Research *Forward*

Cincinnati Children's

A Publication from CCRF Research Administration

EPIC Launch for the Schubert Research Clinic

As you may know, the Schubert Research Clinic is set to open September 8. This epic endeavor (pun intended) has sparked great collaboration among many groups throughout our institution. A great example is the new alliance between the following groups which has been formed in the process of creating functionality within EPIC for the new Shubert Research Clinic:

- IS EPIC team
- EPIC Research team
- Research Foundation (CCRF)
- Center for Clinical and Translational Research (CTRC)
- Office for Clinical and Translational Research (OCTR)
- Imaging Research Center (IRC)
- Cardiovascular Imaging Center Research Laboratory (CIRCL)

The new EPIC department, CCM T1 Clinic, has been designed to maximize the efficiency of research operations within the clinic for all users. Most notably, there will be expanded documentation functionality for patient encounters in the T1 Clinic. This means that providers will have access to their home division templates so that charting clinically relevant research information can be completed more efficiently. We will roll out this expanded template access with a few divisions at a time to ensure proper implementation. The first seven divisions to go live currently have the heaviest utilization of the CTRC in terms of number of studies:

- Allergy
- Endocrinology
- Gastroenterology
- Nephrology
- Neurology
- Pulmonary
- Rheumatology

Research study teams in these divisions have been notified of the changes. Research staff in other departments will be notified as their divisions get closer to going live. Updates and communications will be distributed through direct email, Centerlink, and CRP emails.

CTRC Metabolic Kitchen on T2

The Schubert Research Clinic intake process (the means by which a research study applies to use services) for new researchers/studies will go live when the clinic opens in September. In addition to completing the intake process, all clinic users are required to complete EPIC Research T1 Clinic Training (eLearnings), which are available through Blackboard. Information regarding T1 Clinic (Schubert Research Clinic) EPIC Functionality and Training is can be found on Centerlink at: http://centerlink.cchmc.org/content1/177622/.

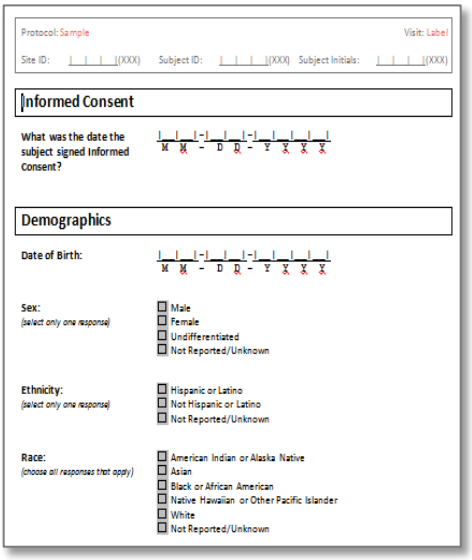
No visits should be scheduled until the intake process for the Schubert Research Clinic and trainings have been completed (see website for details). Scheduling, order entry, and documentation in the T1 Clinic is more robust than ever before for research in any division. The real time availability and scheduling of rooms and services is a great new

(*continued next page*)

IN THIS ISSUE:

Autumn 2015

Rapid Research: Using Templates to Make Your Studies More Efficient


Protocol: Sample Visit: Label

Site ID: |_|_|_|_|(XXX) Subject ID: |_|_|_|_|(XXX) Subject Initials: |_|_|_|_|(XXX)

Informed Consent

What was the date the subject signed Informed Consent? |_|_|-|_|_|-|_|_|_|_| M M - D D - Y X X X

Demographics

Date of Birth: |_|_|-|_|_|-|_|_|_|_| M M - D D - Y X X X

Sex: (select only one response)
- ☐ Male
- ☐ Female
- ☐ Undifferentiated
- ☐ Not Reported/Unknown

Ethnicity: (select only one response)
- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Not Reported/Unknown

Race: (choose all responses that apply)
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Not Reported/Unknown

Starting a new study is always a challenge. There are many decisions to make, and deadlines are often tight. While we all want to be able to work as fast and efficiently as possible, we also do not want to leave out or miss any important details.

In an effort to streamline the creation of case report forms (CRFs, also known as surveys ,measures, data collection forms, protocol forms, etc.), the Data Management Center has developed fourteen standard CRF templates. This development project included input from Clinical Data Managers, Data Specialists, Data Coordinators, Database Programmers, and Statisticians. The standard CRF templates were developed following Clinical Data Interchange Standards Consortium (CDISC) and National Institutes of Health (NIH) guidelines.

