What’s New?

- New Checklist for Exemption or Relief from Further IRB Oversight
- Update to HRPP Pregnancy Testing Policy
- The Joint Commission Personnel File Checklist
- New CRC Charge Verification Report and Charge Correction Requests to PRMO
- REDCap Information
- Duke MedLink
- EPIC 2014 Updates
- ResearchMatch Launches Neuropathy Registry

Education Opportunities

- Research Wednesdays
- Upcoming DOCR Trainings
- Maestro Care Training

Don’t Forget

- Lotus Notes Retirement
- SF-12 License
- DOCR/GME Partnership for Resident and Fellow Research Education

Frequently Asked Questions

- Who is required to complete HSR Training?
- What happens if I don’t complete my HSR recertification by the due date?

CRU Corner

- Heart Center
- Ophthalmology

What’s New?

New Checklist for Exemption or Relief from Further IRB Oversight

A new Checklist for Exemption or Relief from Further IRB Oversight has been posted on the IRB website (Forms/Standard Language page) and on the eIRB website (Download Forms page). The checklist was developed to help Investigators and IRB Reviewers assess whether an activity constitutes research involving human subjects, and whether the activity is subject to IRB oversight.

Note that to obtain an authoritative determination of whether an activity is exempt from further IRB review, the Faculty/Staff Member must request confirmation from the IRB that an activity does or does not constitute research with human subjects, and whether the project
involving research with human subjects qualifies for exemption from further IRB review or meets the definition of “not engaged in research”. If you think your project may qualify for exemption, please submit the project to the IRB and choose the option ‘Application for exemption from IRB Review’ in section 03 of the submission form in eIRB.

**Update to HRPP Pregnancy Testing Policy**
The Pregnancy Testing policy has been updated to include an additional section called “Follow-up Pregnancy Testing throughout a Research Protocol”. With input from Ob-Gyn, this new section was added to address follow-up pregnancy testing during research studies and what kits/tests are appropriate and allowable during that time. To see the updated policy, visit HRPP Policies on the IRB web site.

**CMS Announces “Sunshine” Act Database Registration Open June 1**
The Centers for Medicare and Medicaid Services (CMS) recently announced that on June 1, physicians and teaching hospitals can register to review data submitted on payments made to them by drug and device manufacturers. Registration in the CMS Enterprise Portal is the first of a two-step process that must be completed to access information in the CMS’ “Open Payments” database, established under what is commonly known as the “Physician Payments Sunshine Act.” Manufacturers have submitted information to CMS on all payments or transfers of value made to physicians or teaching hospitals between Aug. 1 and Dec. 31, 2013. After establishing their identity in the portal, physicians and teaching hospital delegates still will need to register in the Open Payments system when it becomes available to gain access to the past records and those submitted annually going forward. The delegates will have a 45-day review window to access the data and dispute an entry. The resulting database is scheduled to be made publicly available by Sept. 30, 2014. CMS requested comments on the proposed dispute resolution and corrections process by June 2. The AAMC planned to submit a comment letter.

**The Joint Commission Personnel File Checklist**
The Joint Commission Checklist Survey Tool for Personnel File Reviews is posted on the DOCR website. This checklist should be used as an index for all required credentialing and training documents in a nurse’s file. The individual documents themselves are required to be present in the nurse’s personnel file. If a research employee is a NC licensed nurse and functions in that role the DUHS system, the RPM is responsible for seeing that all credentialing documents are current and present in the file.

**New CRC Charge Verification Report and Charge Correction Requests to PRMO**
The new RPB466 report is ready for CRC use. You will be able to see charges that go to your fund code as well as charges that go to the patient’s insurance. Charges will be available to be viewed by the CRC after the biller has reviewed. So, if the patient was seen last week, you will not see those charges until a biller reviews them first. If there are missing charges from your patient, do not panic--they may just be awaiting biller review. Please review all protocols where bills are generated on at least a weekly basis. There is a remaining glitch in the system: the CRCs may not see some charges to review if the visit has a professional charge only and the biller has reviewed and released any holds. EPIC R & D is still working to resolve this
issue. We will keep you updated. Tip sheets for how to run the Charge Verification Report and how to complete Charge Correction Requests are found on the Maestro Care Research Intranet site.

We are also streamlining communication with the PRMO regarding charge corrections. All charge corrections must be submitted using the Charge Correction Request Link. For those with a CRC Dashboard, it can be found there. If you do not have a CRC Dashboard, please use this link. The PRMO will return all charge correction requests that arrive via email or phone and ask that the link be used.

**REDCap Information**
Correction from previous newsletter: For questions about REDCap, please contact redcap-docr@duke.edu, or you may speak with a programmer at our office hours held the first and third Tuesday of every month at 11:00a in Hock 9047 (not Wednesday as previously indicated).

Archiving projects:
Please contact DOCR, if you have a project that is no longer being used and should be archived. Email us at redcap-docr@duke.edu.

User Rights Review:
Starting in August, we will begin contacting project owners to confirm the User Rights are correct for your project. You now have the ability to see who has access to you project and what access they have by clicking on “Current Users” under “Applications” in your REDCap project. It is recommended that you notify us at any time if you need to change user access to your project, especially when someone is no longer on your project. Please use this link to request User Rights changes to your project.

**Duke MedLink**
DOCR is currently working with HIM, DUHS Compliance, DECO, and the Duke Maestro Care and MedLink teams to set up Duke MedLink (DML) for external monitoring. This system will replace the current Release to Inspector functionality and provide an improved ability to review records. We will continue to provide updates as this project moves forward. The goal is for DML to be available after July’s Epic 2014 upgrade.

