What’s New?

New Temporary Monitor Request Procedure
Beginning October 14, 2013 any temporary monitor request to access electronic medical records must be sent to the Health Information Management (HIM) office using the new online system. Users can access the new e-form system at the following link: https://redcap.dtmiduke.edu/redcap/surveys/?s=pyuZcW, and it will also be available on the DOCR website beginning in mid-October. At this time, requests will go directly to HIM through the new system and will no longer be sent to the DOCR inbox. The required information on the form is the same as the old paper forms and should seem very familiar. Requests, once submitted, are not able to be amended. However, if you submit a request and need to change it, you simply submit an additional request to update your information. Please send any questions about the new process to docr.help@dm.duke.edu.

Updated HSR Training Available
Beginning on October 3rd, an updated version of the annual Human Subjects Research at Duke (HSR) online training will be available in the SABA Learning Management System. Users will take the updated version of the training moving forward, and new registration instructions are listed below (and are also available on the DOCR website):

1. Go to https://bcw-lmsa.duhs.duke.edu/SabaLogin and log into the system using your Net ID and password. If possible, please use Internet Explorer (rather than Firefox or Google Chrome) for the course to work properly. If you are unable to log into Saba with your net ID and password, please contact DHTS at 684-2243 for assistance.
2. From the Home Page under Catalog Search, Select “Required Learning” from the drop down menu.
3. Type DOCR into the Search box and select “Search”.
4. Click “Begin Registration” under the “DOCR-HSR Annual Renewal” course.
5. Click “Complete Registration”
6. Click “Launch Content” to begin the course.

Please send any questions about the updated training to docr.help@dm.duke.edu.

Clinical Trials Disclosure Policy Modification
Effective January 1, 2014, CMS will require reporting a clinical trial number (NCT number) on claims for items and services provided in qualified clinical trials. More information is located on
the **Palmetto GBA website**. In anticipation of this change, DOCR has updated the Clinical Trials Disclosure policy. DOCR will work with PRMO and study teams to ensure the NCT number is recorded in Maestro Care for all Qualifying Trials.

**Phlebotomy Competency for Research Course**
The “Phlebotomy Competency for Research” course is now available through DOCR, and is being offered on October 30\(^{th}\) and November 22\(^{nd}\). This course describes the process for safely completing a venipuncture and provides an opportunity to practice venipuncture under instructor supervision. Please note that this course verifies competency for a research study team member (who is not otherwise licensed or certified) to perform a venipuncture on an adult. This course does not train the participant to be a phlebotomist or certify the participant in any way, and more information is available in the Phlebotomy Training Policy. Registration information for both courses is available on the DOCR website.

**DOCR Satisfaction Survey Results**
During the month of August, DOCR solicited responses to our customer satisfaction survey. **THANK YOU** for all your responses. We received 276 responses and will use these data and your comments to improve our services over the next year. Please continue to send your feedback to DOCR.help@dm.duke.edu throughout the year. We welcome your partnership in fostering a strong research community!

<table>
<thead>
<tr>
<th>DOCR CONTRACT WORK</th>
<th>Cost (salary + fringe) of using DOCR (former RMT) staff</th>
<th>Ease of getting an estimate for DOCR (former RMT) support</th>
<th>Benefit to your research</th>
<th>Data integrity, compliance and security</th>
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<tr>
<td>Very dissatisfied</td>
<td>0.0%</td>
<td>0.0%</td>
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<tr>
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<table>
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<th>Benefit to your research</th>
<th>Format offerings</th>
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</tr>
<tr>
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<td>5.0%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Somewhat satisfied</td>
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<td>45.3%</td>
<td>39.7%</td>
</tr>
<tr>
<td>Very satisfied</td>
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<td>44.8%</td>
<td>48.6%</td>
</tr>
<tr>
<td>Ease of process</td>
<td>Benefit to your research</td>
<td>Responsiveness of support staff</td>
<td></td>
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<td>-----------------</td>
<td>--------------------------</td>
<td>-------------------------------</td>
<td></td>
</tr>
<tr>
<td>Very dissatisfied</td>
<td>5.5%</td>
<td>7.7%</td>
<td>3.6%</td>
</tr>
<tr>
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<td>3.5%</td>
<td>7.9%</td>
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<tr>
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<td>35.9%</td>
<td>25.7%</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>51.4%</td>
<td>52.8%</td>
<td>62.9%</td>
</tr>
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</table>

