What’s New?

**Research Data Integrity/Data Security Course Available Online**
The Research Data Integrity/Data Security Course is now available in an online format. This course presents the basic principles of data management and examines how these principles contribute to data security. The course also reviews the implications of various recruiting techniques and the importance of keeping recruiting metrics for ongoing studies. Registration is available through the SABA Learning Management System (participants will need to search for “DOCR Research Data Integrity and Security” and choose the “web based” option). DOCR is working on developing an online training course library. If there’s a topic that you want to submit for online consideration, please send an e-mail to DOCR.help@dm.duke.edu.

**Spring Core Facility Voucher Program**
The School of Medicine recently announced the 2014 Core Facility Voucher Program in an effort to provide investigators access to a wider range of research core facilities. This joint program with the School of Medicine (SOM) and the Duke Translational Research Institute (DTRI) Pilot Program will offer vouchers in amounts ranging from $500 to $10,000, redeemable for provision of services at Duke University core facilities/shared resources. A list of SOM core facilities as well as proposal requirements for the program is available on the DTRI website. Please send any questions about the program to SOM-voucher@duke.edu.

**Interim Activities Policy**
A new IRB policy titled *Permissible Interim Activities* took effect on Saturday, March 15th. The new policy provides clarification regarding research-related activities that are permissible in the interim between IRB approval and institutional approval. The full policy detailing the list of permissible activities is available on the IRB website.

**PB/HB Charge Corrections Request Forms**
Effective immediately, the PB/HB Charge Corrections Request forms will no longer be used for corrections regarding clinical research. All correction requests regarding clinical research should be submitted using the Service Now ticket instructions, and the ticket should include the statement “Assign to Julie McCauley, assignment group Maestro Care-Operational-Clinical Trials Billing Office- PRMO”. Please use your preferred document type (Excel, Word, etc.) to request corrections. This document can be attached to the Service Now ticket and should include information such as protocol number, hospital account ID, patient name/MRN, and the date of
service, procedure, and the correction(s) to be made. Protected Health Information (PHI) can be included in the attachment, but should not be included in the “Details” section of the Service Now ticket.

Maestro Care Mobile Apps Now Available
Maestro Care mobile apps Haiku and Canto are now available to providers and house staff across Duke University Health System. These apps have been developed by Epic to allow access to a subset of Maestro Care features. Haiku is available for iOS and Android smartphones, while Canto is available for iPad. These apps will allow providers to view patient charts, manage in-basket messages, view clinical schedules, e-prescribe outpatient medications, and take clinical images and save to a patient encounter. To get started, simply visit the Maestro Care Mobile Device Support website from your mobile device while on the hospital intranet (i.e., “clubs” network) and follow the steps to download, configure and login to the apps. If you have any questions regarding app configuration, then please refer to the “Frequently Asked Questions” section on the support page. Please note that the Duke Medicine Service Desk cannot provide assistance with downloading and installing the apps on your device. Finally, prior using the apps, be sure to complete the 7-minute LMS training entitled “Maestro Care Mobile Apps Security and Compliance Considerations,” which highlights proper use of the applications. You will also receive an email reminder to complete the training within 30 days.

Microsoft Office App
In March 2014, Microsoft released Office app, an iPad version of its popular software suite, allowing users who download the app to work within Word, Excel, and PowerPoint. Use of the app requires a subscription to Microsoft’s Office 365. While Duke has an O365 license, it is for the migration of the mail system and does not include use of any other Office application. Per the Duke Medicine Secure System Usage Memo, “use of file sharing or cloud-based services for data containing SEI (e.g. Dropbox, SkyDrive, Google Drive, etc.) is not allowed without prior approval from the Duke Medicine ISO.” Use of the Office app with a personal Microsoft O365 account is allowable, but this requires cloud storage using a personal account. For this reason, Microsoft’s Office app cannot be used with documents containing Duke SEI/PHI.

Education Opportunities

Maestro Care Patient Verification and Financial Reconciliation Training
DOCR is introducing a new training titled Maestro Care Patient Verification and Financial Reconciliation Training. This course will enable Clinical Research Coordinators and financial research staff (Financial Reconcilers) to gain skills needed for the verification and reconciliation of research patient charges. The course also focuses on generating and interpreting financial reports from Maestro Care and SAP, navigating patient charges and identifying errors.
or discrepancies for patient research related charges. Information about additional course offerings will be announced in an upcoming newsletter.

**DUMC Clinical Research Training Program**
Duke University offers a Clinical Research Training Program for clinical fellows and other health professionals seeking an academic career in research. The program offers a degree track as well as a non-degree option, and the deadline to apply for the 2014-2015 academic year is May 15, 2014. More information is available on the [DOCR website](#).

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesdays sessions in the month of April. Kevin Smith will present *Understanding Copyright: Owning, Using and Licensing Research* on April 9\(^{th}\), and Jeff Hawley and Rick Sloane will present *Data Management in RedCap and Statistical Data Analysis* on April 23\(^{rd}\). More information about the sessions is available on the [DOCR website](#).

