Duke University School of Medicine
Clinical Research Update
March 2014

What’s New?

Maestro Care Completed Studies
Has your study recently completed? Did subjects complete study activity during the initial migration period to Maestro Care? Either way, it’s time to review the study status information for all the patients who have been enrolled in Maestro Care. Please log into Maestro Care and update the status to “Completed” for all study patients who are no longer “active” in Maestro Care. This includes “Enrolled Bill Risk and Enrolled Non-Bill Risk” categories.

Second Sign for Beacon Studies in Maestro Care
Clinical Research Coordinators (licensed and non-licensed) are approved to tee-up orders and have them second signed in the DUHS. That means that the order must be signed by a provider before it is acted upon. For Registered Nurses (RNs), this process is different than the functionality they would have if they were a DUHS nurse. Recently, it was discovered that some CRC RNs had the ability to implement orders prior to a provider signing it. This ability to get a verbal order and act upon it prior to a provider signing it was removed from the CRC RNs who had it this week.

Research Active Flag No Longer Pink
Please note that the Research Active “flag” in Maestro Care is no longer pink, with the exception of Duke Raleigh. Although it is not pink, the functionality of pulling up the research protocol is still present. When working with clinicians and providers, please educate them about this recent change.

Linking to the Timeline in Maestro Care
Recently, Maestro Care users have reported issues linking encounters to their timeline. If a request is made to edit a timeline (even if it is only a change to edit the visit due dates or visit windows) a new version of the timeline is required. Any patients that have already been added to the timeline will need to be added to the newest version of the timeline in order to be able to link encounters to specific visits on the study. To add the patient to the new version of the timeline, click the “Add to Timeline” button in the upper right corner of the timeline section. Choose the newest version of the timeline, and enter the visit dates. Any past visits already associated with that patient do not have to be moved to the new timeline, but any future visits needs to be added to the timeline. Instructions for linking to the timeline are also available on
Note: if you only need to change the dates on your timeline, you can do that manually and do not need to change the timeline version.

**Changes to the Regulatory Binder Checklist**
DOCR has recently retired the retrospective chart review documentation requirements guidance document, and this information has been incorporated into the Regulatory Binder Checklist instead. Study documents that need to be maintained in a regulatory binder (based on study type) can be located in the checklist, and a copy of the document is available on the [DOCR website](#).

**Important Changes to the Maestro Care RHB233 and RHB234 Reports**
Some important changes have recently been made to the Maestro Care RHB233 and RHB234 Reports. First, the single/multi fund code reports can now be processed as an Excel file. The second change involves the process for submitting the PB or HB Charge Corrections Request Forms. The PB and HB Charge Corrections Request forms are now located on the [DOCR website](#), and should only be submitted via email (not through a Service Now ticket):

- **PB** (Professional Charges) should be entered on the Maestro Care Request Form and sent to PRMO-EpicPBChargeCorrections@dm.duke.edu.
- **HB** (Technical Charges) should be entered on the Maestro Care Request Form and sent to PRMO-EpicHBChargeCorrections@dm.duke.edu.

**Duke Regional and Duke Raleigh are Live on Maestro Care!**
As of March 1st, all Duke Health System hospitals are using Maestro Care! DOCR has been communicating with personnel who work with research protocols at both hospitals in preparation for the change. During the first week, Terry Ainsworth will be on site at Duke Raleigh and Chris Chin will be on site at Duke Regional for assistance. We do not anticipate any problems for research, but want to make sure that individuals are available for support. Please contact docr.help@dm.duke.edu if you experience any research-related problems at these hospitals.

**Monitoring Consent for Order Scheduling and Enrollment for Studies that Order and/or Bill in Maestro Care**
Now that all patient-based clinical research activity is live on Maestro Care, DOCR has retired the former activities related to eResearch validation. This monitoring activity will be replaced with a revised review of consent activities for billing studies, and DOCR is scheduled to begin monitoring in April/May. A revised policy detailing the new process is available on the [DOCR website](#).

**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) whether to place a copy of the consent form in the subject’s medical record or to maintain it in the regulatory binder for the study.

Education Opportunities

Global Health 2035 Event
Global Health 2035: A World Converging within a Generation is a discussion sponsored by the Duke Global Health Institute. The event is free to participants, and will provide information about the findings of the Global Health 2035 report followed by a reception. The discussion will be held on April 1, 2014 from 3:30pm-6:00pm in the Mary Biddle Trent Semans Center for Health Education. More information and registration is available on the Duke Global Health website.

Research Wednesdays
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesdays sessions in the month of March. On March 12th, Mina Silberberg will present Community Engaged Research, and on March 26th, Terry Ainsworth will present Devices. More information is available on the DOCR website.

Adverse Events Training
The first Adverse Events training session was held in February and was well attended. This course will help participants define adverse events and unanticipated problems, and it will help investigators identify study team member responsibilities in recognizing these events. It will also define reporting responsibilities of study team members to the FDA, funding agencies, and the DUHS IRB. The next course will be offered on April 16th from 2:00pm-4:00pm, and registration instructions are available on the DOCR website.

