ResearchFoundation. As a member of the Sponsored Programs Office, she has been a regular contributor to this Research Forward newsletter as well as in the ORCRA-provided classroom training programs.

While she will be sorely missed, we wish her a long, happy, fun-filled retirement! We're all really jealous….

Join in wishing her well at her retirement celebration on Friday, December 12th from 2:00 p.m. to 4:00 p.m. in S1.203 or send her an email before December 19th.

Research Horizons magazine Zeroes in on Asthma

Investigators at Cincinnati Children's are making progress against asthma on several fronts.
Here are highlights of the Fall 2014 issue:

Asthma Attack
Cincinnati often makes the list of worst cities in the nation for asthma sufferers, particularly among African American, city-dwelling children. As asthma rates have risen, so has the rate of asthma research at Cincinnati Children's.

Small Steps, Big Difference
Small improvements, used consistently, pack a powerful wallop. Learn how Cincinnati Children's has reduced asthma-related emergency visits and hospitalizations among children covered by Medicaid.

Beyond the Bench
From diesel exhaust to substandard housing, scientists take to the streets to find answers to the asthma dilemma.

A New Design for Research
Remarkable insights happen when you talk to people.

Tracking Toxic Exposure
Backpack-sized sensor measures toxin levels.

Read the entire magazine

Send comments, story ideas or questions to:

Mina Busch
Office of Research Compliance and Regulatory Affairs

Cincinnati Children's
Hospital Medical Center
3333 Burnet Ave. MLC 7040
Cincinnati, OH 45229-3039
Mina.busch@cchmc.org
513-636-3342

Contributors

Editor – Mina Busch
Writer – Kacey Appel
Writer – Beth Bloomberg
Writer – Timothy Bonfield
Writer – Krystal Bradford
Writer – Jeremy Corsmo
Writer – Jim Flessa
Writer – Kris Justus
Writer – Julie Kramer
Writer – Mike Pistone
Writer – Mark Schuller

Cincinnati Children's