Coming Soon: New Automated System for Study Fund Payments

The Medical Center has recently signed a contract with Greenphire Inc. to provide an automated solution for payment of study funds called ClinCard®. This system provides research participants with reloadable debit cards as a replacement for payments by cash or check. The debit cards utilize the MasterCard payment system and are accepted at virtually every institution that accepts a credit card. Participants will also be able to withdraw funds at banking institutions and are not required to have a bank account, although institutional processing/ATM fees may be charged.

The Greenphire system gives the Medical Center reporting capabilities to track payments by individual study. Reports will also be available to summarize payments across departments by study participant to aid in annual IRS Form 1099 reporting. The Greenphire system will also provide the Medical Center with improved internal controls by providing a secondary level of management approval.

The Greenphire system has been undergoing a proof of concept trial in the Infectious Diseases Clinical Research Program since January, 2012. Michelle Dickey, Manager of the Infectious Diseases Clinical Research Program, stated that her division has found the system to be very user-friendly and experienced few issues transitioning from their old process to the new Greenphire system. Infectious Diseases also reported no significant negative feedback from participants in their ability to access funds via the ClinCard debit cards.

Currently, the Greenphire system is beginning a larger scale pilot roll out with 3-4 divisions. The goal during this period will be to identify solutions to any unanticipated issues, develop clear implementation guidelines and to engage key faculty stakeholders in preparation for a broader rollout later in 2013. This rollout will include a requirement that within the next 12-18 months, all new studies will utilize the Greenphire system for research participant payments. The Medical Center’s Accounting Department is committed to ensuring that the costs associated with administering this new system will not be an impediment to implementing this new system. Studies initiated prior to the deadline will only be transitioned on a case-by-case basis based on the status of the research and the preference of the PI.

Three training Webinars will be scheduled at periodic intervals. The implementation team also plans to record one of the sessions and place it on the ELM system.

Questions on the Greenphire system can be directed to Mike Bauer, Marie Hafertepen or Michelle Dickey.
On Monday, October 29th, the Cincinnati Children’s Research Foundation (CCRF) kicked off its first-ever Shared Facilities and Cores Day event. These Shared Facilities and Cores are open to all members of the CCHMC research community (as well as UC College of Medicine) in support of basic, translational, clinical and outcomes research.

This event was held to create greater awareness of the availability of these Shared Facilities and Enabling Cores as well as initiate some of the interactions necessary for successful collaboration. Michael Barnes, Ph.D., Director of the Cincinnati Biobank and Assistant Professor of Rheumatology commented:

*The Shared Facilities/Cores Day event was a great time to showcase what the Cincinnati Biobank offers and see the many other cores that operate in the institution. During the event, I met with several investigators who expressed interest in working with us on projects, making it clear that biobanking is vital to further improving research at CCHMC. An opportunity to increase our exposure like this has great impact to expand collaborations.*

Over 20 Shared Facilities and Cores were represented at the event. Each had a poster or supporting information identifying specific services provided and contact information. The booths spanned from very basic sciences (such as DNA sequencing) through to the very applied (such as clinical trials support).

Over 300 people attended this kick-off event, which is great attendance for a first-time event. We hope it will grow even larger in the future.

Some of the Shared Facilities and Cores got into the spirit of showing what they do by bringing treats to share including mice (chocolate covered grapes) and slides (frosted graham crackers).

Attendees entered to win certificates of up to $250 to use in a Shared Facility of their choice. Those winners were: Kasper Hoebe, PhD; Mindy Applegate; Kayla Kinker; and Joe Sherrill, PhD. The coveted First-Place ribbon for outstanding Shared Facility poster was awarded to Matt Kofron, PhD, of the Confocal Imaging Core.

