What’s New?

HIPAA Compliance Presentation
The Duke Medicine Information Security Office will be hosting a HIPAA compliance update presentation titled "Preparing for Omnibus Rule Enforcement & Compliance Audits" from CynergisTek's Mac McMillan on Friday, September 6th from 9:00am-11:30am. The event will be held in the ground floor auditorium of Hock Plaza. The event is free, but attendees are asked to pre-register at the following webpage: http://cynergistek.com/hipaa-compliance-updates-in-north-carolina/ to ensure an accurate head count. The agenda is as follows:

- 9:00am – 10:00am: How to Prepare for Omnibus Rule Enforcement
- 10:00am – 10:30am: Interactive Q&A Session
- 10:30am – 11:30am: Audit Roulette – OCR Random Audits, OIG, CMS & Outlook of Enforcement Trends. What’s your audit readiness score?

If you have any questions about the event, please contact the Duke Medicine Information Security Office at iso@mc.duke.edu.

New Standard IRB language for Images
Shelly Epps from the Information Security Office (ISO) and Doc Muhlbaier from the SoM Compliance Office recently presented information about hidden PHI identifiers within images during the DOCR Research Wednesdays series. Most images will not be fully de-identified or anonymized, as they will usually retain study dates to maintain the clinical utility of the exams as well as to meet audit requirements. Researchers are encouraged to use new IRB standard language when they are sending images to a sponsor or other outside entity. If you missed the recent DOCR Research Wednesdays presentation, slides are available on the DOCR website.

Gabriella Hecimovich Joins OCRC
The Office of Corporate Research Collaborations (OCRC) welcomes Gabriella Hecimovich as a Clinical Contracts Manager. Gabby holds a Bachelors of Business Administration, International Finance & Marketing from the University of Miami, and a JD from the New England School of Law. She has extensive and varied legal experience, most recently at Blue Cross and Blue Shield of North Carolina, where she was a Contract Negotiator and Business Risk and Compliance Advisor. Welcome, Gabby!

New Payment Term Guidelines and Duke University Established Facilities and Administrative Rate (F&A)
The Duke University School of Medicine Industry Clinical Trial F&A rate remains at 28%. As of June 30, 2013, the School of Medicine implemented a policy stating that all new industry-funded clinical trials should also contain a CRU Management Charge of at least 10% that is incorporated into the study’s direct cost budget (Internal Cost Assessment). This management charge may be labeled as such in the negotiated budget shared with an industry sponsor or it does not have to be shown. In either case, the management charge is intended to be an internal charge derived from the “margin” built into a study budget to support the CRU infrastructure. The institutional F&A rate should always be reflected as 28% and should not be combined with the 10% or greater CRU Management Charge (i.e., do not list the rate as 38%). If you have any questions about the implementation of the CRU Management Charge, please contact Michelle Smith or Ellen McCarthy Steinour in the School of Medicine Finance office (michelle.smith@duke.edu or 668-4037 and ellen.mccarthy@duke.edu or 684-4868).

**Education Opportunities**

**New Education/Training Sessions**
School of Medicine Finance is holding a new training in September titled “Financial Basics for Clinical Research” for those who want to gain a broad understanding of financial concepts associated with the life cycle of a clinical research study. The course will be held on September 23rd from 9:00am-11:00am in Erwin Square. In addition, the “Phlebotomy Competency for Research” course is now available through DOCR, and is being offered on September 26th and October 7th. This course describes the process for safely completing a venipuncture and provides an opportunity to practice venipunctures 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.

**SRA Annual Meeting**
The Society of Research Administrators (SRA) is an organization that supports research administrators internationally in various settings including universities and hospitals. SRA will be holding its 2013 annual meeting in New Orleans, LA on October 26th-30th, and registration is available for members and non-members. The meeting schedule and registration details are available on the SRA website.

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesday sessions in the month of September. Chuckie Chinault and Jan Collins will present IDE Billing and Medicare NCD Coverage Updates on September 11th, and Jim Tuttle and Paolo Mangiafico will present Knowledge in the Service of Society - and Your Own Career: An Overview of Some
**New Services at Duke to Help You Share Your Research with the World and Track How Others are Using It** on September 25th. Both presentations will be held from 12:00-1:00pm in Duke North 2001, and more information is available on the [DOCR website](http://example.com).

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**Maestro Care Updates**

**Transition from Command Center to DHTS Service Desk**
A dedicated support group was created to coordinate the activities of the Maestro Care Command Center and assist the research community during the go-live period, and now that the system has been live for over two months, we are transitioning back to the established DHTS support model. Please direct all Maestro Care requests and questions to the DHTS Service Desk (684-2243) or submit a [Support@Duke ticket](mailto:Support@Duke) at [Support@Duke]. Please email [docr.help@dm.duke.edu](mailto:docr.help@dm.duke.edu) with any policy or procedure questions you may have.

**Accessing Race and Ethnicity in Maestro Care**
Maestro Care users are now able to access a patient’s race and ethnicity within the system. To view this demographic in Maestro Care, follow the instructions below or refer to the instructions on the [Maestro Care website](http://example.com):

For Licensed and Non Licensed CRCs:
- Open a patient encounter.
- From the demographics tab on the left side, the “Patient Ethnicity and Race” are available in the second section.