Utilization of these standard CRF templates can offer greater consistency across a division's studies, or even within a particular study that has multiple time points. Questions are asked the same way every time, which reduces the possibility of getting inconsistent results across study participants (or different study visits for the same participant). Question consistency also provides a common framework or context that the entire research study team can understand.

These standard CRF templates also promote improved CRF structure. A well-structured CRF can be easier to follow for the participant and the study staff. A well-structured CRF can also be completed faster. The uniformity encouraged by these templates can lead to reduced duplication of efforts and increased sharing of knowledge.

The Data Management Center's fourteen standard CRF templates can be used as-is for research projects. They may also be used as foundations for the creation of additional forms. Variables can be added as needed to meet the requirements of a study's protocol. At the very least, elements of the templates (e.g., font, header, etc.) can be used to create additional CRFs for which a standard has not been created.

The standard CRF Templates and related information (like completion guidelines) can be found on the Data Management Center's CenterLink pages at the following address:

http://centerlink.cchmc.org/content1/168107/

Also on those Data Management Center pages are tips for the creation of your own CRFs. Data Management Center employees have both academic and industry experience. On the "CRF Design Tips" page, they share both their collective professional wisdom and additional insights gleaned from CDISC and NIH guidelines.

If you have any questions, comments, or suggestions, please send them to the following e-mail address: dmc@cchmc.org

---

EPIC Launch *(continued)*

feature and the visit type selected will influence the rooms and services that are available.

The new functionality in EPIC for the T1 Clinic is remarkable- and like anything truly incredible, there is some complexity to it. We are here to support you through the new process so please look at the new job aides and tip sheets that have been developed for CCM T1 Clinic. They are located on the CenterLink EPIC Research page which can be accessed via the EPIC Quick Link on the Research Tab (or here http://centerlink.cchmc.org/content1/177613/). You can also email your research specific EPIC questions to the newly centralized epicresearch@cchmc.org . Additional information about the clinic and details on the intake process can be found on the Schubert Research Clinic website.

Contributors: Stephanie Hotze and Kacey Appel

Biomedical Informatics Grad Programs Off to Strong Start

In 2014, Cincinnati Children's joined forces with the University of Cincinnati (UC) to create a new, cross-institutional department of biomedical informatics with a goal to educate a wide spectrum of data-centric researchers and clinical staff throughout the combined campus. Plans recently took two major steps forward, with the graduation of the first student to earn a BMI certificate and the start of classes for our initial group of PhD students.

Heart Institute Fellow Earns First BMI Certificate

When Benjamin Landis, MD, came to Cincinnati Children's Hospital Medical Center in 2012 for a three-year pediatric cardiology fellowship, he knew he wanted to research the development and genetics of pediatric cardiovascular disease. He was able to accomplish this goal by earning the first graduate certificate in biomedical informatics from UC in May 2015.

Benjamin Landis, MD

"Working and studying at Cincinnati Children's gave me the opportunity to work with researchers who are doing the most advanced work," he says. "There is a real push for understanding the genetics of disease and incorporating genetic conditions in new ways in advancing care. This type of work will be widely valued in the future." (Read Ben's story here.)

Welcome to First PhD Students!

The start of the new school year brought the start of the new PhD program in biomedical informatics, which is being offered by Cincinnati Children's jointly with UC's colleges of medicine and engineering. Three Cincinnati Children's employees have stepped up to become the first PhD students in the new program:

Phillip Dexheimer earned a master's degree in computer science at the University of Central Florida. He initially developed training simulators for the U.S. Navy before moving into bioinformatics at Vanderbilt University. He joined the HudsonAlpha Institute for Biotechnology in northern Alabama in 2009 to work with next-generation sequencing technology, and then moved to Cincinnati Children's in 2011. His education continues at home, where his seven-year-old son can frequently be found lecturing on the finer points of Pokemon and Minecraft.

