What’s New?

**Request for Maestro Care Volunteers**
Maestro Care is scheduled to go live on June 22\textsuperscript{nd}, and volunteers are needed for support roles. Volunteers will serve as Maestro Care “super users” who are dispersed throughout the user community and act as first-level support for those needing assistance. Volunteers would continue to work within their unit and perform their job, but would also be available to other staff needing assistance. If volunteers are unable to solve a Maestro Care issue, then they may refer individuals to the DHTS Help Desk/Maestro Care Research Command Center or complete a paper form for a Service Now request, depending on the nature of the issue. The volunteer support role will take place from June 23\textsuperscript{rd} - July 12\textsuperscript{th}. For more information or to volunteer, please contact Cory Ennis at cory.ennis@duke.edu.

**Maestro Care Training for Clinical Research Intranet Page**
The Maestro Care Training page for clinical research can be found at the following web address: [https://intranet.dm.duke.edu/sites/MaestroCare/SitePages/ClinicalResearch.aspx](https://intranet.dm.duke.edu/sites/MaestroCare/SitePages/ClinicalResearch.aspx). This page contains all of the information available to study teams about using Maestro Care within clinical research as well as information about town hall meetings and trainings. Please be sure to visit this page to find valuable resources and announcements as Duke transitions to using Maestro Care.

**Maestro Care goes live for Clinical Research on June 22\textsuperscript{nd}**
On June 22, Duke Maestro Care at Duke University Hospital and 127 ambulatory clinics will go live. Importantly, on that same day, the clinical research component of Maestro Care also will go live. Maestro Care will transform clinical research management by offering standardized, streamlined and more efficient access to data across the clinical research enterprise. This new technology will create one system with which to manage site-based clinical research, including patient registration for research protocols, clinical research appointments, billing, and clinical research orders. It will reduce the complexity caused by using multiple systems and will dramatically improve the workflow process. eBrowser and other clinical research management systems used in the past will be retired simultaneously on June 22 as Maestro Care goes live. Beginning on June 22, faculty and staff engaged in clinical research with patients will begin to use Maestro Care for the management of existing protocols as well as select new protocols. Eventually, Maestro Care will be used to manage all protocols involving patients.
Individuals who will be using Maestro Care to manage clinical research involving patients have been trained or are currently undergoing training.

Support and Additional Information is Available
• For faculty and staff using Maestro Care to manage clinical research involving patients, information including a comprehensive Quick-Start Guide can be found at maestro.duke.edu under the Maestro Care – Clinical Research tab in the left-hand navigation.

• Individuals with questions can contact docr.help@dm.duke.edu.

In addition, those individuals who will be using Maestro Care for clinical research management should plan to attend one of the upcoming Town Hall Meetings in preparation for Go-Live:
• Town Hall Meetings
  • Tuesday, June 11, 5-6 p.m., Great Hall, Mary Duke Biddle Trent Semans Center
  • Wednesday, June 19, 5-6 p.m., Great Hall, Mary Duke Biddle Trent Semans Center

• Individuals also can also attend the Duke Office of Clinical Research (DOCR) “Research Wednesday” meetings on June 12, in room 2001 of Duke North, from 12 – 1 p.m. DOCR staff will be available to provide information and answer questions about the use of Maestro Care for clinical research involving patients.

Thank you to everyone for your hard work in preparation for this important milestone for Duke’s clinical research enterprise.

Maestro Care Playground
Clinical research coordinators and staff who have attended Maestro Care training for clinical research do not have immediate access to Maestro Care. DOCR will be providing this information to the Maestro Care team and alert you when you have access to the system. In the meantime, please check out the Maestro Care Playground, download Hyperspace to your computer, and practice, practice, practice! Familiarize yourself with the navigation so you are ready to go on June 22nd!

DCRU Volunteer Registry
The Duke Clinical Research Unit (DCRU) recently created a Research Volunteer Registry that is available online for individuals who want to participate in clinical trials. The Registry has been approved for use by the IRB, and it allows individuals to provide their information and find out if they may qualify for a clinical trial. More information about the Registry is available on the DTMI website.

Current Grid Process to be Revised
DOCR will be changing the current process for how grids are built and reviewed. Beginning July 8th, instead of sending a billing risk determination e-mail, DOCR will email study teams to schedule a meeting to discuss their protocol and related study documents. Study teams will no longer need to send DOCR a grid to review. From this meeting, DOCR will gather the information necessary to create the study calendar and order set that will be built in Maestro Care. DOCR will release the study for institutional approval in the eIRB system once all approvals are met. We hope that by beginning this process in the early stages of IRB submission, DOCR can provide better navigation for study teams throughout the study approval process at Duke. If you have questions about this process change, please contact Patrick Barrera at 668-2349 or Patrick.Barrera@duke.edu.

