Protecting Data at Duke
The Data Loss Prevention Program was recently announced as a means to protect sensitive and confidential information on the Duke Medicine Network, and to help employees improve their data management practices starting in January 2013. The U.S. Department of Health and Human Services (HHS) recently published a guidance document on its website with information about how to appropriately de-identify a data set, which may be helpful for individuals who want to take the proper steps to protect their data. The full guidance is available as a reference on the HHS website.

Video Update on Clinical Research at Duke
Denise Snyder, Assistant Dean for Clinical Research, was recently interviewed on Duke TV about the ways that clinical research is being improved at Duke University. The interview presents an update about the improvements being made in the clinical research community, as well as a vision for the future of site-based clinical research at Duke. A link to the video is available for viewing on the DOCR website.

DOCR Project Team Update
DOCR employs a group of highly skilled individuals who are trained in aspects of data and project management and are available for hire on a short-term contract basis to provide cost-effective research solutions for investigator-initiated research at Duke. Benefits to using DOCR contract staff include paying only for the skills and time that you need, reduction in time spent hiring/managing research staff and immediate access to experienced, service-oriented, research-trained staff with a broad skill set. For those of you utilizing the DOCR Project Team for your data or study coordination needs, please contact Justin Levens (justin.levens@duke.edu) if you have questions about data management or Joan Wilson (joan.wilson@duke.edu) for questions about study coordination. They would also be happy to meet with anyone who is looking for assistance on individual studies or departmental needs.

New Education Policy
A new education policy titled Human Subjects Protection (HSP) Education and Training has been developed to outline education requirements for all Duke Medicine employees who engage in, or support, clinical research at Duke. The policy will be effective January 7, 2013, and the changes will
affect all Duke personnel who work in clinical research. The policy is available on the DOCR website, and DOCR will be working with the Clinical Research Units (CRUs) to track training for the Duke clinical research community.

**New Privacy Article**
The DUHS Compliance Office has posted a new privacy article to their website titled *Guidelines for Alternative Means of Communications vs. Authorization to Release PHI*. This article provides helpful tips on a patient’s rights to receive communications containing PHI from Duke through an alternative means or location. The article can be found by clicking here.

**Education Opportunities**

**Pregnancy Testing Training**
A new training will be available starting in January 2013 on administering urine pregnancy tests, and a number of trainers have received training to lead these sessions for the CRUs. An updated IRB policy outlining the requirements for pregnancy testing in clinical research will be available on January 14th on the IRB website. In addition, DOCR will be offering a Research Wednesdays session on January 23rd at 12:00pm titled “Pregnancy Testing for Research (Serum vs. Urine)” presented by Evan Myers, MD and Bonnie Thiele, OB/GYN Research Practice Manager. The following individuals are approved trainers for the Urine Pregnancy Testing sessions when they begin in January:

- Ana Garcia-Turner, RPM Ophthalmology
- Barbara Kurth, RPM Radiology
- Bonnie Thiele, RPM, OB/GYN
- Catee Mullen, RPM Heart Center
- Deborah Hannah, RPM Dermatology
- Eang King, RPM CFM
- Holly Tiemann, DOCR
- Sharon Minda, RPM Psychiatry
- Terry Ainsworth, DOCR

**NCURA Conferences**
The National Council of University Research Administrators (NCURA) is an organization that offers educational and professional development programs for the research community. NCURA will be holding two national conferences in New Orleans in March 2013, and both are still available for registration. The Financial Research Administration Conference will be held March 10th-12th, and the Pre-award Research Administration Conference will be held on
March 13th-15th. More information about the conferences and registration requirements can be found on the NCURA website.

**Research Wednesdays**
DOCR and the Medical Center Library will be hosting two Research Wednesday sessions in the month of January. John Kessler will be presenting on the topic of *Adverse Events* on January 9th, and Dr. Evan Myers and Bonnie Thiele will be presenting on the topic of *Pregnancy Testing for Research (Serum vs. Urine)* on January 23rd. More information is available on the Research Wednesdays page of the DOCR website.

**Maestro Care—Wave 3**
If you perform research activities in a Wave 3 clinic, you will need to take the Clinical Research Coordinator Wave 3 Maestro Care training before this part of the system goes live in March 2013. Trainings are currently being scheduled for Maestro Care Wave 3, and research personnel will be alerted concerning scheduling in the next few weeks. Please contact DOCR if you are adding staff who need to receive Maestro Care training.

