Duke Medicine
Human Research Protections (HRPP) Newsletter
July 2012

What’s New?

Duke Office of Clinical Research (DOCR)
The Clinical Research Support Office (CRSO) and the Research Management Team (RMT) have joined together to create the Duke Office of Clinical Research (DOCR). The new DOCR e-mail address is docr.help@dm.duke.edu, so please be sure to send any e-mails or questions to the new address moving forward. The new web address is: http://docr.som.duke.edu/ (but the “old” address also works), and the new physical address is DUMC Box 104428, 411 West Chapel Hill Street, 11th Floor Durham, NC 27701-3616.

SBRs become Clinical Research Units
Effective immediately, Site-Based Research Units (SBRs) will be called Clinical Research Units (CRUs) within the Duke Clinical Research Community. CRUs will continue to be the operating business units responsible for clinical research activities aligned with specific therapeutic areas within the Duke University School of Medicine.

New IRB Chair Assignments
The new Institutional Review Board (IRB) chair assignments for the various boards are now available for viewing on the IRB website. Click here to view the updated chair assignments, which became effective on July 1.

New Assistant Dean for Clinical Research
Denise Snyder, MS, RD, CSO, LDN has been appointed as the Assistant Dean for Clinical Research in the Duke University School of Medicine. In this role, Denise will be responsible for the operations, coordination and management of site-based clinical research projects in the Medical Center. Congratulations, Denise!

New Senior IT Manager Named
Cory Ennis will be the new Senior IT Manager for the DOCR effective July 1, 2012. Cory will be responsible for managing the development, implementation and maintenance of information systems for clinical research. Welcome, Cory!

FDA Initiative Accomplishments
The Food and Drug Administration (FDA) has listed some recent accomplishments on their website concerning achievements in their Human Subject Protection (HSP)/Bioresearch Monitoring (BIMO) Initiative. The HSP/BIMO initiative has sought to update measures to
FDA Issues Draft Guidance
The US Food and Drug Administration (FDA) has posted a draft guidance document about transferring to another IRB’s oversight, titled Considerations When Transferring Clinical Investigation Oversight to Another IRB. To read the full document on the FDA website, click here.

Education Opportunities

Research Wednesdays Lunch Series starts July 11th
The Clinical Research Support Office and the Medical Center Library are partnering to bring the Duke Research Community the latest in lunch series educational opportunities. Research Wednesdays will be held the 2nd and 4th Wednesdays of the month (beginning July 11th) in Duke North 2001, noon – 1:00 pm. The series will provide subject matter experts an opportunity to address the Duke Research Community on timely topics that impact the work of the community. Click here for more information.

Upcoming Education Opportunities
The Duke Office of Clinical Research along with 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 topic specific learning opportunities such as Informed Consent, IRB, Data Integrity/Data Security, Documentation, and Budgeting. Stay tuned for more information and registration opportunities as September approaches.

Don’t Forget!

Posting Trials on DukeHealth.org
Duke employees can enter information online about their IRB-approved clinical trials at http://www.dukehealth.org/clinicaltrials. Posting a trial online can help study teams recruit subjects for their clinical trials, and the posting will be made available to anyone who visits the site. Please remember to remove your trial from the website when you’re done enrolling as
well. For more information about entering your study online, click here. For guidance on what can be advertised online without prior IRB approval, click here.

Redacting SSNs on Payment Forms
Do you collect Social Security Numbers (SSNs) for research subject payment? Under directives that were publicized in September 2009, we need to register our retention (electronic or paper) of social security numbers with the Information Security Office. Fortunately, we can modify our processes to minimize the risk of identity theft for our research subjects and to avoid the need to register. After you complete the subject payment forms and send them off to the appropriate offices for payment, just obliterate the SSN on the form before filing. You can usually do this effectively with a black felt tip marker. You should also add a page to your SOPs to document this process. If you fill in forms electronically, you will need to go into the document after printing and remove the SSN or delete the document altogether. If you scan the form, it may be more difficult to obliterate the SSN effectively (check with your IT Support for assistance).
For additional information, please see the memo on Server Security for Social Security Numbers.

V70.7 Review Required in Charge Review Process
When completing your weekly Charge Review and Validation Report (Grant Billing Report), there are five parts of each line item to review for correctness: 1) the patient is enrolled and active in study; 2) the fund code is correct; 3) the charge/service is correct; 4) the charge has been posted to the correct payer (grant vs. insurance); and 5) the diagnosis code V70.7 (“Y” or “N”) is correct for line items posted to insurance. If a test or service's values or results are retained as part of the research, the V70.7 code should be applied. Note that for the same patient and same date of service, only one line item needs to be marked as V70.7 “Y” to have it applied to the entire insurance account. For more information and training presentations, click here.

IRB Protocol and Consent: Say what you do and do what you say!
The IRB protocol and consent should say what you actually do to secure the data, not just cut-and-paste from earlier ones. For instance, if you say "identifiers are stored in a locked file cabinet" and, in reality, they are in a secured spreadsheet on a server, then that is a protocol deviation. Both approaches to storing data are acceptable, but the protocol and consent need to reflect the reality of data storage.

Did You Know?

Research with Children
Individuals at Duke who are conducting clinical research involving children must take the “Research with Children” module in the CITI system to ensure that they are up-to-date on regulations that protect children. For more information on research with children, visit the IRB website.

**Requesting Temporary eBrowser Access**
When requesting eBrowser access for a temporary monitor visit, please note that users cannot access the account on PIN stations, laptops or through virtual PIN. The account can only be used on a desktop computer owned by Duke, so be sure to login to the account on these computers. In addition, if you need to request that new MRNs be added to a previously approved request, please send an updated eBrowser request form to docr.help@dm.duke.edu for approval. Please be sure to give us at least 7 days’ notice prior to the visit.

**Inicialing Consent Forms**
When a subject signs and initials a consent form, that individual must initial each page of the form, but is NOT required to initial the last signature page as well. The blank for initials has been removed from the last page in most consent forms, and there is no longer any need to provide initials on that page. Please contact the IRB office with any questions regarding the requirements for consenting subjects to a study.

**SBR Corner**

**School of Nursing**
Phyllis Kennel has been welcomed as the new Research Practices Manager for the School of Nursing CRU. Congratulations, Phyllis!

**Oncology**
Congratulations to Beatrice Nelson, RN ONC (Gynecology Oncology team) who achieved her CCRP!

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