Chris Wylie, PhD, William Schubert Chair & Director of the Division of Developmental Biology, said that this is an excellent way to get information out to researchers about what cores exist on campus. “Any opportunity for investigators to get together and discuss their research is good. But to provide a forum for everyone to discuss their research technologies with experts in all the major technologies we offer, in the same room, was outstanding. The posters were excellent, and the enthusiasm and expertise of all the core service representatives made this quite an occasion.”

Kristine Justus, PhD, VP for Research Operations and Management, spear-headed the event as a way to acquaint investigators with our Shared Facilities and to generate some buzz around the notable expertise and technological support for research here at Cincinnati Children’s. “It’s exciting to see everyone come together with such enthusiasm around the Research Foundation’s Shared Facilities. This first event was a huge success; numerous attendees commented that they were not aware we have so many Shared Facilities and that they left the event with ideas on how to use these to further their research. You can’t hope for a more suitable outcome.”

Plans for next year’s event are already underway.
Progressive People: Armand Antommaria

Cincinnati Children’s recently filled the long-awaited position for a Director of the Ethics Center... Welcome Dr. Armand Antommaria! Dr. Antommaria has dual reporting requirements to Bill Kent, Senior VP in Infrastructure and Operations, and Dr. Arnold Strauss, Chairman of Pediatrics and Director of the Cincinnati Children’s Research Foundation. The Center’s offices are on the fourth floor of the Kasota Building adjacent to Pastoral Care.

The Center will provide service and education and produce scholarship related to clinical, research, and organizational ethics. Key research ethics questions include what are the boundaries between clinical care, research, and quality improvement and what incidental finding are researchers obligated to return to participants.

Dr. Antommaria has spent much of his initial time at Cincinnati Children’s meeting with faculty and staff to learn more about the organization’s needs related to ethics. In regard to research, he has meet with leaders of the CCTST and the IRB as well as individual scientists. He has already become involved in the eMERGE Network and the planning for the upcoming empirical bioethics conference. He hopes the Center can develop a strong relationship with the CCTST and IRB.

Dr. Antommaria’s experience is primarily in clinical ethics. His clinical practice is in Hospital Medicine and he has chaired Ethics Committees and Ethics Consultation Services. The Center is seeking additional faculty and hopes to recruit an individual with expertise in the ethical, legal and social implications of genetic and genomic research.

Dr. Antommaria’s own research uses both normative and empirical methods. It has focused on ethical issues he has encountered in his clinical and administrative roles. They include organ donation after circulatory death (DCD) and the allocation of ventilators during a pandemic. In addition to publishing in the bioethics literature, Dr. Antommaria has published in medical journals including the Journal of the American Medical Association and Pediatric Critical Care Medicine.

Dr. Antommaria received his MD from Washington University School of Medicine and his PhD in Religious Ethics from the University of Chicago Divinity School. He grew up in Pittsburg and has lived in Indiana, Missouri, and Illinois before moving to Salt Lake City for residency and his initial faculty appointment. His wife and daughter are staying in SLC while his daughter finishes her senior year of high school and then his wife will join him in Cincinnati.

Professional Development

Barnett Webinar: Case Report Form Design, Strategy & Standards
Thursday, December 13th, 12:30 – 2:30pm;
Hosted by the Data Management Center;
CEUs available to first twenty requesting;
ELM Registration; Location: MERC 1103

RAPS Webinar: INDs + IDEs Creating, Checking and Fixing PDF Files (No CEUs available)
Monday, January 7th, 12:00 – 1:00pm;
Hosted by the CCTST at UC - MSB E351

Core Clinical Research Training (CCRT)
Tuesday, January 29th - Thursday, January 31st;
8:00am – Noon; Up to 10.5 hours CME credit;
ELM Registration

RAPS Webinar: INDs eCTD Compilation and Validation (No CEUs available)
Monday, February 4th, 12:00 – 1:00pm;
Hosted by the CCTST at UC - MSB E351

Clinical Research Orientation
Monday, February 11th - Tuesday, February 12th;
8:00am – Noon; ELM Registration

ePAS – IRB Submissions
Wednesday, February 13th; 8:00am – Noon; ELM Registration

Clinical Research Skills Training
Thursday, February 14th; 8:00am – Noon; ELM Registration