For View Only users:
- Open a patient either from the Schedule tab or the Patient List tab.
- From the demographics tab on the left side, the “Patient Ethnicity and Race” are available in the second section.

**Accessing the Operating Room Schedule**
How can I access the operating room schedule in Maestro Care?
1. Click the EPIC button.
2. Select Master Daily Schedule.
3. Choose the OR that you wish to view.
4. Run.

**Maestro Care Training Available for CRCs**
CRC (licensed and unlicensed) research training is still available for those who are new to Duke Research. The “New to Duke: DOCR MC Clinical Research 100” course is being offered in September on the following dates:
- 9/9 from 12:30pm-5:30pm
- 9/11 from 8:00am-1:00pm
• 9/16 from 12:30pm-5:30pm
• 9/18 from 8:00am-1:00pm
• 9/23 from 12:30pm-5:30pm
• 9/25 from 8am-1:00pm

Please send an e-mail to docr.help@dm.duke.edu and copy your CRU RPM in order to be registered for a course. All trainings will be held in Duke South, Green Zone, #429 (Toto Room).

Maestro Care – Are You Linking to the Timeline?
For CRCs who are registering patients as “Enrolled (IC obtained – under waiver or signed form)” or in cases of enrolling a healthy control group volunteer use “Enrolled Healthy Control Group Volunteer (IC obtained – under waiver or signed form),” please remember to associate patients with your research study AND link to the timeline!

For CRCs who are registering participants as “Enrolled No Bill Risk Protocol (IC obtained under waiver or signed form),” please remember to NOT link it to an appointment or timeline because there should not be any charges associated with the research study. If you do have charges associated with the study, please contact the PRMO Clinical Trials Billing Office and DOCR so that a billing calendar can be created and study billing status changed. If you have linked appointments to no bill risk studies, please contact PRMO and provide your protocol number so these studies can be removed from the billing review queue. The best method of contact is to submit a Service Now ticket to the DHTS Helpdesk. Tickets will be forwarded to DOCR and the research support help team.

Maestro Care Bug Fixes
• All providers, regardless of whether or not they are listed as key personnel on a study, now have access to view the study details by clicking on the "research flag" in a patient's record. This is a fix that was recently deployed.
• Providers are no longer getting notified to both second sign and co-sign orders before release. The only electronic signature that is required for research orders is the second sign, NOT the co-sign.
• If you have a “blood draw” order set only (either associated with a charge or not), type in the eIRB # into the smartest search field. If you ad hoc the order, you can type in “Research Blood”.

Maestro Care Financial Report Changes
The R3 Detail Report that reflects patient care costs that are posted to the studies via the general ledger will no longer be used after Duke Raleigh Hospital and Duke Regional Hospital go live on Maestro Care around the beginning of March, 2014. Current patient costs that are charged within the Maestro Care system will be viewable via the RHB233 and RHB234 reports within Maestro Care. In preparation for this change, individuals should begin archiving the information within the Lotus Notes Database to ensure that nothing is lost. Any questions about these changes can be directed to the PRMO.
**Don’t Forget!**

**Charging Studies for IRB Amendments**
The IRB charges a fee for IRB amendments requiring a full review. This fee was not executed in the past as the previous system did not have the capability to manage this function. However, the finance group will be going back through fiscal year 2013 and will begin to assess these charges to study fund codes in retrospect. Please direct any questions about this process to Michelle Smith (michelle.smith@duke.edu).

**National Cyber Security Awareness Month is Coming!**
October will see the 10th anniversary of National Cyber Security 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. Learn more about NCSAM at www.StaySafeOnline.org.

**Frequently Asked Questions**

**Encryption requirement for SEI**
The [Duke Medicine Mobile Computing and Storage Device Standard](#) outlines the requirements for encryption of Sensitive Electronic Information (SEI). 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 online to assist Duke Medicine employees in meeting these requirements.

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

**Sunshine Act Reporting**
On August 1st, pharmaceutical companies began reporting to the government certain payments they make to physicians and teaching hospitals. That information will be publicly posted on a CMS website by September 30, 2014. CMS is to provide each affected individual
and hospital the information that will be posted on or before by March 1, 2014. There will then be a 60 day period for corrections to be made. Payments for the conduct of research, clinical and non-clinical, will be reported, but unlike payments for consulting and other payments for individual services, will not be reported as payments to the individual. Research payments will be reported as payments to Duke, and the PI will be identified, along with amount of payment and title of the study. Payments for CME-accredited programs will not be reported, but payments for other educational endeavors will be, and will be attributed to either institution or individual depending upon to whom payments are made. For additional information, please contact Gavin Foltz, J.D., in the Office of Corporate Research Collaborations.

**CRU Corner**

**School of Nursing CRU**
Welcome to Nancy Hassell, who became the School Of Nursing ARPM on September 1!

**Dermatology/Pathology CRU**
The Dermatology/Pathology CRU is pleased to welcome Mary Ann Iannacchione to our team as a Clinical Research Nurse. Mary Ann is a long-time Dermatology employee who has been working as a Clinical Research Nurse on a project for us at the VAMC for the last 4 years. We are excited to have her back in our group.

To be added or removed from the newsletter distribution list, please contact the DOCR at [docr.help@dm.duke.edu](mailto:docr.help@dm.duke.edu).