RDSP Training Available
Research Data Security Plan (RDSP) trainings are still available for research teams who are completing RDSPs. We have moved the RDSP Training taking place on March 13, 2014 from 8:30am-9:30am to Duke North Lecture Hall, Room 2002 to accommodate additional
attendees. No registration is necessary for the event, but please remember to bring your Duke ID badge to check into the session.

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

1. *Research Data Integrity/Data Security* will be held on April 15th.
2. *Human Subjects Research at Duke* will be held on April 15th.
3. *Informed Consent* will be held on April 10th.
4. *Study Documentation: Regulations and Best Practices* will be held on April 21st.
5. *Workshop: Informed Consent Writing* will be held on April 1st.
6. *Investigator Responsibilities* will be held on April 8th.
7. *Adverse Events* will be held on April 16th.

**Don’t Forget!**

**Adjunct Faculty on Key Personnel Lists**
The IRB confirmed with University Counsel that Adjunct Faculty should be removed from internal key personnel lists in the eIRB system. Adjunct faculty should be listed as outside key personnel if they are involved in a particular protocol at Duke.

**HSR Annual Training is Required!**
Thanks to everyone who has taken their Human Subjects Research at Duke (HSR) Training. Since training is required annually, please make sure to take your HSR training when you are automatically notified in the Saba LMS system about a renewal. Also, if you are new to clinical research, you have 90 days to complete the online training. Overall compliance with the HSR Training policy is at 91% for all faculty and staff, and registration instructions for completing the training are available on the [DOCR website](#).

**HSR Annual Renewal**
What happens if I don’t complete my HSR Recertification by the due date?

- The Duke LMS system will not show you as “successfully completed” because you completed it after the expiration date which then your record will be considered ‘non-compliant’
- If the expiration date has passed and you are registering for the ‘Refresher’ course per Renewal Instructions – the system will let you register; however, you will not have a ‘Launch’ button

To resolve, you may go back into the Duke LMS and drop yourself from the ‘DOCR – HSR Annual Renewal’ and then Re-enroll yourself in the ‘DOCR – HSR Annual Renewal’ selecting ‘Main’ path. This will then trigger the Duke LMS to show you as complete or if you are unable to see the ‘Launch’ button, it will now be displayed for you to complete.
You may contact DOCR.Help@dm.duke.edu and they will reset your record the same way.

This is why it is important to complete your ‘Renewal’ before the due date. If you have any questions regarding the process, please contact DOCR.Help@dm.duke.edu.

**Frequently Asked Questions**

**Can copays or coinsurance be charged to a fund code?**
Copays and coinsurance are the responsibility of the patient and should not be charged to a fund code. Duke cannot waive copays or deductibles per Medicare rules, and these cannot be charged to the grant even if the sponsor offers to pay. The patient should apply for charity care if there is financial hardship. Based on the assessed financial need, Medicare allows assistance for patients by offering to reduce their payments, but no patient balances can be applied to the grant.

**Where can I find information about RDSPs?**
Information about Research Data Security Plans (RDSPs) is available on the DOCR website. Instructions for RDSP Submissions, as well as an RDSP training presentation are available to users needing additional information.

**Where can I find more information about Maestro Care Financial Reconciliation to SAP/R3?**
A detailed guidance document about Maestro Financial Reconciliation to SAP/R3 is currently available on the DOCR website to assist users in this process.

For additional training, a Maestro Financial Reconciliation to SAP/R3 course is available where participants will learn how to perform reconciliations, run the financial reports, interpret financial reports, and reconcile them to Duke’s General Ledger system. Participants will analyze the reports and make the necessary corrections to ensure the information is accurate, complete, and consistent in both systems. Reports covered in the training session are RHB233 (single fund code report), RHB234 (multiple fund code report), and AMB559 [all patients in clinical trials (enrollment list)], along with a review of the transaction history. The participant will also gain exposure to the CRC’s role in financial reconciliation through monitoring and notification to the financial staff. Registration information is available on the DOCR website, and participants should search for the “Maestro Financial Reconciliation to SAP/R3” course in order to register.

**Tip Sheet for Clinical Research Coordinator Verification of Research Subjects and Services on Maestro Care Reports**
CRCs should work with their financial analysts on financial reconciliation of charges by verifying patient care charges in Maestro. A tip sheet can be found on the Maestro Care Clinical Research
website that provides additional information on CRC Verification of Research Subjects and Services.

**CRU Corner**

**School of Nursing CRU**
The School of Nursing CRU would like to welcome Suzi Berndt to the team. Suzi will be a CRC II and working on three faculty research projects with the SON.

**Orthopaedic Surgery CRU**
The Orthopaedic Surgery CRU would like to congratulate Jennifer Friend on being promoted to CRC II beginning on March 1st.

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