Regulations, Policies, and Procedures

DOCR Policy Updates

The Duke Office of Clinical Research recently updated two policies.

FDA and External Regulatory Agency Audits and Inspections
- Policy amended to include external agency audits in addition to the FDA and added required notification of an upcoming audit to DOCR and DUHS IRB

Duke Human Research Training (DHRT)
- Policy updated to reflect the name change of the course and also updated to reflect current process in administering the program

Collaborative Institutional Training Initiative (CITI) Module Requirements for Duke Medicine Human Subject Protection (HSP)
- Policy wording changes to provide greater clarification and addition of the required Research with Children module

Duke Annual Research Training (DART)

The Duke Office of Clinical Research recently changed the name of the Human Subjects Research Training at Duke to Duke Annual Research Training (DART). The DART acronym conflicts with a previous initiative at Duke. To minimize confusion, this training will once again (I) be renamed – now to DHRT (Duke Human Research Training). Learners will see the name DHRT instead of the name Human Subjects Research at Duke on their Duke Learning
Management System transcripts for courses taken prior to May 13th, as well as courses completed in the future. For questions about the name change, contact DOCR.

**Maestro Care Clinical Research Associating Patients with Study Training**

Employees who need the Maestro Care Clinical Research Associating Patients with Study training are able to attend a portion of the frequently-scheduled MC Clinical Research 100 training. If you or someone on your study team needs to learn how to associate patients with a study, just attend the first hour of class only. Learners will receive a Maestro Care Overview and be shown Research dashboard and enrolling patients. The Duke Learning Management System transcript will then be modified to show that the learner completed Maestro Care Clinical Research Associating Patients with Study. Upcoming class dates and times are available.

**Clinical Trial Competencies for Research Professionals**

The Joint Task Force for Clinical Trial Competencies (JTFCTC) released a domain “wheel” that depicts the various competencies embodied by research professionals. This wheel is being used to guide the revision of job classifications for research professionals at Duke. To better understand our workforce and the relevance of these domains, we would appreciate your participation in a survey being conducted by the JTFCTC. This is an ambitious global initiative of the JTFCTC in collaboration with a number of professional organizations and corporate entities involved in the clinical research enterprise. You can access the external survey at the following link (it should take approximately 20 minutes to complete and please note, this survey is being administered externally): https://www.surveymonkey.com/r/RN6NBNC

**CRC Time Available from DOCR’s Research Management Team (RMT)**

The Duke Office of Clinical Research currently has CRC time available to assist study teams with research project needs. Core services available include project coordination, research design, IRB/Regulatory submissions, protocol and consent form development, chart abstractions, subject recruitment, subject consenting and interviewing, and subject tracking and follow-up. For additional information or for a percent effort quote, please contact the Duke Office of Clinical Research.

**Research Data Security Plan (RDSP) Submission Instructions and Staff Training Job Aid Available**

Research Data Security Plan (RDSP) Submission Instructions as well as a Staff Training Job Aid are available on the DOCR Website. These documents provide detailed guidance to staff members who are responsible for submitting the RDSP. These documents are made available to the Duke Research Community from the Duke Medicine Information Security Office.
**Research Wednesdays Moves to New Time**

Beginning **July 8th 2015**, the Research Wednesdays education series will move to a new time, 1:00 – 2:00 pm Duke North 2002 or 2001. The time change is a result of room availability with the new academic year. Additional information about this series along with a list of upcoming dates and speakers is available on the [DOCR website](#).

**PEDIGENE Access is Now Free to Duke Researchers and Their Collaborators**

The Research Informatics Core is pleased to be able to offer use of the PEDIGENE® information management system to all Duke researchers and their collaborators without the monthly user access fees. This proven research tool has served as the database repository for hundreds of studies over the past two decades. On a robust and secure Oracle database platform, the system utilizes ClinApps and/or REDCap for clinical data entry, stores subject, 'omic and analysis result information, integrates with the Biofluids Bank (for sample storage and processing), and tracks data provenance for data that are managed by it. For current users, fees will no longer be collected. Additional information about the system or getting started is available.

**Definition of Key Personnel**

Please note the definition of Key Personnel to guide your choice of whom to list on the Key Personnel list in all IRB protocol submissions:

“Key Personnel” for a research study are research personnel who are directly involved in conducting the research with human subjects through an interaction or intervention for research purposes, including participating in the consent process by either leading it or contributing to it; OR who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study.

**Closing a Study That Has Been Declared Exempt from IRB Review**

A final Progress Report is not required by the IRB to close an Exempt study in the eIRB. When all study activities have ended on a study that has been declared exempt from IRB review, simply click on “Close Exempt Research” at the left side of the screen to close an Exempt study.

