What’s New?

Core Services Offered by DOCR
DOCR offers a number of core services that can help you and your staff have more time to focus more on your scientific expertise. DOCR employs a group of highly-skilled individuals who are trained in aspects of data and research management. Staff are available for hire on a short-term contract basis to provide cost-effective research solutions for investigator-initiated research at Duke. These services include:

Data Core Services
- REDCap: A secure, web-based application designed to support data capture for investigator-initiated research studies or quality improvement projects
- MS Access: A customizable relational database that can be used for study tracking
- Other Programming software including: CfMC (CATI), FileMaker Pro, Adobe Captivate, SAS, SPS

Research Management Core Services
- Clinical research coordination
- Participant recruitment and tracking
- Interviewing, transcription, chart abstraction, and data entry
- IRB application support

If you have questions about data services, please contact Justin Levens (justin.levens@duke.edu). For questions about research management services, please contact Joan Wilson (joan.wilson@duke.edu).

HIPAA Regulations Modified—Positive Changes for Research
On January 25, 2013, the revisions to the HIPAA regulations were published with a compliance date of September 23, 2013. Fortunately, the changes related to research are minor and are similar to the pre-2003 use of the Common Rule. The changes also clarify the ways the regulation was originally interpreted. In particular, conditional and unconditional authorizations could be combined in one consent/authorization which allows us to make full use of checkboxes/initials for optional parts of a study (though IRB policy still requires a
separate consent/authorization for biorepository sample collection). In addition, “future use”
can be included in a consent/authorization. The School of Medicine Compliance Office and the
IRB will be working together to review and incorporate these changes for you. Look for more
information over the summer.

**New IRB Chair**
Julie Adams, MD, of the Department of Psychiatry, has recently joined the Internal Review
Board (IRB) as a Chair, and she will initially vice-chair IRB #8. In addition to her Psychiatry
expertise, Dr. Adams brings valuable research experience in international settings to her work
at the IRB. Welcome, Dr. Adams!

**New Location for DOCR**
DOCR has recently moved to the 9th floor of Hock Plaza. The phone number remains the same,
but the DOCR address has changed to DUMC Box 2713, 2424 Erwin Road Durham, NC 27701-
3616. Please contact docr.help@dm.duke.edu or call us at 681-6665 with any questions.

**Services from OIT**
The Duke Office of Information Technology (OIT) is offering several new services provided by
Cisco WebEx technologies. The new services are available to Duke faculty, staff, and students
and will enable users to connect online in new technological platforms including Concourse,
WebEx Meeting, and WebEx Meeting Lite. More information about these new services is
available on the [Duke OIT website](#).

**Pregnancy Testing Policy**
A new training on administering pregnancy tests for clinical research is now available, and a
number of trainers are prepared to lead these sessions for the CRUs. An updated IRB policy
outlining the requirements for pregnancy testing in clinical research is now available on the [IRB
website](#). A Research Wednesdays session the topic of *Pregnancy Testing for Research (Serum
vs. Urine)* was held on January 23rd, and a recording of this presentation can be viewed on the
[DOCR website](#) along with the [SOP on urine pregnancy testing](#). Contact docr.help@dm.duke.edu
with questions about setting up a training session.

**Education Opportunities**

**CCRP Exam Date**
Duke Cancer Center Raleigh will be hosting the SoCRA Certified Clinical Research Professional
(CCRP) Exam on Saturday, September 21, 2013 from 8:00am -12:00pm. Please see the [SOCRA
website](#) for additional information. Registration is limited to 25 participants.

**MAGI Conference East**
Model Agreements & Guidelines International (MAGI) is an organization that works to
standardize best practices for clinical research operations, business, and regulatory compliance.
MAGI will hold their next Clinical Research Conference in Boston, MA on May 5-8, 2013, and it will be an opportunity for professionals to network, attend workshops and lectures, and work on certifications in the field of clinical research. For more information about the conference and registration, visit the [MAGI website](#).

**Research Wednesdays**
DOCR and the Medical Center Library will be hosting two Research Wednesday sessions in the month of February. Julia Trimmer and Amber Welch will be presenting on the topic of “Research Networking and Professional Management at Duke” on February 13th at 12:00 in Duke North 2001, and Michelle Evans will be presenting on the topic of “Conflict of Interest Reporting and Updates” on February 27th at 12:00 in Duke North 2001. More information is available on the [DOCR website](#).

**REDCap Survey Tuesdays**
REDCap Survey Tuesdays has changed locations and will now be held in Hock Plaza Room 9047. The sessions will continue to be held on the first Tuesday of each month from 11:00am to 12:00pm. During this time, a DOCR staff member will be available to provide guidance with any REDCap survey issues you may be having during an informal roundtable format. This meeting will be a chance to ask general or specific questions concerning existing or potential projects (and may include demonstrations if requested). For additional information contact REDCap support at dtmiredcap@dm.duke.edu. We look forward seeing you there.

**Don’t Forget!**

**Guidelines for ClinicalTrials.gov**
ClinicalTrials.gov is the national registry of federally and privately supported research studies conducted in the United States and around the world. Most prospective clinical trials involving drugs, biological products, and devices regulated by FDA must be registered on ClinicalTrials.gov within 21 days of enrollment of the 1st subject to comply with FDAAA (Food and Drug Administration Amendments Act of 2007). This law also requires reporting of results and adverse events for a subset of these studies within one year of the study’s primary outcome completion date. The primary completion date is the final data collection date for the stated Primary Outcome Measure in the registration record. The International Committee of Medical Journal Editors (ICMJE) guidelines for registration are different than those for mandated by FDAAA. ICMJE guidelines require registration prior to enrollment of the first subject for any human research project that prospectively assigns human subjects to an intervention for publishing in some journals. Many journals follow the ICMJE guidelines for publishing. Result reporting is not required for ICMJE.

