What’s New?

Maestro Care Access Requests
DOCR has posted instructions for requesting access to Maestro Care via the Support@Duke system on its website. The instructions provide detailed screen shots illustrating how to request access to Maestro Care for another employee. Any questions about this process can be e-mailed to dempoid-admin@mc.duke.edu, or a ticket can be opened in Support@Duke for DHTS-DHIS.

GME Research Education
DOCR and the Office of Graduate Medical Education (GME) are collaborating to provide a program that will teach GME trainees basic skills in clinical research during their time at Duke. The program will be available for those working towards research, clinical, or administrative careers, and two unique programs will be available this year:

Sessions:
1. Intended for RESIDENTS: Four live 90-minute workshops (offered 4 times each)
   - Human Subjects Research & Research Data Collection and Security
   - How to Ask and Answer Research Questions Using Library Resources & Ethics of Conducting Research
   - IRB Overview, Informed Consent and Regulations
   - Presentation and Dissemination of Data

2. Intended for FELLOWS: One half-day weekend blitz (offered 2 different times)
   - Training in Advanced Research Principles and Practices. (Residents who complete all 4 workshop topics are eligible to attend a blitz.)

Registration options for these sessions are available at the following site: https://www.surveymonkey.com/s/GME_Research_Training.

Flu Vaccination Requirements
The Duke University Health System is implementing a new policy that makes an annual flu vaccination a condition of employment for all people who provide care, treatment or services in the organization including physicians, staff, volunteers, vendors, and health profession students. School of Medicine faculty and staff who work as key personnel on clinical protocols
and have in-person interaction with patients or study subjects will be required to be vaccinated prior to December 6, 2013. Those individuals will be notified directly. More information about this requirement is available on the [SOM website](#).

**WBSE Transition**

Due to the pending depletion of available 393x WBSEs (fund codes) in SAP, OSP has started creating 293x WBSEs for non-governmental sponsored projects that do not require financial reporting. There will be no change in the process for establishing WBSEs, and individuals will continue to receive the system-generated email when a new WBSE is created for their project. Individuals will now be provided with a 293x instead of a 393x WBSE as appropriate. More information is available on the Financial Services [Accounting Codes Overview](#) page.

**External Monitor Access for MaestroCare**

DOCR has been working with Health Information Management (HIM) on the new external monitor access for MaestroCare. This access occurs through an Epic electronic health record tool called Release to Inspector. This tool is considered the electronic medical record – it is not a copy – and the tool allows a locked down view of the medical record by the monitor. HIM has noted that some pages are supposed to be blank in this view. For example, an appointment might have a date in the system, but the patient misses the appointment or they are admitted to the hospital. The appointment still appears in the system and is blank in the Release to Inspector view. Intermittently, HIM has also noted that some documents may not be crossing over into MaestroCare, such as large TIF/PDF documents, imaging reports, etc. There is a MaestroCare group that is working on this issue, but HIM cannot predict when this problem will occur. Thus, for the interim, please request access to both MaestroCare and eBrowser access for monitors until further notice using the form located on the [DOCR website](#). DOCR is working with HIM to develop a form for electronic data capture that will go directly to HIM (removing DOCR from the middle of the process). The [HIM policy manual](#) has been updated, but is currently missing information about Release to Inspector and rules related to external monitors. Please follow the [eBrowser policy](#) until this section has been updated in the manual.

**Updated CRU Change Request Policy**

DOCR has updated its CRU Change Request Policy to outline the process for changing a study from the oversight of one CRU to another CRU or responsible oversight organization. The policy removes DOCR as the intermediary and allows each CRU to provide CRU Director approval on the provided form for upload into the eIRB system. A copy of the revised policy and form is available on the [DOCR website](#).

**Education Opportunities**

**MaestroCare Training Available for CRCs**
CRC (licensed and unlicensed) research training is still available for those who are new and new to research staff. The “New to Duke: DOCR MC Clinical Research 100” course is being offered in August on the following dates:

- 8/19/2013 from 12:30pm-4:30pm
- 8/21/2013 from 8:30am-12:30pm

Please send an e-mail to docr.help@dm.duke.edu with any questions.

**MaestroCare Q&A Sessions**

An “External Research Monitor Access – Release to Inspector” demonstration will be given by Hannah Jackson from Health Information Management during the next MaestroCare Q&A session (date and time are TBD). Please note this session will be for Duke employees only and attendees will need to bring their Duke ID Badge. More information will be available on the DOCR website in the next several weeks.

