What’s New?

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. In order to speed up the process, send information to procurement (Bill Trofi) at the same time you send to PRMO so it can be worked on simultaneously. The “SAP Material Master Maintenance Request” form to complete for Procurement is located on the DOCR website. For additional information or for questions, please contact Terry Ainsworth at 681-7084 or email docr.help@dm.duke.edu.

Maestro Care Update
Transition
The conversion to the new electronic health record, 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”. Study Coordinator training is expected to begin in early May and the Research Practice Managers are involved in the pilot testing of the research curriculum.

Training
Maestro Care training for clinical research coordinators (CRCs) and research staff is slated to begin May 14, 2013. CRCs and research staff will be assigned training dates and times. It will be their responsibility to work with DOCR to reschedule these times if absolutely necessary. Rescheduling opportunities will be limited, so please be proactive and patient.

Validation sessions
Validation sessions are being scheduled beginning next week. Study teams will be grouped by Clinical Research Units for reviewing the Maestro Care protocol builds that will be used by study teams beginning June 22nd. We will try to group studies by PIs and study teams that involve medications versus those without medications.

**Presentations**
On May 8th, a presentation titled *Maestro Care (Epic and Clinical Research Updates)* will be given by Denise Snyder, Terry Ainsworth, and Cory Ennis, and on May 22nd the topic will be *SOM Informatics Vision and the CTSA* presented by Iain Sanderson. All Research Wednesdays sessions will be held at 12:00pm in Duke North 2001.

In June prior to Go-Live, there will be another presentation regarding Maestro Care for the clinical research community. More details about this session will be forthcoming in the June HRPP newsletter.

**Updated IND Best Practices Workshop**
An updated IND workshop titled *Best Practices for IND Exempt Studies and IND Preparation/Maintenance* will be offered on Tuesday, May 14th and Wednesday, May 15th from 9:00am-1:00pm, and registration is still available. The presenters will be Jelena Berglund, PhD and Amanda Parrish, PhD from the Duke Translational Medicine Institute (DTMI). For more information about the offerings and registration options, visit the [DTMI website](#).

**Revised QI Policy Posted on IRB Website**
The IRB has updated its policy regarding Quality Improvement (QI) projects. You can find the revised policy on the [HRPP Policies page](#) of the IRB Web Site.

This policy is titled “Quality Improvement Activities in Health Care Versus Research” and it more clearly distinguishes between QI projects not requiring IRB review, and those projects that cross the regulatory line into the area of research involving human subjects, requiring IRB review. A new checklist is provided at the end of the policy to assist clinicians and researchers planning to conduct QI projects, to help determine whether their proposed activity may require submission to the DUHS IRB.

A clinician/investigator or staff member may always request an authoritative determination from the IRB to confirm or assist with determining if an activity is a quality improvement project. To obtain this determination, the project should be submitted through the eIRB using the new QI template summary, found on the eIRB “Download Forms” page, or the “Forms/Standard Language” page of the IRB Web Site.

**Education Opportunities**

**SRA International Conference**
The Society of Research Administrators (SRA) is holding its Basics of Research Administration Meeting in Louisville, Kentucky on July 10th-12th. Educational credit will be offered for attending the meeting, and more information about registration and the meeting agenda is available on the SRA website.

Updated Guidance on Training Requirements for DON-Supported Researchers
To clarify human research protections training and education requirements outlined in SECNAVINST (Secretary of the Navy Instruction) 3900.39D, the Department of the Navy (DON) has issued new Training and Education Guidance. The new Guidance does not add any new requirements for non-Department of Defense institutions (such as Duke) but we ask that you read and familiarize yourself with the information presented, if you are a Duke Medicine Investigator or Staff Member conducting DON-supported research, and please ensure your compliance with the DON training requirements. As of March 22, 2013, this new Training and Education Guidance is in effect and the DON HRPP Training and Education Guidance of 2011 is cancelled. The new Training and Education Guidance is posted online on the Navy Medicine website as well as the Office of Naval Research website.

If you have questions, please contact DOCR, or the DUHS IRB Office, or Ms. Christy Borders at 703-696-4312 (human.research@med.navy.mil) with the Department of the Navy.