**EPIC 2014 Update**
In July, Duke will begin upgrading Maestro Care by implementing the EPIC 2014 upgrade. As part of this upgrade, there will be some downtime in the production system. From July 8th through July 12th, newly validated order sets and Beacon treatment plans will not be put into the system. Please be mindful of this downtime as you plan for your validation session and timeline for enrollment.

**ResearchMatch Launches Neuropathy Registry**
ResearchMatch is launching a research registry for neuropathy in collaboration with The Neuropathy Association, a national non-profit patient advocacy organization dedicated to
bringing help, hope, and healing to people with various forms of neuropathy. All volunteers who register with ResearchMatch indicating neuropathy as one of their conditions will be prompted to answer additional questions about their condition to better enhance the precision and prescreening processing for matching volunteers with research teams who are studying neuropathy. For more information, please visit the ResearchMatch site.

Education Opportunities

Research Wednesdays
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesdays sessions in the month of June. Billy Newton will present School of Medicine Finance Updates on June 11th in Duke North 2003. Susan Natoli and Diane Wilson, JD, from the University of Michigan will present ClinicalTrials.gov on June 25th in Duke North 2001. More information about the sessions is available on the DOCR website.

Upcoming DOCR Trainings
The following DOCR trainings will be held in the month of July for research staff at Duke, and registration instructions are available on the DOCR website:

1. Study Documentation: Regulations and Best Practices will be held on July 8th.
2. Human Subjects Research at Duke will be held on July 10th.
3. Urine Pregnancy Screening for Research will be held on July 17th.
4. IRB Overview will be held on July 22nd.
5. Adverse Events will be held on July 22nd.
6. ClinicalTrials.gov Introduction will be held on July 22nd.
7. Phlebotomy Competency for Research will be held on July 24th.
8. ClinicalTrials.gov Reporting Practical will be held on July 31st.

Maestro Care Training
An updated New to Duke: DOCR MC Clinical Research 100 research training for licensed and unlicensed CRCs is still available for staff who are new to research or Duke, or who just want a refresher. The course is being offered in July on the following dates in the Seeley Mudd Computer Training Lab, 1st Floor:

- 7/2/2014 from 8:00-11:30am
- 7/7/2014 from 12:00-3:30pm
- 7/9/2014 from 8:00-11:30am
- 7/14/2014 from 12:00-3:30pm
- 7/16/2014 from 8:00-11:30am
- 7/21/2014 from 12:00-3:30pm
- 7/23/2014 from 8:00-11:30am
- 7/28/2014 from 12:00-3:30pm
- 7/30/2014 from 8:00-11:30am
Don’t Forget!

Lotus Notes Retirement
The Duke Medicine Lotus Notes system is scheduled for retirement in July 2014. If you have Lotus Notes email archives on local drives, shares or on Domino servers that contain email data you need, you should print, forward or convert the email data to an Outlook pst files PRIOR to the retirement of the DM Lotus Notes system. Once the system is retired, you will NOT be able to access the Lotus Notes email archives to view, print, forward, or convert email data in the archive.

SF-12 License
Duke does not have a blanket license for use of SF-12 surveys, or other Quality Metric surveys. If you would like to use these surveys, you must complete an information sheet at Quality Metric’s website. That will result in a draft license agreement being generated. You should submit that agreement with an accurate description of funding source and intended use to Procurement through the Buy@Duke system. Procurement will review the license and let you know about any necessary revisions or additional agreements that may need to be in place regarding the sharing or storing of sensitive information or PHI.

DOCR/GME Partnership for Resident and Fellow Research Education
DOCR and the Office of Graduate Medical Education (GME) are collaborating to provide a program that will teach GME trainees basic skills in clinical research during their time at Duke. The program will be available for those working towards research, clinical, or administrative careers. This year’s combined sessions with residents and fellows will be held during the late summer and early fall. DOCR will also provide project support to residents/fellows who attend the program and request assistance with their project. The curriculum and schedule are posted on the DOCR website.

Frequently Asked Questions

Who is required to complete HSR Training?
- The Human Subjects Research (HSR) training is required for all employees working within clinical research at Duke.
- As a condition of this requirement, DOCR approval will not be given for a study in the eIRB until everyone on the key personnel list has successfully completed his or her HSR training.
- The Human Subjects Research at Duke course is 2-hour instructor-led course in the classroom, and an online version of the training is available as well.
- Participants in this course will receive an overview of the complex regulatory environment of human subjects research, examine the various types of human subjects research, identify study team roles and responsibilities, and will receive an overview of Duke’s clinical research structure.
What happens if I don’t complete my HSR recertification by the due date?

- The Duke LMS system marks your record as “expired”.
- You will encounter problems following the instructions to renew your certification because the instructions are designed to recertify within a certain time period.
- If you were able to complete the HSR module after expiration date – your record will not display correctly in the system.
- Please contact DOCR.Help@dm.duke.edu to have your HSR record reset in order for your record to display correctly or to be able to re-take the HSR training.

CRU Corner

Heart Center CRU
The Heart CRU would like congratulate Krista Camuglia on her recent promotion to CRC III. Krista will lead the Cardiac Cath Cluster’s Structural Heart Group. Congratulations Krista!!

Congratulations to James Gibbs for his recent promotion to CRC II with the Heart Center CRU Cardiac Cath Cluster. Congratulations James!!

Ophthalmology CRU
Becky Sullivan joined the Ophthalmology CRU in May 2014 as Financial Practice Manager. She joins us from OSP where she served as a liaison, and brings with her significant clinical research experience she gained while in the Department of Neurology at Johns Hopkins University. Welcome to Ophthalmology Becky!

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