What’s New?

Welcome Back Dr. Iain Sanderson
Duke Chief Research and Academic Information Officer (CRAIO) Dr. Iain Sanderson holds a faculty appointment in Anesthesiology and is responsible for the Information Technology infrastructure for research and biomedical informatics for Duke Medicine. In this role he will initiate a coordinated transformation of our research IT environment, with emphasis on the transition to a service model and working with DOCR to create a cohesive framework for the underlying systems for clinical research administration. Other responsibilities include the configuration of Maestro Care for the research mission, providing a vision for clinical research IT, and working with DHTS to provide IT support for the School of Medicine. Welcome, Dr. Sanderson!

Assistant Director of Education and Communication Selected
Terry Ainsworth, RN, ACNP has accepted the Assistant Director of Education and Communication position with DOCR. Education and training are an important component of DOCR as the office rolls out a new overview course required for researchers working with human subjects, tailored education modules on clinical research process at Duke, and ensuring that the annual qualifying assessment requirement is met by all clinical researchers. Terry is currently the Research Practice Manager in the Department of Surgery. DOCR will work closely with Terry and the Department of Surgery on ensuring a smooth transition during the next two months. Terry will assume her new role effective November 1, 2012.

More New Faces in DOCR to Support Clinical Research
Lindsey Long Spangler, JD has joined DOCR as a contract liaison. Lindsey will be responsible for facilitating contract throughput across offices including DOCR, OCRC, ORA, IRB and the Clinical Research Units (CRUs). She also will interface with these offices and DOCR on streamlining processes and assisting with communicating “how-to” information to clinical researchers at Duke.

Sal Munguia has joined the DOCR IT staff as a Sr. IT Analyst. Sal will be responsible for application and server administration of information systems for clinical research and assume primary responsibility for support of REDCap.
**OCRC Relocation**
The Office of Corporate Research Collaborations (OCRC) is relocating its offices to the 9th floor of the Erwin Square Building. Effective September 4th, OCRC’s physical address be 2200 West Main Street, Suite 910B (not Suite 700). The mailbox number and all telephone numbers will remain the same.

**New Privacy Article**
The DUHS Compliance Office has posted a new privacy article to their website detailing the necessary authorization requirements to access medical records. This article details information about frequently asked questions in accessing medical records, and includes resources from the Compliance Office. The August 2012 Privacy Article can be found by clicking here.

**DOCR Satisfaction Survey**
The Duke Office of Clinical Research sent out a satisfaction survey to the HRPP community on August 1, 2012. The survey closed on August 31st after receiving 275 responses from research staff in all 15 Clinical Research Units, Central Administration, DCRI, DTMI, Global Health Institute, Basic Sciences, and other research staff. The results of the survey will be reported in the next HRPP newsletter. Please continue to send any feedback to us at docr.help@dm.duke.edu.

**Research Data Security Plan (RDSP)**
In order to assist departments, centers and institutes in Duke University to effectively inventory, track and secure data associated with human subject research protocols, the DOCR is conducting an online data capture survey to collect retrospective information for all active IRB studies. This data capture will occur via a REDCap survey, and the questions will follow the same format as the existing prospective "Research Data Security Plan" (RDSP) that is associated with all new studies initiated since November 21, 2011. The RDSP is used to indicate to departments and Clinical Research Units (CRUs) where you are storing your data and how it is secured. In August 2012, the DOCR began the process of working with investigators to catalog 3800 active IRB protocols that did not have a RDSP on file. Of the first 1000 requests sent out, we have received over 500 completed RDSP surveys. We greatly appreciate those who have worked so hard to complete their information thus far, and those who have not completed the initial survey should do so. A second round of 1000 surveys has been sent out, and the DOCR will begin to work through those while continuing to follow up on the original group of surveys as well. The goal is to catalog all 3800 protocols by the end of the calendar year. Please contact docr.help@dm.duke.edu for assistance or to answer questions.

**Duke REDCap Survey Procedure Update**
New procedures are being implemented to ensure that REDCap continues to meet Duke compliance and information security guidelines. As of September 1st, REDCap Surveys will require a REDCap superuser review through the Duke Office of Clinical Research (DOCR) before push to production or any post production changes can be made. The REDCap superuser will
verify that all PHI (all 18 HIPAA identifiers) have been designated accordingly prior to production push. In addition, the ability to assign user privileges will be administered by DOCR. To request a user change, you may contact the DOCR REDCap Team at dtmiredcap@dm.duke.edu. Access to your data will not be affected by these changes.

**New Procedures for Clinicaltrials.gov**
New procedures for clinicaltrials.gov registrations are being implemented for clinical trials where the investigator holds an IND/IDE for the study. Clinicaltrials.gov registrations for these studies should list the Responsible Party as “Sponsor-Investigator”. This change to the Responsible Party field means that the investigator has the authority and responsibility to approve and release the registration record for publishing to clinicaltrials.gov. For current clinical trial registrations where the investigator holds the IND or IDE, the Responsible Party field is being updated from “Sponsor” to “Sponsor-Investigator” and investigators are being contacted to make them aware of this change. For clinical trials not conducted under an IND or IDE, the Responsible Party field should continue to be listed as “Sponsor” and the Sponsor listed as “Duke University”. For questions or assistance, please contact Nancy Hassell at 684-9425 or send an e-mail to docr.help@dm.duke.edu.

