What’s New?

Welcome to Susan Budinger
Susan Budinger joined DOCR on April 1st as the new Associate Director for Research Operations. Susan’s expertise in data management and extensive clinical research experience at Duke will be a helpful addition to DOCR.

New IRB Policy
The Institutional Review Board (IRB) has added a new policy to its website titled “Use of Research Data by Former Duke Students or Former Duke Employees”. The policy details the conditions for employees, students, and external personnel to access research data, and the full policy is available on the IRB website.

Neurology—the Newest CRU
Neurology recently became the newest CRU within Duke Medicine. Dr. James Burke is serving as the Director, Lisa Gauger is the Research Practice Manager, and Megan Phillips is the Financial Practice Manager. The approved Neurology CRU charter is available for viewing on the DOCR website.

New Privacy Article
The DUHS Compliance Office has posted a new privacy article to their website titled “Sharing Sensitive Electronic Information”. This article provides helpful tips on safeguarding Sensitive Electronic Information (SEI) in day-to-day work. The article can be found by clicking here.

ResearchMatch Available at Duke
Duke University now has a ResearchMatch site available to help in the process of recruiting research study participants. ResearchMatch brings together people who want to take part in clinical research studies with researchers who need participants for their studies. This is a free and secure registry developed by major academic institutions across the United States to advance the mission of helping today’s studies make a real difference for everyone’s health in the future. For more information or to register, please visit http://researchmatch.duke.edu.

IRBshare Available for IRB Review
Recently, Duke joined the IRBshare System as a participating institution. IRBshare is a shared IRB review model for multi-site studies comprised of participating institutions utilizing common
review documents and a shared review process. The IRBshare effort is supported by a centralized, secure web portal and an IRBshare Master Agreement. IRBshare reviews can only be used for the initial review of a study. All amendments, safety events, and continuing reviews revert back to the original institutional IRB.

The overarching goal of the IRBshare System is to optimize human subjects protection nationwide through operationalizing this new shared multi-site IRB review model that reduces duplicative reviews and promotes collaboration and communication among the participating FWA-holding IRBs.

Presently, based on extensive input from the OHRP, IRBshare is used for only new multi-site studies that are funded by the National Institutes of Health (NIH) and undergoing the initial round of reviews conducted by the respective participating IRBs. To learn whether IRBshare review could be used for your new NIH-funded study, contact Jody Power, the Duke IRB Executive Director. If you are interested in learning more about IRBshare, you may visit their web site at https://www.irbshare.org/.

**Education Opportunities**

**CISCRP Educational Brochures**
The Center for Information and Study on Clinical Research Participation (CISCRP) is a nonprofit organization dedicated to educating and informing the public about clinical research and increasing participation in clinical trials. CISCRP has made educational brochures about participating in clinical research available on their website in many different languages, which may be useful for recruiting clinical trial subjects. More information about the brochures can be found by clicking here.

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesday sessions in the month of April. Emily Mazure and Brandi Tuttle will present on the topic of *Research Support from the Medical Center Library & Archives* on April 10th and the Information Security Office (ISO) will present on the topic of *Information Security Office Overview* on April 24th. On May 8th, Research Wednesdays will feature a presentation titled *Maestro Care (Epic and Clinical Research Updates)* by Denise Snyder, Terry Ainsworth, and Cory Ennis. Click here for more information about these events.

**Are You an Early Career Researcher?**
Are you interested in sharing your research experience at Duke? The Medical Center Library & Archives and the Duke Office of Clinical Research are scheduling focus groups to learn what works well for early career researchers at Duke and any areas of concern. We want your input on what resources or services you need to support your research. If you are interested in
sharing your perspective and experiences, please contact Leila.Ledbetter@duke.edu. You can learn more about this Duke IRB approved research study (eIRB#00040524, PI: Emily Mazure) at: http://guides.mclibrary.duke.edu/investigation. Snacks or lunch will be provided for the focus groups.

Don’t Forget!

eBrowser Request Reminder
Monitors who are using temporary eBrowser access must be sure to use the following link to access the eBrowser system: http://clinapp/default.asp. This link should NOT be bookmarked, and monitors should be sure that they are visiting the correct URL for each visit. Additionally, if you experience any difficulties logging into the eBrowser system or using the assigned password from HealthIM, you should contact the HealthIM team for assistance.

Pregnancy Testing Policy
A new training on administering pregnancy tests for clinical research is now available, and a number of trainers are prepared to lead these sessions for the CRUs. An updated IRB policy outlining the requirements for pregnancy testing in clinical research is now available on the IRB website. Please note that Quidel pregnancy testing kits are the only tests currently used for screening at Duke. Quidel kits are available through DOCR, purchased individually or may be provided by the sponsor. A Research Wednesdays session on the topic of Pregnancy Testing for Research (Serum vs. Urine) was held on January 23rd, and a recording of this presentation can be viewed on the DOCR website along with the SOP on urine pregnancy testing. If you would like more information, please contact docr.help@dm.duke.edu with questions about setting up a training session or ordering test kits.