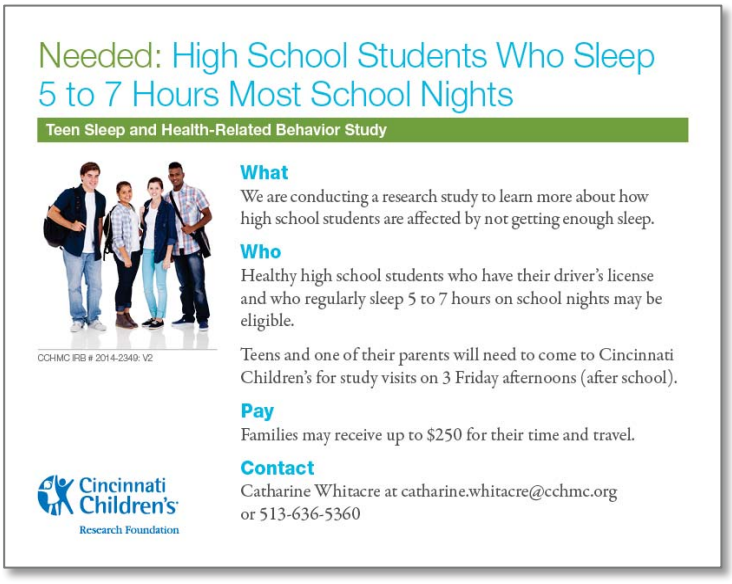
Todd Lingren has been an application developer in BMI for four years. He specializes in natural language processing and clinical informatics. He holds masters in linguistics and computational linguistics. Past projects include autism phenotyping for the national eMERGE consortium, adverse drug reaction detection in clinical oncology notes, and crowdsourcing gold standards for a named entity recognition system. He and his wife, a nurse practitioner in the Emergency Department, live in Anderson Township with their four children and two dogs. He's an avid motorcycle rider and runner, and recently completed the anchor leg of the Flying Pig Marathon relay with a BMI team.

Guillaume Labilloy graduated in France with a dual master's degree in electronic and computing engineering with a specialization in image analysis. He first worked in the development of electronic systems in the military industry, then for a tech company on the development of mobile services throughout Europe. Guillaume moved to the United States in 2011 to attend Carnegie Mellon University. After graduating in 2013 with an MS in business administration and software technologies, he developed bioinformatics applications for the University of Pittsburgh, then joined Cincinnati Children's in November 2014. Guillaume and his wife Anatalia, also at Children's as a resident in pediatrics and genetics, have a cat and like to cook and travel.

About the BMI Graduate Programs

Biomedical informatics encompasses the implementation and management of information technology used to improve the delivery of healthcare, as well as computational and analytical methods that advance biomedical research. The discipline emerged at the boundary between medicine, computer science and multidisciplinary research efforts spanning genomics, biostatistics, epidemiology, and related fields. Applications for both the graduate certificate and PhD programs are now being accepted for the 2016-17 academic year. For more information, visit med.uc.edu/bmi, call 513-636-6250, or email bmi-education@cchmc.org.

Now Enrolling



New IACUC Protocol in ePAS

On Monday, July 6, 2015 an entirely new IACUC ePAS application was launched that replaced the first application. This newly revised application was designed and built after over a year of collaboration and planning between the IACUC, the Office of Research Compliance and Regulatory Affairs, animal researchers, the Division of Veterinary Services, and the IS department. The revisions will make it much more user-friendly. You will notice a number of changes in the application that are intended to make protocol creation a much simpler and faster process. To help answer any questions regarding the new protocol application, a list of FAQs has been posted on CenterLink. You can access them by searching "IACUC" or by clicking here.

If you have any questions regarding the new application, IACUC processes, or protocol requirements, please contact Rachel Murray at Rachel.Murray2@cchmc.org or 803-4562. For questions regarding training or personnel additions please contact Julie Kramer at Julie.Kramer@cchmc.org or 636-2922.

We look forward to working with you to get your animal use protocol approved!

Paper and Electronic Certified Copies of Research Files - An overview

Sponsor requirements, space limitations, and study team preference can affect how research study documentation is maintained and stored. Fortunately, CCHMC has research standard operating procedures (SOPs) to assist you with these challenges.

SOP 41-1.9, which delineates the requirements for maintenance of source documentation, indicates "the original form of all source documents must be retained and accessible for source verification of all collected research data". Note that source documents may be maintained in paper or electronic format. If it's not feasible or possible to maintain all original source documents due to sponsor requirements (for example, if the sponsor requests the original documents be returned to them, etc.), the SOP goes on to detail the process that should be followed in order to create a certified copy of the original document. In short, a copy of the original may be made along with a notation listing the date the copy was generated, the initials of the person generating the copy, the actual location of the original record, and the reason why the original could not be included.

Alternatively, SOP 41-1.13 outlines the process for converting original paper research records to an electronic format. The creation of a certified electronic copy includes securing documented approval from the PI or his/her designee for the transition, scanning the original paper research record into a pdf, carefully verifying the scanned pages contain the same information and attributes as the paper copy, and then documenting the completion of the conversion process. The SOP includes additional detail regarding this process, along with a Documentation of Conversion Process template document that may be utilized by the study team. Additional information regarding electronic document storage can also be found on CenterLink at http://centerlink.cchmc.org/content1/163936/.