Research Wednesdays
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesday sessions in the month of May. On May 8th, a presentation titled Maestro Care (Epic and Clinical Research Updates) will be given by Denise Snyder, Terry Ainsworth, and Cory Ennis, and on May 22nd the topic will be SOM Informatics Vision and the CTSA presented by Iain Sanderson. On June 12th, Dr. Mark Stacy will present the Duke Medicine Clinical Research Community Update and Q&A. On June 26th, Marilyn Hockenberry will present on the topic of Quality Improvement vs. Research: Updated IRB Policy. All sessions will be held at 12:00pm in Duke North 2001. Click here for more information about these events.

Don’t Forget!

Required Human Subjects Research Training
For Duke Medicine employees who engage in or support clinical research at Duke, the Human Subjects Research at Duke training course is required. This training is available online in the SABA Learning Management system in an audio format or text format, and users can choose the one that suits their needs. Please follow the instructions below to register, complete, and take either the on-line module and assessment or just the assessment.

1. Go https://bcw-lmsa.duhs.duke.edu/SabaLogin (log in with your Net ID and password)
2. On the Home page go the Catalog Search box, enter hsr and click Search.
3. Click the blue Register link for the DOCR HSR at Duke (the Audio Version and Text Version will be available in the search results) or DOCR HSR Assessment 1 course.
4. The course should auto launch, if not click the Launch Content link.
5. View all the slides (if you registered for the (Web Based) and complete the quiz (80% or above is needed to pass).

**ResearchMatch at Duke**

Sign up for ResearchMatch. Research Match is a tool that can help recruit participants for your study. There are 1,150 volunteers registered on the site within 50 miles of Duke and this number continues to grow. We’ve already had a number of researchers register and begin recruitment efforts through ResearchMatch. If you have questions about how ResearchMatch can help you recruit participants or if you would like to become a research volunteer, please contact DOCR or visit our [ResearchMatch](#) page.

**Frequently Asked Questions**

**Data Capture Survey Programs at Duke**

If you are interested in collecting research data using a web survey, Duke has two survey tools already reviewed and approved for this type of data collection: Qualtrics and REDCap Survey. Qualtrics is a robust, vendor-supported survey tool available through OIT, in which Duke has established a Business Associates Agreement (BAA). Information regarding the use of Qualtrics can be found on the [OIT website](#). REDCap Survey is another survey tool that is designed for web-based data capture. This survey tool is supported through the Duke Office of Clinical Research and all data is stored on servers located behind the Duke firewall. REDCap Survey is academically licensed with Vanderbilt University through the Clinical and Translational Science Awards (CTSA). Information regarding the use of REDCap can be found by visiting the [REDCap Training](#) website or by contacting the [Duke Office of Clinical Research REDCap team](#).

**Data Management Support through REDCap and DOCR**

DOCR has been approached to assist study teams with data management needs. We would like to help the CRUs with any “unfunded” work that will benefit from moving data collection out of Excel or MS Access to REDCap. Each CRU can work with DOCR to develop a triage plan for these “unfunded” projects.

Also, DOCR would like CRUs to encourage funded, investigator-initiated projects to use REDCap for data collection, but these funded studies can be handled through the Research Management Team (RMT) data services. Please contact Susan Budinger at [Susan.Budinger@dm.duke.edu](mailto: Susan.Budinger@dm.duke.edu) or 919-613-8278 for more information. In addition, Susan will be notifying CRUs when investigators and study teams propose work with DOCR. We are planning to visit CRUs to demonstrate more of what the Research Management Team (RMT) can do for your CRU investigators and study teams.
Sending Appointment Information to Study Participants Via E-mail

Q: I have a lot of trouble with my study participants understanding how to use the Duke secure mail when communicating appointment information. Is there a way for me to send them appointment information without using the "Sensitive Electronic Information" button [also known as placing (SEND SECURE) in the subject line of the email]?  

A: Communicating appointment information to a patient can be done without using the “Sensitive Electronic Information” button so long as the communication does not contain information regarding specialty, disease group or research protocol. It would be acceptable to include information such as date, time, physician name, or name of clinic (so long as the name of the clinic does not give away the specialty – So Clinic 1A would be appropriate, but Breast clinic would not be acceptable).

CRU Corner

Orthopaedic Surgery CRU
Maria Manson recently became the Research Practice Manager for the Orthopaedic Surgery CRU.

Oncology CRU
Lynn Spear recently became the Research Practice Manager for the Oncology CRU.

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