**Speed Science Event**

Duke Translational Research Institute (DTRI), the Office of Biostatistics and Bioinformatics, and the Duke Office of Clinical Research will be holding a Speed Science Event on October 24, 2013 from 3:00pm-6:00pm in the Searle Center Lecture Hall. This event is aimed at the many clinical and translational investigators at Duke who would like to incorporate "omic" methods into their research, but lack the quantitative expertise to properly analyze the data, as well as computational researchers who develop advanced analytic methods, but lack high quality datasets to which to apply them. The event will be divided into three sessions:

- **Hour 1**: Each participating *in vitro/vivo* researcher will give several 7-minute interactive presentations of his/her research interests, scientific questions, biospecimens, and data types to small groups of quantitative researchers.

- **Hour 2**: Each participating *in silico* researcher will give several 7-minute interactive presentations of his/her research, desired data types, and analytic expertise to small groups of clinical and translational researchers.

- **Hour 3**: Networking and posters over food and drink.

Registration and additional details about the event are available online.

**ResearchMatch Adds New Sub-Registries**

ResearchMatch recently added several new sub-registries to collaborate with researchers and volunteers who are studying a specific condition. Sub-registries for Postural Orthostatic Tachycardia Syndrome (POTS), Ehlers-Danlos Syndrome (EDS), and Eosinophilic Esophagitis were added to ResearchMatch in September in an effort to facilitate new research for these conditions. More information about the new sub-registries is available on the ResearchMatch news page. To register as a volunteer or a researcher in the system, please visit researchmatch.duke.edu.

**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 are listed as key personnel on clinical
research studies 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.

**Education Opportunities**

**eIRB System Training Available**
The IRB Office offers customized training on navigating the eIRB, including preparation of IRB submissions. Research groups or individual researchers with a need for targeted eIRB training should email Minna Pak in the IRB office at minna.pak@duke.edu. The email should contain the number of individuals to be trained and the requested training emphasis (navigation, submissions, ancillary reviews, etc.).

**SAVE THE DATE! 2013 Symposium for Research Administrators**
The annual 2013 Symposium for Research Administrators will be held on Thursday, November 7, 2013 at the Hilton Durham near Duke University. This year’s Symposium focuses on *Dynamics for Tomorrow’s Research Administration* and will provide insight into the many changes and enhancements occurring both federally and institutionally. Additionally, there will be some clinically-focused sessions. To register for the 2013 Symposium for Research Administrators and learn about how to become a volunteer, please visit http://finance.duke.edu/research/training/symposium/index.php.

**Clipp Symposium on Trajectory Science**
The Duke University School of Nursing and the Duke Center on Aging & Human Development will hold the Clipp Symposium on Trajectory Science on October 9, 2013 from 1:00pm-5:00pm. The event will feature a panel presentation on trajectory science at Duke among other speakers. Additional information and registration instructions are available on the School of Nursing website.

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesday sessions in the month of October. On October 9th, DOCR will host a panel discussion titled *What Can Your CRU Do for You?* featuring Ken Lyles, Amy Murtha, Phyllis Kennel, Catee Mullen, Christeen Butler, and Zarrin Brooks, and on October 23rd, Julia Trimmer and Damaris Murry will present Scholars@Duke. Both sessions will be held from 12:00pm-1:00pm in Duke North 2001. Click here for more information about these events.