**Upcoming DOCR Trainings**
The following DOCR trainings will be held in the month of May for research staff at Duke, and registration instructions are available on the [DOCR website](#):

1. *Research Data Integrity/Data Security* will be held on May 5\(^{th}\).
2. *Human Subjects Research at Duke* will be held on May 5\(^{th}\).
3. *IRB Overview* will be held on May 20\(^{th}\).
4. *Informed Consent* will be held on May 15\(^{th}\).
5. *Study Documentation: Regulations and Best Practices* will be held on May 21\(^{st}\).
6. *Workshop: Consenting a Subject to a Research Study* will be held on May 6\(^{th}\).
7. *Phlebotomy Competency for Research* will be held on May 20\(^{th}\).
8. *Urine Pregnancy Screening for Research* will be held on May 7\(^{th}\).
9. *Research Data Security Plan (RDSP)* will be held on May 13\(^{th}\).

**Don’t Forget!**

**Duke Medicine Secure System Usage**
Every member of the Duke Medicine workforce has a role to play in protecting the confidentiality, integrity, and availability of the valuable clinical and research data that Duke collects, produces, and maintains. The Duke Medicine Information Security Office recently published the [Secure System Usage Memo](#), and the purpose of this memo is to provide an overview of the information security policies, standards, and procedures that apply to all Duke Medicine faculty, staff, students, and affiliates. Your commitment to following the steps outlined in the memo can help protect the personal information of our patients, their loved ones, and each other.
Remove PHI from PowerPoint Presentations
Individuals using the cropping tool for images in a PowerPoint presentation may unknowingly leave the cropped portion of the image available for users. This may be problematic if the cropped part of the image contains Protected Health Information (PHI) or identifiers that should not be available to viewers. Placing identifiers behind another picture within the PowerPoint can also leave protected information available for viewers as well. However, an image can be permanently cropped, or identifiers can be removed from the middle of an image within a PowerPoint presentation in order to protect PHI. Techniques for these protecting identifiers in images can be found on the Information Security Office (ISO) intranet.

ClinicalTrials.gov
Serious Adverse Event (SAE) and Adverse Event (AE) data can now be uploaded to ClinicalTrials.gov using an Excel spreadsheet. The Arms/Groups in the spreadsheet file must exactly match the current ClinicalTrials.gov entry for your study in order to be successful. To obtain the necessary Excel spreadsheets, click “Download/Upload” in the menu located on the “Results: Adverse Events Overview” screen. Download one Excel spreadsheet for SAEs and one for other AEs. For questions, please contact Susan Natoli at 919-684-9425 or send an e-mail to docr.help@dm.duke.edu.

Placement of Research Consent Forms in the Medical Record
A new DUHS IRB policy was developed to address consent form placement in the medical record. A research consent form must be placed in the subject’s medical record if it meets the definition of being ‘clinically relevant’. ‘Clinically relevant’ is defined as any study-related activity that could have an effect, adverse or otherwise, on the clinical treatment of the subject. This definition includes investigational drugs, devices, or biologics that could, separately or in combination with other substances or activities, interfere with the clinical treatment of the subject or place the subject at greater risk of harm. The research consent form must always be placed in the participant’s medical record in the case of FDA-regulated research studies. In all other cases, it is left to the discretion of the Principal Investigator (PI) on placing a copy of the consent form in the subject’s medical record, but it is no longer required for all studies that enroll Duke patients. As always, all studies must retain the original consent form in the research study record.

Frequently Asked Questions

How do I pay a research subject who is also a foreign national?
When paying research subjects for their participation in a clinical trial, study teams are often required to collect a social security number before providing payment. However, research subjects may be unable to provide a social security number if they are also foreign nationals. In this instance, study teams can follow the instructions for paying foreign nationals found on the Duke Financial Services website.
How can I use ResearchMatch as a recruitment tool for my study?
ResearchMatch is available as a recruitment tool for study teams at Duke who are seeking participants for their clinical research studies. Study teams wanting to use ResearchMatch to locate potential participants must list ResearchMatch as a recruitment tool in their Research Summary submitted to the IRB. An amendment can also be submitted to the IRB adding Research Match as a recruitment tool if it wasn’t previously listed in the Research Summary for your study. We’ve already had a number of researchers register and begin recruitment efforts through ResearchMatch, and if you would like to register your study, please visit our ResearchMatch page for more information or contact docr.help@dm.duke.edu with any questions.

CRU Corner

Heart Center CRU
The Heart Center CRU would like to congratulate Krista Camuglia and Latasha Phillips for passing their ACRP exams this past month. Congratulations, Krista and Latasha!

Jennifer Langefeld has been promoted to Grants and Contracts Administrator in the Heart Center CRU. Congratulations, Jenn!

Ophthalmology CRU
Christina Bunn joined the Ophthalmology CRU in December 2013 as a Clinical Trials Assistant II. She joins the group with extensive ophthalmic experience, and is easily integrating into the human research world. Welcome to our CRU, Christina!

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