**Sickle Cell Disease Conference**

Save the date for the Sickle Cell Disease Conference on November 8th-9th at the Duke University School of Nursing. The conference is targeting health care providers, family members, and caregivers of those affected by Sickle Cell Disease. Registration will open soon, and 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 August. Shelly Epps and Doc Muhlbaier, PhD will present *DICOM and Image De-Identification* on August 14th, and the topic for August 28th session will be available on the DOCR website soon.

**Don’t Forget!**

**DOCR Satisfaction Survey**

We want your feedback! In our continuing efforts to refine and improve our model, we would like to hear your feedback in our annual DOCR Satisfaction Survey. You can access the survey here and all responses will be anonymous (unless you choose to provide your name). If you have any questions or concerns, please direct them to docr.help@dm.duke.edu.

**ResearchMatch Requirements**

Study teams wanting to use ResearchMatch as a recruitment tool to locate and potentially contact participants for their research 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
Research Record and Data Retention
In general, research records and associated data must be maintained for 6 years after the IRB protocol has been closed. For pediatric studies, the records and data must be maintained until the last study participant reaches age 21 or for 6 years, whichever is later. If a research agreement requires the maintenance of the records or data for a longer period, that retention period may be longer.

CITI Module Requirements—Research with Minors
An additional CITI module is required for those individuals listed as key personnel on studies in the eIRB that include minors as one of the subject population groups. Individuals on these studies must complete the “Vulnerable Populations: Research with Children” CITI module to receive full credit. All employees involved in human subjects research are required to take the Duke Medicine Biomedical Basic Course containing eight modules (as well as a refresher course every two years), and those individuals who work with minors must complete the additional module in order to receive credit. To check on the status of your CITI modules, you can login to your account at www.citiprogram.org.

Frequently Asked Questions

1572 Signature and Delegation of Authority Log
Q: When must this form be completed and signed by an investigator?
A: Whenever a sponsor selects a new investigator to participate in a clinical investigation that is being conducted under an investigational new drug application (IND), the sponsor must obtain a completed and signed 1572 before permitting the investigator to begin participation in the clinical investigation (21 CFR 312.53(c)). The investigator should sign the form only after being given enough information to be informed about the clinical investigation and to understand the commitments described in Section #9 of the 1572. Having enough information about the study typically means that the investigator has received copies of, has read, and understands the protocol and investigator’s brochure (if required), and is familiar with the regulations governing the conduct of clinical studies.

The investigator’s signature on this form constitutes the investigator’s affirmation that he or she is qualified to conduct the clinical investigation and constitutes the investigator’s written commitment to abide by FDA regulations in the conduct of the clinical investigation. More information about this is available on the FDA website, and a sample form is available on the DOCR website.

Working with Images in a Research Setting
Are you sending images to a sponsor, core lab, or collaborator for a research study? If so, have you listed the identifiers within the image in your informed consent? Images may contain the subject’s name, MRN and other identifiers, both in the image itself and in the data that make up the image. Some identifiers may be hidden within the image and cannot be seen without a DICOM viewer. The Information Security and Compliance offices can help you make sure that what you send is what you intended to send. In the upcoming DOCR Research Wednesdays series on August 14th from Noon-1:00pm in Duke North 2001, Shelly Epps from ISO and Lawrence Muhlbaier from the SoM Compliance office will present information about DICOM and answer questions about how to work with images in a research setting. Please plan to attend the session if you have questions about this topic.

CRU Corner

**Oncology CRU**

Congratulations to Susan Boulton, RN, BSN who recently became an Oncology ARPM for Brain Tumor Center!

Congratulations to Jami Linn, RN, OCN who recently became an Oncology ARPM for Women’s Oncology!

Welcome to Crystal Horton, RN who recently became a CRNC III Manager for the Oncology CRU Research Lab Services!

Congratulations to Jami Linn, RN who recently became an ARPM in Women’s Oncology Research Services!

Congratulations to Debra Shoemaker, RN who recently became the ARPM for Endocrine, Melanoma, Sarcoma and Thoracic Oncology Research Services!

Congratulations to Susan Boulton, RN who recently became the ARPM for Brain Tumor Oncology Research Services!

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