Medical Device Studies
Medical device studies utilizing category B devices under an IDE require Centers for Medicare & Medicaid Services (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 which the device will be billed 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 Terry Ainsworth at 681-7084 or email docr.help@dm.duke.edu.
**Did You Know?**

**Maestro Care Update**
The transition to Maestro Care on June 22, 2013 creates an opportunity for Duke Clinical Research to take advantage of efficiencies offered by an electronic medical record. One expected change is that we will be able to track all participants that are recruited from a Duke patient pool. This will allow us to track all Duke patients participating in clinical research. Previously, we have been restricted to including only those Duke patients participating in a study that was deemed “billing risk”. The transition to Maestro Care allows us to track those studies that were deemed “no billing risk”. If you are a study coordinator of a “no billing risk” study and have not been previously identified by your clinical research leadership as requiring Maestro Care training, please contact docr.help@dm.duke.edu or call (919) 681-6555 and give us your name, NetID and Duke Unique ID. Study Coordinator training is expected to begin in early May.

**Data Transfer Agreement Guidelines**
The Office of Corporate Research Collaborations (OCRC) recently presented guidelines for Data Transfer Agreements to document and protect transfers of human subjects information from and to other organizations. In all cases, the IRB needs to be informed of the proposed transfer. Whether a formal agreement is needed and the type of agreement depend upon the nature of the information to be transferred, including what identifiers are included, the planned use of the data, the uses permitted by a subject’s informed consent, and what other agreements are already in place for the project. Different forms of agreements are used for fully-identified data (when allowed by the consent), limited data sets (data without direct identifiers, but may include dates, ages>89, or addresses less specific than street address), and de-identified data. These agreements are handled in OCRC, which coordinates with the IRB when necessary, and signed by an authorized individual in OCRC on behalf of the institution.

For anonymous data, the PI can send an e-mail to the IRB and the recipient attesting that the data are fully de-identified and anonymized (no link to identifiers held by either provider or recipient of the data) and will be used in manner consistent with the informed consent. No formal agreement is needed in this instance. The same process would be used for a fully de-identified data set, but would also include a statement acknowledging that the key linking the data to the identifiers will not be provided to the recipient. No formal agreement is needed in this instance either.

A formal agreement will often be necessary, or at least advisable, even if not required by HIPAA regulatory considerations if any of the following apply:
• There is a need to restrict how the data will be used, such as it being maintained in confidence or not being further transferred to others.
• There are third party constraints on use of the data, such as it having been collected other than at Duke, received by Duke under a Data Transfer Agreement, or collected under a sponsored research agreement.
• The data being transferred are associated with intellectual property developed by Duke, such as supporting a patent or patent application, or being part of a larger proprietary data set unique to Duke.
• The data are being transferred in conjunction with the transfer of human-derived samples.
• A payment will be made to or from Duke for the transfer or preparation (selection, coding, matching, aggregation, etc.) of the data.
• The external entity requires an agreement.

The Powerpoint presentation and handout on “Agreements for Transfers of Data and Materials Relating to Human Subjects” given by Gil Smith, PhD are available on the DOCR website for review.

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.

ClinicalTrials.gov
As part of the study start-up process, DOCR is screening all protocols to ensure prompt registration in ClinicalTrials.gov for studies requiring registration to comply with the FDAAA law as well as for those interventional studies requiring registration in accordance with ICMJE publishing guidelines. Study teams (PI and Coordinators) will receive a short REDCap form via email to fill out after eIRB submission of their study. The purpose of this form is to collect information in a database regarding the ClinicalTrials.gov registration status for all new studies at Duke.

DOCR is requesting that study teams who receive an email complete the form whether the protocol has already been registered (thus has NCT #), is in the process of registration, or will not be registered.

Please note, Institutional approval will be held for studies meeting the definition of an Applicable Clinical Trial until the trial is registered in ClinicalTrials.gov. Please contact DOCR.help@dm.duke.edu for further information or assistance.
CRU Corner

Heart Center CRU
Congratulations to Daphyne Bennett who received the President’s Award from the North Carolina Chapter of the Society of Research Administrators at their Annual meeting in March. Great job Daphyne, we are so proud of you!

Medicine CRU
The Medicine CRU would like to welcome to Marguerite Thoma, RN as the new ARPM for the central office. Welcome, Marguerite!

OBGYN CRU
Congratulations to the Hematologic Malignancies group for achieving recognition as a Center of Excellence in the diagnosis and treatment of Myelodysplastic Syndromes (MDS) by the MDS Foundation. This designation is awarded to institutions that meet the highest standards in diagnostic capability, research excellence, treatment, education, and patient care. This designation also allows the MDS Foundation to provide referrals for patients to our program. Congratulations to the staff and thanks to Dr. Carlos De Castro for his leadership!

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