References:
CCHMC SOP for Research Involving Human Subjects 41-1.9 (Documentation Procedures)
CCHMC SOP for Research Involving Human Subjects 41-1.13 (Converting Paper Research Records to Electronic Format for Storage and Retention)

Contributors: Carla Hanekamp, Teresa Latham, and Renee Doughman

Trivia Corner

According to the CISCRP Perceptions & Insights Study conducted in the US in 2013:

88% believed that people who participate in clinical trials are making a contribution to science.

61% believe that those participating in clinical trials get access to the best doctors.

84% believe that those participating in clinical trials are able to learn more about their health and/or health condition.

62% believe that those participating in clinical trials get access to the best possible treatment.

23% believe that those participating in clinical trials are gambling with their own health.

CISCRP
THE CENTER FOR INFORMATION & STU
ON CLINICAL RESEARCH PARTICIPATIO

Eight Scientists Featured in Research Horizons

Innovation happens every day at Cincinnati Children's. These eight investigators are just a few of the many people bringing fresh perspectives and bold ideas to a wide range of stubborn research challenges. Read more about their work in the summer 2015 issue of *Research Horizons*.

Size Matters

Amy Sanghavi Shah, MD, MS, works closely with obese teens who have developed Type 2 diabetes and have begun showing signs of heart disease risk. In the laboratory, she works to find better ways to reduce those risks. In the process, she has learned that the relationship between heart disease and HDL is much more complicated than previously believed.

Corralling Natural Born Killers

Stephen Waggoner, PhD, leads a team of researchers using a $2.5-million Avant-Garde grant from the National Institutes of Health to find ways to stop natural killer cells (NK cells) from interfering with vaccines development for HIV, tuberculosis, hepatitis C and other diseases.

Much More Than a Hormone Problem

Andrew Dauber, MD, and Vivian Hwa, PhD, have gone far beyond hormonal factors to understand the causes of severe growth disorders. They have identified gene variants in DNA damage repair, cell cycle dynamics, growth plate signaling and other aspects of growth and development. Their findings suggest that severe growth disorders require a wider menu of treatments than most medical centers provide.

Muscular Discovery

Recently named Pew Scholar Doug Millay, PhD, has demonstrated that a gene dubbed "myomaker" is necessary for normal adult muscle cell regeneration. In mice, this gene also can be expressed on non-muscle cells, allowing these cells to fuse to skeletal muscle. These findings suggest a new target for treating a number of muscle-wasting conditions, ranging from Duchenne muscular dystrophy to cancer to the natural aging process.

Gut Reaction

Also recently named a Pew Scholar, Theresa Alenghat, VMD, PhD, studies how bacteria interact with mammalian cells in the intestine to impact immunity and trigger disease. New insights into how histone deacetylase 3 (HDAC3) regulates this process could lead to new ways to treat immune-mediated diseases, such as inflammatory bowel disease.

A Fuzzy Debate About A Foggy Condition

Is it a form of ADHD or its own condition? Stephen Becker, PhD, is advancing scientific understanding of sluggish cognitive tempo (SCT); a condition with attentional difficulties similar to ADHD, but marked by a quieter set of symptoms including daydreaming, foggy thinking and lethargy. As many as 2 million children in the U.S. may be affected.

Medicinal Motivation

Meghan McGrady, PhD, is using concepts developed to understand consumer spending to gain new insights into the moment-of-decision motivations that affect whether teens follow strict medication regimens. Her work could lead to a tool clinicians can use to prescribe treatment plans that patients will be more likely to follow.

Professional Development

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

- -

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

- -

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

- -

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

- -

CRP Appreciation Day
Wednesday, September 30, 1:00 – 3:00; Awards announced at 2pm. Sabin Aud.

- -

CRP Networking Lunch with the Experts
Wednesday, October 7; Noon – 1pm; S1.203

- -

Core Clinical Research Training
Tuesday, November 3 - Thursday, November 5th; 8:00am – 12:30pm

- -

Clinical Research Orientation
Monday, November 30 - Tuesday, December 1st; 8:00am – Noon

- -

Clinical Research Skills Training
Thursday, December 3; 8:00am – Noon

- -

CRP Newhire Luncheon
Thursday, December 3; 11:00 - Noon; D2.40

- -

Clinical Research Phlebotomy Training
Thursday, December 3; 12:30 – 5:00pm

- -

CRP Networking Lunch with the Experts
Friday, December 4; Noon – 1pm; S1.203

- -

EPIC Research Registration
Friday, December 11; 8:00am – 2:00pm

- -

Informed Consent Role Play
Friday, December 11th; 9:00am – 11:30

Progressive People – Stephen Waggoner, PhD

Still considered "junior" faculty, Steve Waggoner is getting it right. In an era faced with increasing work with viruses, bacteria, and toxins, Steve keeps his priority on SAFETY!