**Upcoming DOCR Trainings**
The following DOCR trainings will be held in the months of October and November for research staff at Duke, and registration instructions are available on the DOCR website:
1. **Research Data Integrity/Data Security** will be held on October 10th, October 24th, November 4th, and November 20th.
2. **Human Subjects Research at Duke** will be held on October 10th, October 24th, November 4th, and November 20th.
3. **IRB Overview** will be held on October 22nd and November 19th.
4. **Informed Consent** will be held on October 17th and November 11th.
5. **Study Documentation: Regulations and Best Practices** will be held on October 16th and November 18th.
6. **Phlebotomy Competency for Research** will be held on October 7th, October 30th, and November 22nd.
7. **Investigator Responsibilities** will be held on October 15th.
8. **Workshop: ClinicalTrials.gov Results Entry** will be held on October 21st.
9. **Urine Pregnancy Screening for Research** will be held on October 14th and November 12th.
10. **Financial Basics for Clinical Research** will be held on November 5th.

**Don’t Forget!**

**Basic Science Day**
The School of Medicine will hold its fourth annual Basic Science Day on October 14, 2013 in an effort to recognize progress in basic research at Duke University. The conference will feature keynote speakers Donald McDonnell, Ph.D. and Robert Lefkowitz, M.D. among other notable speakers. More information about registration and the events of the day are available on the [School of Medicine website](https://medicine.duke.edu).  

**Clinical Science Day**
The School of Medicine’s third annual Clinical Science Day will take place on October 18, 2013 to celebrate the clinical research activities taking place across campus. Keynote speaker Kurt Newman, M.D. will present *Leadership Lessons from the Laboratory* along with other sessions throughout the day. More information and Registration is available on the [School of Medicine website](https://medicine.duke.edu).

**National CyberSecurity Awareness Month**
October celebrates the 10th anniversary of National CyberSecurity Awareness Month (NCSAM). Duke Medicine and Duke University Information Security Offices will host a number of events and activities including weekly blogs, drawings for prizes, and practical tips on how to keep information secure, both at work and at home. Duke University events will be posted through the Duke Information Technology Security Office ([ITSO](https://security.duke.edu)) and Duke University Health System events will be posted through the Duke Medicine Information Security Office ([ISO](https://infosec.dukemedicine.org)). Check back weekly for new information and chances to win! To get started, faculty, staff and students are encouraged to participate in an online quiz during the entire month of October to facilitate how to recognize and report phishing.
activity. Those who enter will be eligible for weekly giveaways and a Grand Prize drawing for an iPad Mini.

**Encryption Requirement for SEI**

The [Duke Medicine Mobile Computing and Storage Device Standard](#) outlines the requirements for encryption of Sensitive Electronic Information. Any mobile computing and storage device containing Duke Medicine SEI, regardless of ownership, must employ encryption as outlined in the standard. Duke Medicine laptops must employ Whole Disc Encryption (WDE) and have the IBM Endpoint Manager (IEM) client installed. Other mobile storage devices (such as flash drives, discs, tablets, etc.) may use WDE or file encryption. An [Encryption FAQ](#) and instructions on [How to Encrypt](#) are available to assist Duke Medicine employees in meeting these requirements.

<table>
<thead>
<tr>
<th>Device</th>
<th>How to Encrypt</th>
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<tbody>
<tr>
<td>Windows laptop</td>
<td>Symantec WDE</td>
</tr>
<tr>
<td>Mac OS X laptop</td>
<td>Symantec or FileVault2* WDE</td>
</tr>
<tr>
<td>Tablets, smart phones</td>
<td>WDE native to device</td>
</tr>
<tr>
<td>Flash drives, discs, CDs, DVDs, other</td>
<td>Symantec file encryption or other AES 256 apps</td>
</tr>
</tbody>
</table>

*allowed via current policy exception

**Staying Compliant with the NIH Public Access Policy**

Current PIs must create a My NCBI account and use My Bibliography to track compliance with the NIH Public Access Policy. The process is easy, and full instructions are available at on the [Medical Center Library website](#).