Clinical Research Phlebotomy Training
Thursday, February 14th; 1:00pm – 3:00pm; ELM Registration

EPIC Research Registration
Friday, February 15th; 8:00am – 2:00pm; ELM Registration

Save the Date...
2013 OCTR Annual Research Symposium
Monday, April 29, 2013

IRB Inquiry: Request to Close -- A Step-by-Step Guide

All studies at CCHMC must complete a closure report to the IRB upon completion of the research study. Some researchers in the past have allowed their studies to expire thinking this will close the study. This is a form of non-compliance that conflicts with our research policies and AAHRPP accreditation.

All study closures are a form of the continuing review process. Below is a step-thru of the pages for the closure report. Some questions have additional information to clarify their intent.

To obtain the closure report:

**Step 1:** Enter the study via ePAS – at the main study page select the “Create new continuing review” button located under the list of MY ACTIVITIES on the left side of the screen/page.

**Step 2:** General Information (first page of the request form)
- Review the contents.

**Step 3:** Conflict of Interest
- Enter the required responses and review for accuracy.

**Step 4:** Status of the Research
- Select “Request to Close”.

**Step 5:** Assurances
- Enter the required responses and provide any additional information the reviewer may require.
  - De-identification can happen in many forms:
    - Researcher destroys the key that links any identifiable data to the participant.
    - Researcher gives the linking key to a 3rd party that will not release the key to the researcher unless provided with documentation that the study has a current IRB approval.
  - Note: If your data is completely de-identified, then it is no longer human research and you can continue to analyze the data. When data is identifiable, you cannot continue analysis without current IRB approval.

**Step 6:** Research Category
- Review the information and respond to the question.
- Note the importance of the FDA question and that files are being stored properly.

**Step 7:** Enrollment
- Complete the enrollment table (even for chart reviews you would enter the actual number of charts reviewed); refer to the enrollment guidance for completing the table.
  - This information is needed even on a closure. The closure request shows activity since the last continuing review, which could have included additional enrollment/completion/withdrawals of the participants.

**Step 8:** Compensation for Injury and Audits
- Respond to the questions adding any information that may be required by the reviewer.

**Step 9:** Reportable Events (*this page will reveal reportable events submitted since the last continuing review*)
- Respond to the question.

**Step 10:** Deviations
- Respond to the question.

**Step 11:** Publications (*any documents created as a result of this study such as articles, posters, presentations, manuscripts, etc. They do not have to be published.*)
  - Upload the requested document(s).
  - If none, please provide an explanation in the text box.

**Step 12:** Project Summary to Date
- Respond to all questions with as much information as possible.
- Upload any additional documentation for review.

**Step 13:** Next Steps
- Review the instructions for completion.
- Select finish, you will return to the main study page.

**Step 14:** Main Study Page
- Select the Submit Continuing Review button (under the list of MY ACTIVITIES on the left side of the screen).
- You must submit the continuing review and click OK to send the report to the IRB. Failure to complete this step will leave the CR status in pre-submission and it will not appear in the IRB office inbox for processing.

*(continued next page)*
PCAST's Report on Innovation in Drug Discovery and Development

The President’s Council of Advisors on Science and Technology (PCAST) advises that the United States should set a goal of doubling the output of innovative new medicines that meet critical public health needs over the next 10 to 15 years, while continuing to increase drug safety. The council recommends a number of actions involving industry, academia, and the Federal Government.

While basic biomedical sciences have seen stunning progress in past decades, challenges remain in translating those advances into practical solutions. To support innovation and accelerate the development of new therapies, PCAST’s report makes a number of detailed recommendations aimed at:

- Bolstering the discovery and development of new therapeutic compounds
- Optimizing processes used by the FDA to evaluate the safety and efficacy of candidate drugs
- Enhancing long-term monitoring of approved medicines and
- Enhancing public understanding about the benefits and risks of medicines.