I met Steve at his office recently and we discussed his role on the Institutional Biosafety Committee (IBC). Though having joined the IBC over a year ago, he's only recently taken on the role of IBC Chair and other leadership responsibilities. Steve had an early start in his research career…at the age of 16 with an internship with the National Cancer Institute (NCI). He worked there in high school and then on and off through his college years at St. Mary's College of Maryland, where he was studying Chemistry and Biology. He built upon this research experience by obtaining his PhD in Microbiology from the University of Virginia in 2007 and then completing post-doctoral work at the University of Massachusetts Medical School until 2011, when he became faculty. He joined the CCHMC faculty in 2013 with an appointment as an Assistant Professor.

Throughout his career, Steve has had quite a bit of exposure to research with viruses, bacteria, parasites, and toxins: hence biosafety heavy work. He brings this expertise to his role as PI where he personally trains his team and all those with potential exposure to pathogens. He emphasized that it's not just those in the lab, but also other service providers who could come in contact with the materials (including outside labs/services, Environmental Services, and others who might come into the lab without prior training) that are at risk as well. He wants to make sure all have the right education (even at the moment via door signage) and are Safe!

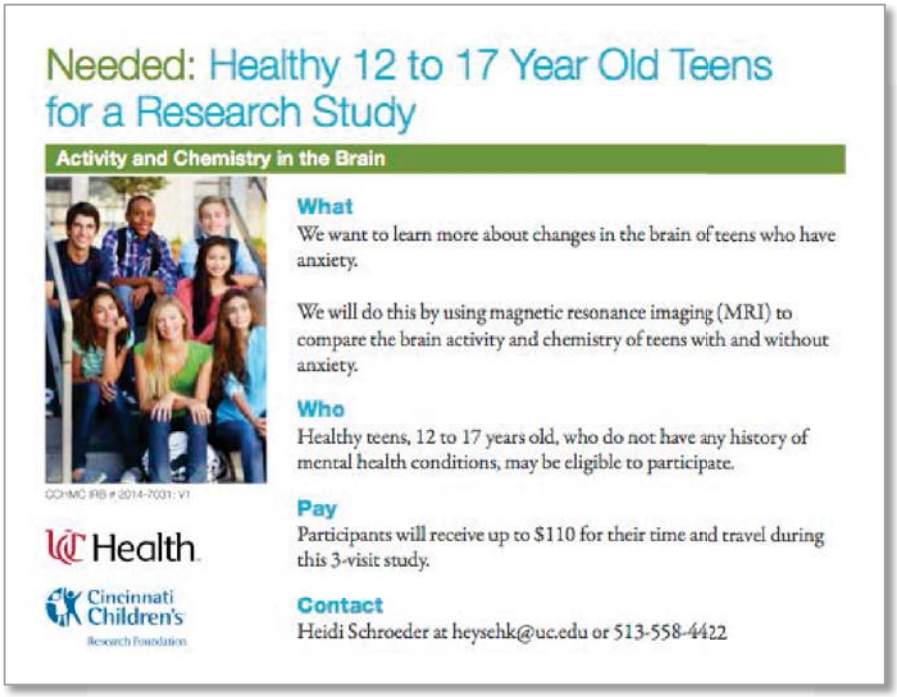
In his role as IBC Chair, he's in a unique position as a collaborative hub between researchers, being able to refer researchers to others well suited to partner with them. Or, connecting researchers to the resources they might need to more efficiently conduct their research. Through this networking role, he's helping shorten the learning curves among CCHMC researchers.

If this isn't enough reason to work with the IBC, he also mentioned all the regulatory requirements (federal and institutional). Any research involving human derived materials needs to go to the IBC so they can review it against NIH guidelines. Failure to follow NIH guidelines can risk the entire research program at CCHMC. And, don't forget…people could be put at risk too.

Steve moved to Cincinnati with his wife Lisa, Lab Manager in Allergy and Immunology. They have four children: daughters age 6 and 3 and twins (boy and girl) just born August 14th. For now, Steve is operating on little sleep and only surviving with lots of coffee.

Sleep deprivation aside, Steve's emphasis remains on safety and he brings this focus to the IBC. Effective operations with and by the IBC will help our researchers make discoveries both faster and more efficient, and without sacrificing safety.