**HITECH Final Regulations Require Executing Revised Business Associate Agreements**
The Health Information Technology for Economic and Clinical Health Act (HITECH) final regulations require Duke Medicine to revise its current Business Associate Agreement (BAA) template. The Duke Medicine [Business Associate Policy](#) and [agreement template](#) have been updated to incorporate the requirements of the HITECH regulations. Business Associates are also required to execute a business associate agreement with its subcontractors. If Duke Medicine is functioning as the covered entity (i.e., a provider, or a business associate performing services on behalf of a provider), Duke Medicine is required to enter into a business associate agreement before sharing protected health information. Staff members are required to use the revised Duke Medicine BAA template. Current agreements that include an existing business associate agreement must be replaced with the revised Duke Medicine template at the time of renewal or no later than September 22, 2014, whichever comes first. Any new agreement requiring a BAA should use the new template, available on the [Duke Medicine Intranet](#). Please contact the Office of Corporate Research Collaborations with any questions regarding the requirements of Business Associate Agreements.

**Education Opportunities**

**ACRP Deadline Approaching**
Applications are due on July 31, 2013 for The Association of Clinical Research Professionals (ACRP) CRC certification exam. Applications are accepted until August 14th, but a late fee of $150 will be charged, so be sure to apply for the exam as soon as possible. More information about the exam is available on the [ACRP website](#).

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesday sessions in the month of June. Iain Sanderson will present *Maestro Care: More Updates for Clinical Research* on June 12th and Marilyn Hockenberry will present *Quality Improvement vs. Research: Updated IRB policy* on June 26th. Both sessions will be held from 12:00-1:00pm in Duke North 2001.
Don’t Forget!

Maestro Care Go-Live Reminder
Please remember that after the Maestro Care Go-Live on June 22nd, your primary study management activities should occur within Maestro Care rather than eResearch. Enrolling patients to studies, changing subject statuses, and scheduling appointments will all occur within Maestro Care. eResearch will remain available and may be utilized for tracking non-Duke patients as well as additional data elements related to Duke patients not available within Maestro Care (such as some data required for NCI reporting). In addition, the Subject Billing Registry will remain accessible in a view only format, but updates from eResearch will no longer be added and the data should be viewed as archival.

Reminder about ResearchMatch at Duke
Study teams wanting feasibility access to ResearchMatch need only be affiliated with Duke to gain access to the site. Feasibility access allows you to view and search aggregate data within ResearchMatch, but you may not contact volunteers. Study teams wanting recruitment access to ResearchMatch, giving them the ability 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, visit our ResearchMatch page for more information or contact docr.help@dm.duke.edu with any questions.

ClinicalTrials.gov and DOCR approval in eIRB
An additional requirement has been added to the DOCR study approval process in eIRB. Shortly after study submission in eIRB, DOCR staff contacts study teams via email to determine if ClinicalTrials.gov registration is required for their study. For internal investigator-initiated studies that require registration in ClinicalTrials.gov under the FDAAA law (i.e. “Applicable Clinical Trials” or “ACTs”), the study must be registered in ClinicalTrials.gov before DOCR study approval will be granted in eIRB. DOCR staff will contact study teams to confirm the ClinicalTrials.gov NCT# has been assigned and enter this number into eIRB. Please note that you do not need IRB approval to register your study in ClinicalTrials.gov. Beginning your study registration promptly will help ensure timely assignment of the NCT#. For questions, please contact Nancy Hassell at 919-684-9425 or email docr.help@dm.duke.edu.

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](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).

### Frequently Asked Questions

#### Minors in Research
Duke Human Resources has posted a policy on their website detailing the behavioral expectations of adults who work with children between the ages of 14 and 18 in a laboratory setting. The policy contains specific guidelines about working with minors in a laboratory setting at Duke University, and the full policy can be found on the [Duke Human Resources website](https://www.duke.edu).

#### When is a BAA Needed?
Under HIPAA regulations, a Business Associate Agreement (BAA) is required between covered entities and business associates when they are working to perform "treatment, payment, or operations" functions. However, research does not necessarily fit into these categories, so a BAA is not needed for most activities within research. Researchers do still have a responsibility to abide by the data transfer agreements that Gil Smith described in his Research Wednesdays presentation on March 13th (this presentation is available on the [DOCR website](https://www.docr.duke.edu) under the “Training and Education” section). A BAA is required for the creation of a limited data set or de-identified data set if the person doing the work is not part of the Duke workforce. Contact the Compliance Office or the Information Security Office for more information or questions about utilizing a BAA.

#### Attempting to Consent Potential Subjects after Refusal
You **cannot** approach a potential study subject to recruit them for a research study if they have already refused to consent for that same study in the past. It does not matter how long ago they may have refused to consent—if they said “no”, you may not re-approach. However, you may recruit this potential subject for a **different** research study if you believe they may qualify. If you have any questions about this scenario, please contact your IRB Specialist or [contact the IRB](mailto:irb@duke.edu) at 919-668-5111.
CRU Corner

Oncology CRU
Congratulations to Jennifer Mewshaw, RN for achieving her Oncology Certification in Nursing (OCN), and for being awarded an academic scholarship from the American Cancer Society!

The Oncology CRU would like to welcome Tanya Maxey, RN as a new Clinical Research Coordinator in the Cooperative Group Office. Welcome, Tanya!

Congratulations to Nyssa Schwager, RN, MSN as she has recently completed her Duke MSN – Clinical Research Management and Administration in May 2013!

Heart Center CRU
The Heart Center CRU would like to introduce our newest members: James Gibbs, RN, CRC I and Samantha Wootton, CRC II both joined the Catheter cluster. Susan Gerstl, RN, CRC I recently joined the EP cluster. Welcome to the team!

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