All three major components of the drug development ecosystem—basic biomedical research in universities and research institutes, clinical research in hospitals, and drug discovery and development in the biopharmaceutical industry—are facing growing challenges as the time, complexity, and cost of developing drugs have gone up. The rate of new-drug applications submitted by industry to the FDA, as well as new drug approvals, has remained relatively constant for 20 years. However, the FDA approved 35 new medicines in the past year—among the highest totals in the past decade, which is encouraging.

PCAST concludes there are two critical needs related to drug discovery and development that must be addressed to advance innovation:

1. Scientists need better methodologies and tools for translating basic biological insights into validated therapeutic targets and leads—a gap in the drug discovery and development pipeline that academic scientists often view as “too applied” and pharmaceutical companies often see as “too basic” to justify private investment.
2. Pharmaceutical developers and regulators need to incorporate new efficiencies into clinical trials of candidate medicines—complex and costly human studies that today constitute fully 40 percent of the biopharmaceutical industry’s R&D budget.

The whole PCAST report can be viewed at www.WhiteHouse.gov/ostp/pcast.

IRB: Request to Close (cont.)

Should you need to access the data again:
- Access the Continuing Review form. (same as step 1).
- Complete all the questions.
  - There is not a re-activation option. You will need to state if the study is open to enrollment, closed, or data only (chart/specimen) study.
  - It is important to note WHY you need to re-open the protocol (i.e. Sponsor request, Manuscript publication required additional analysis that required the use of the key, etc.)
- Submit to the IRB. (same as step 14...if you do not hit submit, then it will not come to the IRB for processing.)
- Once you have obtained re-activation, you can continue with your plans. If a third party was holding the key, provide them with the approval letter noting that the study was re-activated.

*   *   *
Note: ORCRA and the IRB office will be closed December 24-25, and January 1.

Healthy Adults 18 to 65 Needed for Brain Development Research

What
The purpose of this research study is to improve EEG techniques and examine how the brain responds to sensory stimuli such as sounds or pictures.

An EEG is a test that measures and records the electrical activity of the brain (or “brainwave”).

Who
Healthy adults 18 to 65 years old with no history of mental illness or head trauma may be eligible to participate.

Pay
Participants will receive $20 for their time and travel.

Details
For more information, contact Sarah von Thomsen at sarah.von_thomsen@cchmc.org or 513-803-3252.
Human Subjects Research Study Registration at ClinicalTrials.gov

Why register the study - Two main reasons:

1) **It’s The Law**: Most prospective clinical trials involving regulated drugs, biological products and devices must be registered on ClinicalTrials.gov or in a publicly available, searchable system.

2) **You Want To Publish**: The Sponsor and/or PI wishes to assure publication rights in certain medical journals.

Who registers a study

Responsible Party - The law defines “Responsible Party” as the sponsor of an applicable clinical trial. The law also allows the role of Responsible Party to be assigned to the Principal Investigator, if the PI is conducting the trial and has sufficient data rights in accordance with the law. For Investigator-Initiated, Institution OR PI can be designated as “Responsible Party.”

Where to go for assistance

The CCHMC Clinical Trials Office: Go to CenterLink, click on the CTO Home page, choose [Helpful Guides to ClinicalTrials.gov](https://clinicaltrials.gov). Next choose, [ClinicalTrials.gov Registering Fact Sheet](https://clinicaltrials.gov) provides a link to a job aid for the initial registration of a study.

Using Patient Databases to Revolutionize Research

There is much potential for research using electronic medical records. In a recent study by Explorys, a Cleveland Clinic spinoff company, they were able to replicate in three months the results of a study that had been completed in Norway taking 14 years! And, they analyzed 40 times more data and completed the research at a fraction of the cost.