Take a walk this fall and kick up some leaves!



Progressive People – Kathy Goodin

Kathy Goodin joined the Office of Research Compliance and Regulatory Affairs at the end of May as the Director of the Sponsored Programs Office. She comes to CCHMC with a wealth of research administration experience. Most recently, Kathy served as Director at the HudsonAlpha Institute for Biotechnology over their Sponsored Projects, Grants, Contracts, and Material Transfer Agreements. As a biotechnology company involved in genetics and genomics, they handled low volume / high dollar research. Prior to HudsonAlpha, Kathy spent time as the Associate Director of the Sponsored Programs Office at the University of Alabama in Huntsville and as a Grants Officer and Administrative Supervisor at the University of Alabama at Birmingham.

Understanding that researchers don't always know where to go with their questions, Kathy hopes to help delineate who (which department) does what so that researchers are better equipped and experience less frustration. She hopes ongoing communications (and potentially trainings) with the research community will be a good start. Improvements in ePAS are also expected to help.

Kathy likes to interact with researchers and wants the SPO office to help provide services to help them get proposals and such successfully submitted. She is open to new ideas and appreciates feedback. Her team is located on the second floor of Vernon Manor.

Kathy grew up in New Orleans before studying English at Mississippi State University. Kathy lives on a farm in Rising Sun, Indiana, with her husband, horse, chicks, cats, dogs, and goats. Her lifelong affinity with animals led to her first job in research around 1990, preparing a grant involving animal and human research. The growth from there is history!

CreFF Pilot Funding Available for Junior Faculty

The **CCTST** is now accepting applications from junior faculty for the next round of **Clinical Research Feasibility Fund (CReFF)** pilot grants. Instructors or assistant professors based at CCHMC, UC or the Cincinnati VAMC utilizing the resources of the **Clinical Translational Research Center** (CTRC) are generally eligible; funding restrictions apply. Fellows anticipating a faculty appointment during the grant period may also be eligible. Applicants must be CCTST members. **Join free of charge.**

Applicants must already have an active CTRC-approved protocol or submit one for review with their proposal. The CReFF provides one-year start-up funding of up to $20,000 for pilot studies. One grant is anticipated this cycle.

A letter of intent is not required. However, potential applicants are strongly advised to contact the program director**,** **Dr. Mark Mitsnefes**, prior to submitting an application, and to submit their protocol to the CTRC Scientific Advisory Committee (SAC) at least one month before the CReFF review meeting to facilitate resolving scientific or other issues. The approval process for the protocol must be completed before it can be considered for a CReFF award.

Applications (electronic and hard copies) must be submitted by 12 noon Monday, November 2, 2015.

- **Request for applications**
- **More information**
- Questions: email **Christy Keller** or call 513-803-1842

Rethink Research: Rebranding the Clinical Research Enterprise

Recruiting patients for clinical research studies is getting harder and harder every year, making medical progress harder and harder. Many people have a skeptical or negative attitude toward clinical research. Although the press often reports positive findings from clinical research, negative news stories tend to get the headlines, to say nothing of the portrayals of "villainous" clinical researchers and pharmaceutical companies in movies, television shows, books, etc.

The clinical research enterprise does very little to combat these negative stereotypes and open people's minds to clinical research. The Center for Information & Study on Clinical Research Participation (CISRCP) is dedicated to educating both patients and the public about clinical research participation, but its resources are limited.

If you ask the typical "man on the street" what he thinks of clinical research — if he knows anything about it at all — he is likely to express reservations about being a "guinea pig" in some sketchy corporate experiment.

Back in 1983, the milk industry recognized that it had a problem. Milk consumption was declining as the public consumed more exciting beverages. To fight back, the industry created the "Got Milk?" advertising campaign, a series of ads unified by the "Got Milk?" slogan. The rest is history.

At a conference earlier this year, Joe Kim challenged the clinical research industry to rebrand itself. Just as the milk industry rebranded milk as a hip beverage, can we rebrand clinical research in a way that deeply resonates with the public? Can we change the man on the street's answer to: "Funny you should ask. I've heard good things about clinical research. I really should find a study that's right for me."

The Rethink Research Competition

The first step in rebranding clinical research is to create a "Got Milk?" advertising concept for clinical research. To accomplish this objective, Rethink Research invited patient recruiting firms to contribute their ideas for a campaign concept to achieve the following objectives:

- Generate ideas for promoting participation in clinical research.
- Create materials that study sponsors, etc., can adapt.
- Generate awareness in the industry of the branding issue and create momentum for it.