**Think Before You Sync**

The newest update to Adobe Reader (Adobe Acrobat Reader DC) offers a free upgrade to Adobe’s cloud solution which allows users to store their PDFs on Adobe’s cloud and access their PDFs on any device. But should you use it? Many of our business documents contain sensitive electronic information that should not be sent to cloud providers. Duke staff should be particularly careful with systems offering device syncing to make sure cloud sharing is allowed.
Staff should familiarize themselves with the Duke Data Classification Standard ([http://security.duke.edu/protect-your-information/data-classification-duke](http://security.duke.edu/protect-your-information/data-classification-duke)) and only sync documents classified Public. Please contact the Duke Information Security Offices with any questions.

**Update of ONC’s Guide to Privacy and Security of Electronic Health Information**

The HHS Office of the National Coordinator for Health Information Technology (ONC) released Version 2.0 of their *Guide to Privacy and Security of Electronic Health Information*. In the updated Guide, you will find practical scenarios that explain when a business associate (BA) relationship forms along with suggested questions health care providers may want to ask their health IT product developers and a seven-step approach for implementing a security management process. Read the blog post and ONC’s updated guide.

**Clarification from April 2015 article re: Process to File an Exception Request for Social Security Number (SSN) Storage**

In our last newsletter, we provided information about a new system that is to be used to request SSN storage. What has not changed is that approval is required in order to collect, store, or use SSNs, electronically or on paper. We wish to clarify that an exception request is needed for each DUHS IRB protocol for which study teams actively collect SSNs, now or in the future. It is also required for business offices requiring storage of SSN. The updated guidance can be accessed [here](http://security.duke.edu/protect-your-information/data-classification-duke). All Exception Requests are to be submitted in the Enterprise Governance, Risk and Compliance (eGRC) system. For training, please watch the LMS video (6 minutes) or access the step-by-step instructions at: eGRC Exception Request - collect or store SSN instructions.

**Training Opportunities**

**Upcoming DOCR Training Offerings**

DOCR training offerings are available in the Duke LMS. You have 2 easy ways to find all DOCR classes: Enter “DOCR” in the search field and click Search, or click the Category link, and then click the DOCR link. The results display all the offerings currently available from DOCR. Hint: If you want to bookmark the Duke LMS in your browser, edit the bookmark to this address: [https://vmw-lmsweb.duhs.duke.edu/SabaLogin](https://vmw-lmsweb.duhs.duke.edu/SabaLogin).

Detailed information about each offering and direct links to the offering are also available on the DOCR website. Following are the upcoming instructor-led DOCR Offerings for May and June 2015:

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<td>- Vice Dean of Clinical Research at Duke: Where are we and where are we headed?</td>
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<td>- Budgets and Feasibility Assessments—Plan for Early Success</td>
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Interactive Workshops on Mentoring, Research Ethics

The Office for Faculty Mentoring has invited Theater Delta, an academic acting troupe, to use interactive theater to explore these and other issues during two upcoming workshops at Duke. Both workshops are open to the entire Duke Community, including faculty, trainees, students, and staff.

**Workshop on Mentorship in Academic Medicine:**  Thursday, May 14, 9:00 am – 10:30 am
**Workshop on Research Ethics in Academic Medicine:**  Thursday, May 14 11:00 am – 12:30 pm

Contact Paige Smith with questions.

CRU Corner

The Oncology CRU welcomes Matt Williamson, BSN, RN our new CRC II to the Adult Bone Marrow Transplant Research team.

The Oncology CRU would like to welcome Coleman Mills, Regulatory Coordinator with the NCTN Clinical Research Program.

Welcome Katie Brummer, RN CRC II to the Oncology CRU. She is working in the Duke Raleigh Cancer Center.

Rhonda Hawkins, M.B.A. has joined the Department of Medicine – Hematology as a Financial Management Analyst I. Rhonda, welcome to the Medicine CRU team!

DCRU would like to congratulate Wan Lan Liang, Clinical Research Coordinator III for her recent ACRP certification as a Certified Clinical Research Coordinator (CCRC).

Juliann Gilchrist was recently promoted to a Clinical Trials Assistant II in the Cath Lab Research Cluster.

Congratulations Tanya Farmer, RN for achieving her CCRP Certification!

The Oncology CRU would like to welcome Mariagrazia (Maria) Fochesato, RN, to join Thoracic Research team. We are very excited to have Maria join our team.
Congratulations to Jennifer Hamill, RN, MSN who has officially accepted the Research Practice Manager position for the Heart Center CRU effective May 1\textsuperscript{st}.

**Partner Resources**

**DTMI Newsletter**

Catch up on the news from Duke Translational Medicine Institute in their [latest Newsletter](#).

**DUHS Compliance Office Newsletter**

Catch up on news from the [DUHS Compliance Quarterly Newsletter](#).

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