Explorys has been collecting data onto a single platform since 2009 and has standardized the records in such a manner that they can be used for both patient care and research. By conducting research using a large electronic medical record database (e.g. EPIC), there is the clear advantage that through traditional clinical care, hospital staff have already completed much of the time-consuming data entry as part of routine care.

The potential to make discoveries is vast! Using an honest broker (e.g. i2B2), researchers can access millions of de-identified patient records very quickly. And, since the data is de-identified, the research would not be classified as Human Subjects Research so IRB approval would not be necessary.

Keith Marsolo, PhD, Director, Software Development and Data Warehouse and Assistant Professor, Bioinformatics, commented that “They managed to replicate the results of the clinical trial using de-identified, aggregate queries. Our i2b2 workbench provides similar functionality, so we have the infrastructure in place to perform this kind of study, though it would take a couple of weeks to prepare the data to replicate this specific one. Not all clinical trial results can be validated through aggregate queries, but those that can are able to take advantage of these tools. Investigators at Cincinnati Children’s have had similar success in validating clinical trials using multi-center research registries that are populated from electronic health record data, which is a different, but related approach.”

Trivia Corner

You can see colorful fall leaves from outer space.

Snow leopards cannot roar.

If your body continued to grow at the rate of an average baby, you would weigh over 400,000 pounds by the age of 10.

Male bees don't sting.

What do you get when you breed a bison with a cow? ...A Beefalo!

In addition to eight legs, most spiders have eight eyes.

Two-thirds of your brain's weight is from water.

The US produces over 1.8 billion candy canes.

Eggnog ice cream is one of Graeter’s holiday flavors, available only in December.
Use of Text Messaging in Research

With the use of cell phones, iPads, etc., the methods for communicating with research subjects and potential research subjects is changing. It is much easier to send someone a text message from your cell phone regarding a study update, than to call them. Today’s pediatric generation would prefer to “text” someone than actually talk to them on the phone. So, what is the appropriate use of text messaging in research?

CCHMC policy is currently silent on the use of text messaging in research and for subject communication. Knowing this, it is imperative that you discuss how text messaging might be used within your protocol that is reviewed and approved by the IRB. Communication, via text messaging, to research subjects is viewed in the same way as recruitment and other study materials given to study participants. Please remember, these template messages must be reviewed and approved by the IRB, prior to use.

Some studies have text messaging as a focus of the research and may utilize a third party web-based service that will send text messages to the participants as approved and agreed upon in your contract with the service provider and with the IRB. This is usually the cleanest method for the use of text messaging, as this provides an audit trail on what messages are sent to whom and what messages are received and from whom.

Other studies utilize a “study” cell phone to send and receive text messages to/from research subjects. This is another great option because this “study” cell phone is never used for personal reasons, can be audited, usage tracked, and paid for out of study funds.

Lastly, some studies do not officially use text messaging as a part of the research, but study staff are communicating with participants via text messaging and often utilizing their personal cell phone for this purpose. Here are the concerns with this method:

1. There are privacy issues with utilizing a personal cell phone for work purposes, as if an issue arises, this cell phone may require auditing.
2. There is no way to confirm whether you are acting in your role as a CCHMC employee or as an individual when communicating with your personal cell phone or other personal electronic device.
3. It is difficult to reimburse for usage (minutes, text message fees, etc) on a personal cell phone. Separating out personal and work usage is cumbersome.

For these reasons, it is recommended that if you are going to use text messaging on a consistent basis which may include private identifiers, private health information, etc., a “study” cell phone is secured and/or you utilize a web-based service like. This may be accomplished by contacting telecommunications at 636-4591. This will also ensure that appropriate password protections and any required encryption settings have been applied to the cell phone or other portable device.

Note: You may also want to consider a “confirmatory code”. Use of such a code will enable you to confirm the proper recipient is on the receiving end of a text message.

Now Enrolling

Children with ADHD Needed for Attention Training

What
This is a research study to look at the effectiveness of a variety of attention-training interventions, in treating children with ADHD.