Four leading patient recruitment firms accepted the challenge and have collectively submitted six entries:

Entry A. Clinical research for your future, and hers.

Entry B. Going study

Entry C. Heroes aren't hard to come by.

Entry D. Missing U

Entry E. Remedi THIS

Entry F. Side effects may include

The entries are at www.magiworld.org/rethink_long. They are a testament to the passion and creativity that characterizes the clinical research enterprise.

We are also asking clinical research professionals, such as yourself, and the general public to vote for the People's Choice Award. **Vote for your favorite concept at: http://www.magiworld.org/vote**. Voting closes September 30, 2015. A panel of judges will also assess the entries in various prize categories.

The winners will be announced at MAGI's Clinical Research Conference in San Diego, October 11-14, 2015.

The Rethink Research competition is just the first step in a long journey to open people's minds to clinical research. Without clinical research, without study participants, there would be no new medicines, no new medical devices, and no new diagnostics. That's not a world we can live in, literally.

Article by Norman M. Goldfarb. Reprinted with permission. Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at ngoldfarb@firstclinical.com.

Dates and Deadlines

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

Note new due date for R41, R42, R43, R44, U43 U44 effective September 5, 2015

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)**	August 31	September 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.

Changes in the NIH Biosketch and the SciENcv Tool

In May of this year the NIH changed the Biosketch format. These changes include:

- extending the page limit total from 4 to 5 pages
- description(s) of up to 5 significant contributions to science (section C)
- list of up to 4 publications can be included in:
  - personal statement section (section A)
  - contributions to science section (section C)
- optional URL link to My Bibliography via PubMed for a full list of peer-reviewed publications (section C)

Coinciding with these changes the NIH has released SciENcv (Science Experts Network Curriculum Vitae), a free tool to create and manage Biosketches. SciENcv can easily construct an NIH or NSF Biosketch in the approved NIH format and then tailored to a specific grant. Other features include:

- create, edit and save multiple versions of a Biosketch
- link publications listed in My Bibliography from the user's NCBI account
- link to a 3rd party account e.g. eraCommons (will pull information into SciENcv including education, work experience and award history) and ORCID iD account (a free way to claim your publications and add publications not found in PubMed-My Bibliography)
- add a delegate (gives another person permission to edit your My Bibliography and SciENcv profiles).
- download PDF, MS Word or XML format

To learn more about SciENcv:

- short video to see all of the special features of SciENcv: https://youtu.be/PRWy-3GXhtU
- full 33 minute webinar presented by the NIH: https://youtu.be/V3VquWmgcco
- sign up for the Pratt Library one hour webinar, **NIH Biosketch and SciENcv Tool**, on September 10, 2015 at 1pm. To sign up go the ELM and search activity code: ES_05302_20150910_1300_WR_WBNR
- check out our guide on SciENcv: http://libguides.cchmc.org/sciENcv

Risks for Healthy Volunteers

Many people believe that Phase I trials with healthy volunteers are very risky and even unethical due to the fact that so many of these appear to pose risks with no benefits. However, in a study led by researchers at the Perelman School of Medicine at the University of Pennsylvania, they found that less than 1 percent of over 10,000 healthy volunteers who participated in almost 400 Phase I trials for new (noncancer) drugs experienced serious complications. Other findings include:

- No volunteers died or suffered persistent disabilities linked to the experimental drugs.
- Only 0.31 % of healthy volunteers experienced serious adverse events.

While there is little systematic research quantifying the risks to healthy volunteers, this study, published in *The BMJ,* found the risks to be very low.

Now Enrolling

HAPPY FALL

Hot Off the Press: OHRP Announces Notice of Proposed Rulemaking

Following up on it's Advanced Notice of Proposed Rulemaking (ANPRM) in 2011, The U.S. Department of Health and Human Services (and fifteen other Federal Departments and Agencies) have moved to the second step of the three-step federal rule making process with the release of a Notice of Proposed Rule Making (NPRM) describing proposed revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as the Common Rule in 1991.

Some of the major changes being proposed that will better protect research subjects and help build public trust are the rules relating to informed consent. With regard to informed consent in general (such as consent to participating in clinical trials), the rules would be significantly tightened to make sure that the process becomes more meaningful.

- Consent forms would no longer be able to be unduly long documents, with the most important information often buried and hard to find.
- They would need to give appropriate details about the research that is most relevant to a person's decision to participate in the study, such as information a reasonable person would want to know, and present that information in a way that highlights the key information.

In addition, to assure that these rules do indeed change current practices, there will be a one-time posting requirement for the consent forms for clinical trials, so that anyone drafting a consent form will do so knowing that it will eventually be subject to public scrutiny.