Please be sure to submit the manuscript for new publications within 90-days of the publication date:

- NIH begins the countdown from the e-publication date or the print date, whichever is earlier.
- If the journal is submitting the manuscript, monitor the citation to make sure they submit it within the deadline.
- Follow up with the journal if you’re not sure whether or not the journal is submitting the manuscript.
- You can begin the submission process of your own version as soon as it is accepted.

Is my article covered by the policy?

- Peer-reviewed research articles MUST be submitted.
- These items are EXEMPT, BUT YOU MUST CHANGE the status in My Bibliography
  - Letters, editorials, reviews of the literature, case studies, and conference proceedings
  - Researchers and activities that were NOT DIRECTLY funded by your grant
  - Grants that ended before April 2008
  - Articles accepted for publication before April 7, 2008
- Follow the instructions at the following website to change the status in My Bibliography: [http://guides.mclibrary.duke.edu/content.php?pid=432927&sid=3541944](http://guides.mclibrary.duke.edu/content.php?pid=432927&sid=3541944)
Have questions about what needs to be submitted, or need assistance with any of the steps towards being compliant? Call the Medical Center Library Service Desk 919.660.1100 or email medical-librarian@dm.duke.edu and ask for assistance with the NIH policy!

Frequently Asked Questions

Do Monitors Need to Fully Log Out of Maestro Care When Leaving a Release to Inspector Record?
Monitors must fully log out of Maestro Care when leaving the record. If they simply close the window, the next time any person signs in with the user name and password, even if they have a different “key”, the patient list from the previous user will populate.

What Should I Do With Sponsor Site Questionnaires Asking About Maestro Care?
Many study teams are receiving site questionnaires from sponsors requesting information about Maestro Care. DOCR is in compiling a list of these questions and answers from the various forms that can be accessed on the DOCR website. If you have additional questions from sponsors that you are not able to answer after reviewing the list of commonly asked questions, please send the questions and/or forms to Lindsey Spangler (Lindsey.spangler@duke.edu) who will be able to help you answer the questions or get additional information from the Information Security Office (ISO).

When Can I Send an MRN to a Sponsor?
As with a patient’s name or other direct identifier, sending the MRN requires a scientific need and a modification to the ICF to state that it is being sent to the sponsor.

How Do I Update a Retrospective RDSP?
Individuals who need to update a retrospective RDSP (i.e. a protocol that has previously been submitted using a REDCap Survey) can do so by submitting a request to docr.help@dm.duke.edu. DOCR will process the request and create a new version of the REDCap Survey information and return it to the requestor. Please send any questions about this process to docr.help@dm.duke.edu.

What Should I Do if DOCR Hasn’t Approved My Study in eIRB and I Have a Site Initiation Visit That Requires IRB Approval?
If the IRB has approved your study, you can view and print the study letter provided in eIRB that shows your study has been reviewed and approved by the IRB (click “View” next to IRB Action Notice, see below). Not having DOCR approval does not indicate that your study has not been IRB approved, it is only the mechanism used to make sure all the necessary pieces are in place in Maestro Care before you can actually begin enrolling subjects.

<table>
<thead>
<tr>
<th>Codes:</th>
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</thead>
<tbody>
<tr>
<td>IRR Review Type:</td>
</tr>
<tr>
<td>IRR Primary Reviewer:</td>
</tr>
<tr>
<td>IRR Review Date:</td>
</tr>
<tr>
<td>IRR Action Notice:</td>
</tr>
<tr>
<td>Current Expiration Date:</td>
</tr>
</tbody>
</table>
CRU Corner

Heart Center CRU
The Heart Center CRU would like to welcome Pat Beck, who will be the new Financial Practices Manager. Welcome, Pat!

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