What’s New?

Research Data Security Plan (RDSP) Changes
In mid-January, you will see minor modifications to the RDSP submission in section 12.1 of the eIRB application to allow for more clarity around research data storage. Section 2.2 of the submission form will now include these options for listing data storage:

- Duke University Office of Information Technology (OIT) Managed Service
- Duke University Campus Department Supported IT Service

Research teams with a Medical Center IRB who intend to store data at OIT or on campus should select this option and provide details for review. Both the Health System and University Information Security Offices, infosec@dm.duke.edu and security@duke.edu respectively, are available to answer questions and provide guidance in RDSP submission.

DOCR RMT Limited Service Agreements: Free in 2014!
Effective January 1st, DOCR is no longer charging an annual support fee for Limited Service Agreements (LSAs), which allows users to build their own REDCap databases. DOCR will continue to provide support for projects built via LSAs, and we will provide additional office hours for builders to meet with DOCR programmers for guidance. Please send any questions about LSAs to Sue Budinger (susan.budinger@duke.edu).

Flu Vaccination Participation
Thank you to all of the School of Medicine faculty and staff who received a flu vaccination under the new policy requiring participation from those who work as key personnel on clinical protocols and have in-person interaction with patients or study subjects. More than 2700 faculty and staff from the School of Medicine received vaccinations and we reported 100% compliance with the new policy. Thank you to everyone for making this initiative a success!

Signature, Date and Time on Consent Forms
Please note that all signature lines on all DUHS IRB consent form templates now have a place to record “time” as well as “date”. While it is not necessary to submit an amendment to the IRB just for the purpose of adding time lines to currently approved consent forms, the IRB will ask you to do this at the time of the study’s next Continuing Review (CR). Alternatively, if you are planning to submit an amendment for some other changes to the IRB in the near future, you
can bundle your changes together and add time lines to your study’s consent form(s) at that time.
If the time is inadvertently missed (not recorded) during the consent process, it is not necessary to submit a deviation report to the IRB. Simply add a note-to-file to the study’s regulatory binder instead. Please contact your IRB Specialist if you have any questions about this process.

New Policy Defines Appropriate Study Personnel to Conduct the Consent Process
A new policy has been posted on the IRB web site (available on the HRPP Policies page), describing the qualifications required for a study team member to conduct the consent process. The policy defines the individuals who are and are not considered qualified by the DUHS IRB to conduct the consent process. The full policy is available on the IRB website.

Contracts Update
DOCR currently provides institutional signature for Duke-as-a-site, industry-funded agreements via the Contracts, Communications & Regulatory team led by Lindsey Spangler. Lindsey is currently out of the office on maternity leave, and study teams can send any questions to Laura Hill (laura.hill@duke.edu) or Denise Snyder (denise.snyder@duke.edu) in her absence. Questions and any documents for specific agreements can be sent to docr.help@dm.duke.edu.

Education Opportunities

2014 NCSRA Meeting
The North Carolina Society of Research Administrators will hold its 2014 chapter meeting on March 3\textsuperscript{rd}-5\textsuperscript{th} in Pinehurst, NC. The schedule will include a number of workshops for research administrators as well as networking opportunities. Registration is available on the SRA website, and a discount will be offered for those who register before February 17\textsuperscript{th}.

CRTP Accepting Applications
The Clinical Research Training Program (CRTP) of the Duke University School of Medicine Biostatistics and Bioinformatics Department provides academic training in the quantitative and methodological principles of clinical research. CRTP is designed primarily for faculty, fellows, and other health professionals. The program offers formal courses in research design, research management, medical genetics, comparative effectiveness, translational methodologies, and statistical analysis. A degree option in the program leads to a Master of Health Sciences in Clinical Research, a professional degree awarded by the School of Medicine. An advanced degree in a clinical health science (or two years of medical school) from an accredited institution is a prerequisite for admission either as a degree candidate or as a non-degree participant.

The program is now accepting applications for the academic year 2014-15. For a detailed description of the program, the course offerings, and a link to the online application, visit the
CRTP website at [http://crtp.mc.duke.edu](http://crtp.mc.duke.edu). Applications will be accepted through May 15, 2014, the registration for fall term courses is July 28th—August 1st, and classes begin on August 25th. For more information, contact Gail Ladd, CRTP Program Coordinator, at 681-4560 or gail.ladd@duke.edu.

**QI vs. Research Policy Discussion**

Please plan to attend a presentation by IRB Chair Dr. Marilyn Hockenberry as she explains the Quality Improvement (QI) vs. Research Policy on Tuesday, January 21st from 12:00pm-1:00pm in the Hock Building Ground Floor Auditorium. Dr. Hockenberry will discuss the distinctions between a QI project and research involving human subjects, and she will point to helpful tools to assist clinicians and researchers in determining if their project is QI and whether or not IRB review is required. No registration is required to attend the event.