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**Don’t Forget!**

**CITI Module Requirements**
DOCR has worked with the IRB to update the required modules for CITI training, which will be available at 9:00am on January 7, 2013. A number of modules have been removed, and new modules have been added to the required Duke Medicine course. The updated course will contain eight modules, including four new modules on Vulnerable Populations (Prisoners, Pregnant Women, and Fetuses), HIPAA, and Conflict of Interest. The additional Research with Children module will only be required for those individuals working with minors. All new employees will be required to take the updated Duke Medicine course containing eight modules, and existing employees who have already taken their modules in the past will be required to take the four new modules the next time their Duke Medicine course is due for renewal. To check on the status of your CITI modules, you can login to your account at [www.citiprogram.org](http://www.citiprogram.org).

**RDSP Date Extended**
The RDSP team has contacted by phone or e-mail all of the investigators with an active study that was initiated prior to November 21, 2011 in an attempt to collect the surveys for all 3900 active studies. The team has collected 2149 usable responses so far, and the deadline to collect the surveys has recently been extended to January 31, 2013. We appreciate your cooperation in this effort, and we are working alongside investigators and study teams to assist them in this
Thank you to all of the study teams who have responded to the e-mails!

**Review Key Personnel Lists**
Just a reminder to all study teams, please review your Key Personnel list(s) on the eIRB protocols for which you are responsible. Remove key personnel who are no longer at Duke and ensure that new study staff are added to Key Personnel in the eIRB as well as the Delegation of Authority logs (for studies that require them) in a timely way. In addition to being a statutory responsibility for the PI, various administrative offices use this list to communicate information to all research staff on clinical research protocols at DUHS.

**Did You Know?**

**Mutual Confidential Disclosure Agreements**
Most Confidential Disclosure Agreements (CDAs) from companies protect only the company's information disclosed to Duke personnel. If an investigator has designed a protocol or a research proposal and wants to present it for industry support, the discussion should be preceded by a mutual confidential disclosure agreement. This type of agreement will allow disclosure by Duke investigators as well as the company. As with all CDA's, the agreement should be forwarded to the Office of Corporate Research Collaborations (OCRC), along with the company contact information, for review and signature as soon as received, or OCRC can draft an appropriate CDA for you. For additional information regarding CDA's for clinical research projects, contact Marti Salguero in OCRC at salgu001@mc.duke.edu.

**Policy on Blood Drawing Updated**
The DUHS HRPP policy on Blood Drawing for Human Subjects Research has been modified to provide simpler and clearer guidelines for collection of blood samples in research. Efforts have been made to: 1) clarify requirements for the youngest research participants, with consultation from Duke’s Neonatology Division in Pediatrics, and 2) align the policy with those of leading institutions in the United States. To find the updated policy titled *Blood Drawing for Human Subject Research* can be found on the IRB website.

**REDCap Secure Use Policy**
DOCR instance of REDCap was voluntarily reviewed by Duke Internal Audit in April 2012, and one of the audit findings concerned user education and data use agreements. In response to this finding, DOCR will require all new and current REDCap users to agree to a Secure Use Policy prior to gaining access to the REDCap system. In the next several weeks, current users of the system will receive a REDCap Survey that will ask users to agree to the Secure Use Policy.
ClinicalTrials.gov (CT.gov) Update
DOCR has assembled a team to assist with ClinicalTrials.gov registration and results reporting to ensure that Duke is in compliance with FDAAA (U.S. Public Law 110-85). When DOCR began this initiative, there were approximately 72 records flagged as overdue for results reporting according to FDAAA. DOCR set a goal to get these registration records up to date, enter results, and compliant by the end of 2012. Given that lofty goal, DOCR has made significant progress working with study teams to get registration records updated and study summary results posted. Currently there are 59 clinicaltrials.gov registration records flagged as overdue for results reporting in clinicaltrials.gov. Of these 54 registration records, 23 records have had results entered into the clinicaltrials.gov system and are in the QA review process at clinicaltrials.gov. 16 registration records have some results entered but require additional attention, and just 16 records remain that need to begin results entry as soon as possible. DOCR staff is partnering with those study teams to post study summary results and hopes to have all the overdue results reported by early 2013. DOCR staff continues to send notifications to study teams with a copy to the RPMs for studies listed in their CRUs and also assists your investigators in posting study summary results for this study registration. Failure to post study results is considered out of compliance with FDA regulations and significant monetary or other penalties could be imposed. Please contact docr.help@dm.duke.edu for assistance.

CRU Corner

OBGYN CRU
Melissa Hall has recently accepted the Assistant Research Practices Manager (ARPM) position within the OBGYN CRU. Welcome, Melissa!

Grace Fulton was recently promoted to a CRC II position within the Division of Urogynecology. Congratulations!

Heart Center CRU
The Heart Center CRU would like to welcome Dana Schrantz, RN to their Cath team. Dana will be working as a Clinical Research Coordinator I. Welcome, Dana!

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