Another big change is that informed consent would generally be required for secondary research with a biospecimen (for example, part of a blood sample that is left over after being drawn for clinical purposes), even if the investigator is not being given information that would enable him or her to identify whose biospecimen it is. Such consent would not need to be obtained for each specific research use of the biospecimen, but rather could be obtained using a "broad" consent form in which a person would give consent to future unspecified research uses.

The NPRM also attempts to strengthen the effectiveness and efficiency of the oversight system by making the level of review more proportional to the seriousness of the harm or danger to be avoided. Research that poses greater risk to subjects should receive more oversight and deliberation than less risky research. The NPRM seeks to avoid requirements that do not enhance protection and impose burden, which can decrease efficiency, waste resources, erode trust, and obscure the true ethical challenges that require careful deliberation and stakeholder input. Cumbersome and outdated regulatory standards overwhelm and distract institutions, IRBs, and investigators in ways that stymie efforts to appropriately address the real risks and benefits of research.

The following list encompasses the most significant changes to the Common Rule proposed in the NPRM:

1) Improve informed consent by increasing transparency and by imposing stricter new requirements regarding the information that must be given to prospective subjects, and the manner in which it is given to them.

2) Generally require informed consent for the use of stored biospecimens in secondary research.

3) Exclude from coverage under the Common Rule certain categories of activities that should be deemed not to be research, are inherently low risk, or where protections similar to those usually provided by IRB review are separately mandated.

4) Add additional categories of exempt research to accommodate changes in the scientific landscape and to better calibrate the level of review to the level of risk involved in the research.

5) Change the conditions and requirements for waiver or alteration of consent such that waivers occur only rarely.

6) Mandate that U.S. institutions engaged in cooperative research rely on a single IRB for that portion of the research that takes place within the United States, with certain exceptions.

7) Eliminate continuing review requirement for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing data or involve only observational follow-up.

8) Extend the scope of the policy to cover all clinical trials, regardless of funding source, conducted at a U.S. institution that receives federal funding for non-exempt human subjects research.

In summary, the proposed modifications are designed to continue to uphold the ethical principles upon which the Common Rule is based, as applied to the current social, cultural, and technological environment. OHRP will be accepting comments for the next 90 days. Please contact the ORCRA office if you have questions or comments to share. Click HERE to access the full NPRM.

CTSA Funding of CCTST Continues

An NIH Clinical and Translational Science Award (CTSA) of $16.7 million over 4 years will support new and ongoing efforts of the Center for Clinical and Translational Science and Training (CCTST) to translate discoveries into clinical practice. The CCTST initially received CTSA funding in 2009.

With CTSA and institutional support, the CCTST will continue to provide access to research methodology and informatics assistance, education programs, and pilot grant opportunities, while leading initiatives to improve the research environment across and beyond the Academic Health Center (AHC) and community including:

- Transformation of the successful Research Central online service portal into a comprehensive Research Commons platform, with more sophisticated tracking and analytic capabilities
- Creation of the Center for Improvement Science, a home for patient-centered outcomes research and interprofessional training with an emphasis on Team Science
- Consolidation of all AHC clinical trials activities under a single umbrella, the Cincinnati HEalth Research Office (Cinci-HERO), which will lead recruitment efforts to increase participation by underserved populations
- Expansion of the successful Community Leaders Institute and research mentorship training programs

The CCTST is directed by James Heubi, MD, professor of pediatrics and associate dean for clinical and translational research. The UC AHC is one of more than 60 sites that receive CTSA funding from the National Center for Advancing Translational Sciences (NCATS). For more information on this award, see the UC news release or visit the CCTST website.

CCTST Offices Move to S2.500

Administrative offices of the Center for Clinical and Translational Science and Training (CCTST) moved from Location S10.300 to S2.500 on August 18. The CCTST has been headquartered in the "S Building" since it opened in 2008, serving the entire Academic Health Center, UC campus and community partners.

The new suite on the 2nd floor provides easier access for researchers and staff. All staff phone numbers remain the same. For more information, visit the CCTST website, email cctst@ucmail.uc.edu or call (513) 803-2612.

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 – Justin Bates
Writer – Timothy Bonfield
Writer – Renee Doughman
Writer – Jim Flessa
Writer – Norman Goldfarb
Writer – Carla Hanekamp
Writer – Stephanie Hotze
Writer – Alison Kissling
Writer – Teresa Latham
Writer – Rachel Murray
Writer – Mark Schuller
Writer – Jill Williams

Cincinnati Children's