What’s New?

Policy on Provider Orders
An updated policy entitled *Provider Orders for Outpatient Clinical Services* has been added to DUHS policies as of July 20, 2012. The updated policy details information about verbal or written requests that order a provider to perform tests, procedures, or services. More information on the updated policy can be found by clicking here or by reviewing the FAQ document.

Research Data Security Plan (RDSP) Survey
In order to assist departments, centers and institutes in Duke University to effectively inventory, track and secure data associated with human subjects research protocols, an online data capture survey is being conducted to collect retrospective information for all active IRB studies. This data capture will occur via a REDCap survey, and the questions will follow the same format as the existing prospective "Research Data Security Plan" (RDSP) that is associated with all new studies initiated since November 21, 2011. The surveys will be sent out in batches to Principal Investigators (PIs) over the next few months. Each PI must complete a survey for each study. Please note that each survey link is unique and is prepopulated with the unique IRB protocol number and study title. If you have questions once you receive your survey, please contact the Duke Office of Clinical Research at DOCR.help@dm.duke.edu and place "Retro RDSP" in the subject line.

A NEW Service for Investigators - CRUs Implement Central Reporting to RPMs
Over the next year, the Research Practices Managers (RPMs) will be responsible for the administrative management of all study staff. The RPM is responsible and accountable (to the CRU Director) for managing the study conduct and regulatory compliance duties of Clinical Research Coordinators (CRCs) in their CRUs. This includes assuring: appropriate training, monitoring of adherence to Good Clinical Practice, performance related to study activity, CRC’s meeting minimum qualifications, adherence to CRU standard operating procedures, and HRPP institutional and departmental policies and procedures. All clinical research staff will remain accountable to PIs for all other study activities, according to departmental practices including the scientific conduct of the study and other, non-research related activities. The RPMs will be in regular contact with the PIs and will work to remove the regulatory and operational burden from investigators. This change in structure promotes equity within the CRU, supports career growth and development, improves performance consistency, and enhances professionalism for research staff.
**Personal Disclosure Form**
The Personal Data Disclosure Form has been updated in cooperation with the School of Medicine Compliance Office, IRB and the Duke University Finance Office. The revised form makes it easier for study teams to redact the subject’s Social Security Number after the form has been sent to Employee Travel & Reimbursement by removing the bottom of the form and shredding it. The form can be found by clicking here.

**New Reporting Capabilities in DOCR**
Thanks to many efforts of Paula Morrison’s ADG group and the DOCR IT staff, we are improving our ability to query data about systems and processes. Not everything is a button push, but we are improving reports distributed to the CRUs and we are able to pull additional data requests from the HRPP repository. The HRPP repository currently holds data from eIRB, eResearch, and the Duke faculty appointment database. We plan on expanding the repository collection to match additional systems for reporting.

**Change in WBSE Request Form**
A new Work Breakdown Structure Element (WBSE or fund code) form has been introduced to the School of Medicine Community. The process of fund code creation for Industry contracts and Pre-award spending will be different moving forward in order to create greater efficiency, and the WBSE form has been revised as a result. Additional information and the revised WBSE forms are available by clicking here.

**Education Opportunities**

**Upcoming Events Offered by the DOCR**
Click here to see new learning events offered by the DOCR.

**New Education Opportunities**
The Duke Office of Clinical Research and the Education Task Force are on schedule to roll-out the education course re-design in September. The re-design will provide the Clinical Research Community at Duke with greater flexibility in selecting education topics based on work functions performed. After taking a 2-hour overview course, community members will be able to select additional topics on specific learning opportunities such as Informed Consent, IRB, Data Integrity/Data Security, Documentation, and Revenue Management. Registration will be available for September classes starting August 6th, so be sure to check the DOCR Training page for upcoming opportunities.

**Don’t Forget!**
**CITI Registration Reminder**
When an individual completes his or her CITI modules for the first time and affiliates with Duke Medicine, it is important to include a Duke Unique ID during the registration process in order to have the CITI data captured by Duke systems. If an individual completes CITI modules before receiving a Duke Unique ID, then the data will not be captured and that person will not automatically have an account created in the eIRB.

**Notice of Privacy Practices**
HIPAA requires that Duke provide the Notice of Privacy Practices (NPP) to anyone we get identifiable health information (PHI) from, whether or not clinical care was involved (click here for the policy). If the study subject is also receiving care at Duke Medicine, then the care team has already taken care of this. However, for studies with PHI in which the subjects are not also Duke patients, the study team is responsible for providing the NPP and retaining the acknowledgement of receipt with the study records (You do not need to Date of Birth or MRN, you just need to file the acknowledgement form with the study records.). NPPs can be ordered through [https://order.StaplesAdvantage.com](https://order.StaplesAdvantage.com). If the study does not involve any health information, then the NPP is not needed. The NPP Acknowledgement of Receipt form can be found by clicking here.

**DOCR Satisfaction Survey**
The Duke Office of Clinical Research (DOCR) recently distributed a satisfaction survey concerning your experience working with the DOCR during the past year. DOCR was recently formed by joining the Clinical Research Support Office (CRSO) and the Research Management Team (RMT). CRSO provides research education to Duke employees and manages billing grids, eResearch, enrollment log validation, ClinicalTrials.gov registration and many other processes. RMT provides contracted data and project management based support for Duke research studies. At your convenience, please take our brief [Duke Office of Clinical Research (DOCR) Satisfaction Survey](https://example.com) to help us improve the quality of our services.

**Did You Know?**

**Billing for Investigational Devices (IDE)**
Clinical trials that involve the use of a medical device that is not FDA-approved for its intended use have reimbursement and compliance regulations that govern payment of trial-related costs by a subject’s insurance carrier. These regulations are separate from any DUHS IRB requirements you must satisfy for approval of your clinical trial. Completion of the “Notice Concerning Use of and Billing for Investigational Devices” is necessary to ensure DUHS’ compliance with federal regulations regarding the billing of costs associated with investigational devices which have been granted an IDE by the FDA.

**Routing of Amendments When the Amendment Adds a Specialty Committee**
An eIRB update release on July 22 automated the routing of amendments to Specialty Committees. The Specialty Committee routing for amendments will work as it does now for new studies. When a study team adds a Specialty Committee on page 15 of the Modified Study in their eIRB submission and submits the amendment, an email notification will be sent to the Specialty Committee approvers. When all Specialty Committee reviews are complete, the amendment will route automatically to the IRB for review. There is a new Amendments Reference Guide for Study Staff and Reviewers in the ‘User Guides’ section of the eIRB Home page. ‘User Guides’ is located on the left side of screen.

**CRU Corner**

**Orthopaedic Surgery**
The Orthopaedic Surgery CRU welcomes two new clinical research team members:
- Paola Noziglia joining the Trauma Section
- Shamina Williams joining the Sports Medicine section

**Heart Center**
Catee Mullen has recently become the new Research Practices Manager for the Heart Center CRU. Congratulations, Catee!

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