**Education Opportunities**

**New Education Offerings**
The Duke Office of Clinical Research is rolling out new educational opportunities for the clinical research community starting in September. These new educational offerings provide employees and CRUs with the flexibility to attend classes at times and locations convenient to a busy work schedule, and the ability to tailor course selections to an individual’s assigned job responsibilities. The first *Human Subjects Research at Duke* overview course will be offered on September 10th, and the first *Data Integrity/Data Security* course will be offered on September 11th. Be sure to check the [DOCR Training page](#) for more upcoming offerings and registration instructions.

**Research Wednesdays**
[Click here to see new learning events offered by the DOCR](#).

**Live Grid Builder Support**
In September, the DOCR will begin offering weekly live support for grid building. Every Wednesday from 11am-12pm at the [North Carolina Mutual Building](#) (411 W. Chapel Hill Street), the DOCR will have staff available to meet in-person with research teams working on developing billing grids. Please contact docr.help@dm.duke.edu if you plan to attend a session on the 12th, 19th or 26th of September, and if you forget to e-mail the DOCR—please drop in anyway!
Live REDCap Survey Support
REDCap Survey First Tuesdays - On the first Tuesday of each month staff at DOCR will be available to provide guidance with any REDCap survey issues you may be having in an informal roundtable format. This will be a chance to ask general or specific questions concerning existing or potential project including demonstrations if requested. The meeting will take place at DOCR (North Carolina Mutual Building, 411 Chapel Hill St., 11th floor) from 11:00 to 12:00. Next date is October 2, 2012.

Don’t Forget!

eBrowser Request Form for Temporary Monitor Access Updated
The Duke Office of Clinical Research (DOCR) has updated the eBrowser request form for temporary monitor access to reflect the new contact information for the DOCR. The updated form notes that all temporary monitor eBrowser request forms should be e-mailed to docr.help@dm.duke.edu for approval in the future. Please remember that requests should be e-mailed 7 business days in advance of the monitor visit in order to provide enough time to create the temporary account. The updated eBrowser request form can be found by clicking here.

Templates Available for Study Advertisements and Flyers
Microsoft Word templates for study advertisements are now available for use on the IRB website. The ad and flyer templates are no longer behind the Duke firewall, so you may now access them from locations outside Duke. These templates for study advertisements and flyers were developed by the Duke Medicine Office of Creative Services & Publications, and a link to them is available on the IRB website. It is not required, but strongly suggested, that you use these templates to advertise your studies. You may also navigate directly to the templates by clicking here. For more information on what content can and cannot appear in Duke advertisements, please refer to the following HRPP Policy and Guidelines for Advertising.

Reminder About eIRB Availability Each Night
As a reminder, system maintenance and database backups are performed each night on the eIRB servers between the hours of 12:00am and 6:00am. During this time, the system is not available for use. We apologize for any inconvenience this may cause.
Did You Know?

International Research and HIPAA
As Duke extends its research boundaries more and more into the international arena, investigators need to know how HIPAA applies to data collected elsewhere. When the data are in the host country, their privacy regulations apply, but when the data come back to Duke, the HIPAA regulations apply (starting with the determination of whether or not the data are individually identifiable health information (IIHI)). If it is IIHI at Duke Medicine, it is Protected Health Information (PHI), and we need to apply the same controls to the data that we do for our own patients, including the storage of electronic data on our Duke Medicine servers when the data are here. There are some "extra" things that we have to do to address the lack of an individual authorization associated with consent for research, so please contact the IRB or the SOM Compliance Office for help in these circumstances.

Medical Device Studies
Medical device studies utilizing category B devices under an IDE require CMS approval before enrolling study subjects. PRMO facilitates this process and requires information from study teams be submitted to them on the “Notice Concerning use of and Billing for Investigational Devices” form located on the DOCR website. This form has been updated to include additional information required by CMS including the following: 1) provider name(s); 2) Medicare provider ID#s; and 3) CPT codes for the study. Early form submission to PRMO eliminates delays allowing PRMO to gather and prepare the required documentation, as well as submit the required paperwork to CMS as soon as IRB approval is received. DOCR will work with PRMO to ensure CMS approval and charge code assignment is in place before final DOCR study approval. For additional information or for questions, please contact Nancy Hassell at 684-9425 or email docr.help@dm.duke.edu.

CRU Corner

Children’s CRU
The Children’s CRU wants to acknowledge Kathy Auten, CRC II in Pulmonary and Sleep Medicine and Mingfen Xu, Clinical Trials Project Leader II in Cardiology. Kathy and Ming provided their time and expertise to the leadership delegation from SingHealth Pediatrics Academic Clinical Program who were interested in learning about human research infrastructure and support. Both Kathy and Ming provided valuable input to the SingHealth team. Thank you for your contribution!

Ophthalmology CRU
The Ophthalmology CRU is happy to welcome back Quintin DeGroot. Quintin will join our team on September 17, as a Clinical Trials Assistant II.

The Ophthalmology group is also grateful to Sara Crowell for all her work and effort over the past three years, and we will all miss her terribly when she leaves us. Best of luck, Sara!

To be added or removed from the newsletter distribution list, please contact the DOCR at docr.help@dm.duke.edu.