Who
Children 7-12 years old may participate who:
– Have been diagnosed with ADHD or
– Have ADHD symptoms including: short attention span for age, difficulty listening to others, easily distracted, excessiveudgeting and/or talking, or often interrupting others

Pay
Families will receive up to $60 and the ADHD intervention free of charge.

Details
Contact the study coordinator at cradhd@cchmc.org or 513-803-1506.
### ELECTRONIC SUBMISSIONS USING THE SF424 APPLICATION FORMS

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### PAPER Submissions Using the PHS 398 APPLICATION FORMS

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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
CCTST Community Health Grant
Applications Due January 18

The Center for Clinical and Translational Science and Training (CCTST) Community Engagement Core requests Community Health Program Grant proposals from academic-community partnerships that focus on health promotion activities for children and/or adults in community settings such as clinics, schools, etc. Two categories of grants are offered, one in which the academic partner is principal investigator, the other in which the community partner leads, both focused on facilitating innovation in research, evidence-based practice or quality improvement. At least $20,000 will be awarded in each category, which may be split among several awardees, based on the merit of applications.

Applications that address childhood asthma, pediatric obesity, pediatric injury, infant mortality, diabetes, adult neuroscience, and minority health are most aligned with CCTST strategic priority areas. CCTST membership (free of charge) is required to apply. Applications are due Friday, January 18, 2013. For more information, please contact Teresa Smith.

Pharmacology Graduate Courses Start in January

The Molecular, Cellular and Biochemical Pharmacology Graduate Program of the UC College of Medicine will offer two courses of potential interest to clinical and translational investigators beginning the second week of January. The courses, “Pre-Clinical Drug Toxicology Studies” and “Emerging Concepts in Targeting Common Metabolic Disorders” each offer two credit hours and meet weekly from 3-5 PM in the CARE-Crawley Building through April.

Those interested may enroll for the courses or choose to attend individual lectures, featuring UC and CCHMC faculty as well as industry representatives. For schedules of topics and speakers and additional details, follow the links above. For more information, contact program director M. Abdul Matlib, PhD.
Congrats & Kudos: Bob Frenck

Earlier this year, Bob Frenck, MD, Professor of Pediatrics in the Infectious Diseases department and chair of the CCHMC IRB was nominated and selected for inclusion on one of the SACHRP (Secretary’s Advisory Committee on Human Research Protections) subcommittees. Bob is among nine representatives on the subcommittee tasked with researching and making recommendations pertaining to general Human Subjects Protections (as per 45 CFR 46, Subpart A). Since much has changed in research since when these regulations were written, one of the big focuses of this group is to assess whether what the regulations are requiring still makes sense and is relevant today.

The subcommittee can get questions from the full SACHRP committee when they want something researched. The Subpart A subcommittee reports their results and recommendations to the SACHRP committee which then makes recommendations to the Secretary of Health and Human Services (Kathleen Sebelius, MPA), the Assistant Secretary for Health (Howard Koh, MD, MPH), and to the Director of OHRP (Jerry Menikoff, MD, JD) for their consideration. Some of their recommendations have centered on Informed Consent and IRB review requirements.

GCP Do's and Don'ts

The September issue of The Monitor shared some important information about common violations of Good Clinical Practices. The top five such violations include:

- Not following the protocol (and/or failing to report any such deviations/violations to the IRB)
- Collection and reporting of adverse events
- Incomplete clinical records such that an audit trail is impossible
- Problems with Consent: obtaining and documenting valid consent that ensures understanding
- Investigational product accountability

The article also mentioned some best practices which include always reading the protocol thoroughly as well as all SOPs and the Investigator Brochure (if applicable). Make sure all documentation follows the ALCOA standards (Accurate, Legible, Contemporaneous, Original, and Attributable). Make sure the study team is properly trained and that analysis is double-checked. Data should be recorded at the first opportunity and all entries should be signed and dated at that time (and in blue/black ink).