**Update on ClinicalTrials.gov Work**
- When DOCR began this effort last August, there were approximately 580 Duke studies
registered in clinicaltrials.gov, with only a handful posting study summary results. There were numerous study records flagged for noncompliance, including 70 records flagged for late results and over 140 registrations not recently updated.

- Today there are approximately 679 study registrations with 28 registration records posting summary results, and another 36 registration records with summary results entered awaiting clinicaltrials.gov internal QA.
- To date, are 5 incomplete registrations, and 13 study registrations not recently updated. While we recognize there’s still work to do, DOCR is encouraged by the momentum and appreciative of the positive response by study teams and leadership in this effort.

DOCR staff is prepared to assist study teams with all aspects of clinicaltrials.gov, from registration to results reporting. Please contact our clinicaltrials.gov staff, Lorna Dula at 919-681-4716 or Jessica Houlihan at 919-668-2340, or email DOCR.help@dm.duke.edu for assistance.

**Reminder about PHI on Laptops**

The following are rules regarding PHI as it pertains to a laptop:

- PHI may be maintained on Duke-owned encrypted laptops that are managed by Duke IT Support staff. Note: Net Friends is considered Duke IT Support staff if Net Friends is providing desktop support services for the unit. However, PHI on laptops is not recommended if it can be avoided.
- PHI may not be kept on personal laptops regardless of encryption status.
- PHI may not be kept on any laptop without encryption.

The authority for these statements comes from several sources:

- Mobile Computing Devices Standard
- Confidentiality Agreement
- The RDSP Checklist is also a good tool to help you quickly understand Duke policy and standards as they relate to research.

**Retrospective RDSP Survey Data Collection – Studies overdue**

Thanks to all study teams who have responded to surveys to capture data for Research Data Security Plans that preceded the initiation of this application in eIRB. The due date for these surveys was extended to January 31, 2013. We really appreciate the assistance of investigators, study teams, and RPMs in helping to complete these surveys. We have less than 500 studies outstanding as of February 1st. If assistance is needed in this effort, please contact DOCR.Help@dm.duke.edu.

**Did You Know?**
**Biorepositories – When Do You Need to Submit a Separate Biorepository Study Protocol and Separate Consent Form to the DUHS IRB?**

Under the [HRPP Database and Specimen Repository (DSR) policy](https://example.com), external repository sites are handled differently than internal, Duke-controlled repository sites. Specifically, a Duke biorepository site requires a separate IRB protocol submission and a separate consent form.

When data/samples are stored for use in future research studies and *Duke researchers control access to the specimens*, whether the physical location of the biorepository is at Duke or elsewhere (such as when Duke has obtained storage space off-campus for the samples), under the [HRPP Database and Specimen Repository (DSR) policy](https://example.com), this is considered an “internal” Duke repository site.

A noteworthy example of this is the biorepository in Kannapolis, NC at a LabCorp facility. Duke has obtained space in this facility for storage of samples obtained for future research. This space is used for storing samples collected for future research under a number of IRB approved protocols, some of which are coordinating center protocols from DCRI, including protocols where Duke is not a site for subject enrollment and/or interventions. Even though the site itself is “external” to Duke, for protocols under which Duke researchers collect and/or control access to the samples, this biorepository would be considered an “internal” Duke biorepository, requiring a separate IRB protocol submission and separate consent form.

When protocols are submitted to the IRB involving storage of samples for future research, please state not only the location of the storage site, but also whether or not Duke researchers will control access to the stored samples.

Please note that waiver of consent/authorization for samples stored in a Duke biorepository is possible, but would generally require that the samples were *not* collected for the purpose of storage for future research (i.e., they were collected in the past for other research studies, for clinical purposes, or for quality improvement purposes). For the IRB to approve such a waiver, the study must meet the criteria for waiver of consent [45 CFR 46.116(d)] and waiver of authorization [45 CFR 164.512(i)(1)and(2)].

**Policy on Minors in Duke University Laboratories**

Duke Human Resources has recently posted a new 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 guidelines about working with Minors in a laboratory setting at Duke University, and can be found on the [Duke Human Resources website](https://example.com).

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**CRU Corner**

**Anesthesiology CRU**
Congratulations to two Anesthesiology CRU staff members on being first authors!

- ARPM Naraida Balajonda for her article “Determinants of a Subject’s Decision to Participate in Clinical Anesthesia Research”. (Published in the Feb 2013 issue of Anesthesia & Analgesia)
- CTA 2 Monique Fontes for her article “Predictors of Cognitive Recovery After Cardiac Surgery”. (Published in the Feb 2013 issue of Anesthesia & Analgesia)

**CFM CRU**

Congratulations to Sarah Weaver, MPH and Alicia Bilheimer, MPH who will serve as lead clinical research coordinators with the Community and Family Medicine Clinical Research Unit.

**Heart Center CRU**

Dahlia Cowhig was recently promoted to CRC III in the Heart Center Cath Cluster. Congratulations Dahlia, keep up the good work!

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