**Research Wednesdays**

DOCR and the Medical Center Library & Archives will be hosting several Research Wednesdays sessions in the next several weeks. Margaret Groves will present *Duke University Ethics and Compliance Office and CTQA Trends* on January 22nd, and Dr. Mark Stacy will present *Duke Site-Based Clinical Research Update* on February 26th. The topic for the February 12th presentation will be posted in the coming weeks on the [DOCR website](http://crtp.mc.duke.edu).

**Upcoming DOCR Trainings**

The following DOCR trainings will be held in the month of February for research staff at Duke, and registration instructions are available on the [DOCR website](http://crtp.mc.duke.edu):

1. *Research Data Integrity/Data Security* will be held on February 10th.
2. *Human Subjects Research at Duke* will be held on February 10th.
3. *IRB Overview* will be held on February 18th.
4. *Informed Consent* will be held on February 17th.
5. *Study Documentation: Regulations and Best Practices* will be held on February 20th.
6. *Phlebotomy Competency for Research* will be held on February 25th.
7. *Investigator Responsibilities* will be held on February 3rd.
8. *Urine Pregnancy Screening for Research* will be held on February 4th.

**Don’t Forget!**

**Reconciling Patient Charges in Maestro Care**

Patient charges for all clinical research projects will need to be reconciled with the Maestro reports back to June 22nd. Please make sure this information is distributed to anyone in your department/center/institute, who reconciles patient charges for clinical research, and send any questions regarding this process to Michelle Smith ([michelle.smith@duke.edu](mailto:michelle.smith@duke.edu)) in the School of Medicine Finance Office.
HIPAA: Accounting for Research Disclosures and Access
The HIPAA Privacy Rule gives an individual the right to receive a listing, known as an accounting of disclosures that provides information about when a HIPAA covered entity discloses the individual’s information to others. Duke Health Information Management provides this listing for Duke patients upon the patient’s request.

If an unauthorized research disclosure or improper access is suspected, contact the Duke University Ethics and Compliance Office (DECO), HIPAA Section immediately at 919-684-2475. If DECO determines that an improper access or disclosure has occurred, DECO may have to account by adding the patients to an accounting of disclosures database. In this case, DECO will require the names and MRNs of the affected patients. If the subjects are not patients of Duke, DECO may require the study team keep a log of subjects affected by the disclosure or access. DECO will provide guidance as to which method should be used.

Remember, in all cases of a suspected unauthorized disclosure or improper access, contact DECO immediately (919-684-2475). The government’s “breach clock” does not begin when DECO is contacted, but when the first person at Duke discovers the incident.

NCT Number Must Accompany Insurance Claims Beginning January 1, 2014
Effective January 1, 2014, CMS is requiring individuals to report 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 with work with PRMO and study teams to ensure the NCT number is recorded in Maestro Care for all Qualifying Trials.

ResearchMatch Available for Recruitment
ResearchMatch is available as a recruitment tool for study teams at Duke who are seeking participants for their clinical research studies. Study teams wanting to use ResearchMatch to locate potential participants 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, please visit our ResearchMatch page for more information or contact docr.help@dm.duke.edu with any questions.

Frequently Asked Questions

Is HSR training required for DOCR approval?
The Human Subjects Research (HSR) training is required for all Duke 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 More information about the training, as well as registration, is available on the DOCR website, or you can send any questions to docr.help@dm.duke.edu.

How do I send a secure e-mail?
When sending an e-mail that contains Protected Health Information (PHI) or Sensitive Electronic Information (SEI), it’s important to send your e-mail securely, even if you are only intending it to go to a Duke account. Since your message could be forwarded to a non-Duke e-mail address, it is best practice to use the “Sensitive Electronic Information” option in your e-mails to ensure that your messages are sent securely. By using this process anytime you are including PHI or SEI in an email, you can be assured that the email lives behind the Duke firewall. More information about sending e-mails securely is available on the DOCR website and the Duke Medicine E-mail Services site, or you can contact the DHTS Help Desk at 684-2243 for assistance.

Maestro Care – What do you do if the record asks you to "Break-the-Glass" when screening or reviewing patient charts?
The Maestro Care system may ask users reviewing a specific record to “Break-the-Glass” in order to certify that they are authorized to access a restricted patient record. For instructions on how to access the record properly, please see the tip sheet located on the Maestro Care website.

CRU Corner

Heart Center CRU
The Heart Center CRU would like congratulate Mary Hill and Tony Waldron for their recent promotions to CRC II. We would also like to welcome our new Cath Cluster employees, Caroline Bishop, CRC I and Latasha Phillips, CRC II. Welcome to the team!

Oncology CRU
Welcome to Ellen Jones, BSHS, CCRP who will be the new ARPM Regulatory for the Oncology CRU!

Congratulations to Cindy Downing, Julia Hoyle, Angela Clayton, and Megan Houpe for achieving their CCRP certifications!

School of Nursing CRU
The School of Nursing would like to welcome Tara Toleman to our Clinical Research Unit. Tara will be working on the Connect study as a Senior Data Tech. Welcome, Tara!
To be added or removed from the newsletter distribution list, please contact the DOCR at docr.help@dm.duke.edu.