Duke University School of Medicine
Clinical Research Update
August 2014

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What’s New?
Annual DOCR Satisfaction Survey
We want your feedback! In our continuing efforts to refine and improve our model, we would like to hear your feedback in our annual DOCR Satisfaction Survey. You can access the survey here and all responses will be anonymous (unless you choose to provide your name). Respondents will also have the opportunity to be entered into a drawing to win an iPod shuffle (while still maintaining anonymity of survey)! If you have any questions or concerns, please direct them to DOCR.Help@dm.duke.edu.

**Duke School of Medicine Flu Vaccination Requirements**

According to the School of Medicine (SoM) policy, all School of Medicine regular and non-regular rank faculty (with the exception of Consulting, Adjunct, and Emeritus) with primary faculty appointments in Clinical Departments and all staff whose positions are in the organizational units of a Clinical Department or the following SoM Institutes, Centers, Programs and Offices are required to receive a flu vaccination in 2014:

- Duke Translational Medicine Institute (all entities)
- Duke Cancer Institute
- Brain Imaging and Analysis Center
- Heart Center
- Center for the Study of Aging and Human Development
- Medical Physics Program
- Duke Office of Clinical Research

Flu vaccination is strongly encouraged but remains voluntary for SoM Consulting, Adjunct, and Emeritus faculty, all post-doctoral researchers (associates and scholars), and all faculty and staff in the Basic Science departments and all other institutes and centers not listed above.

House staff should adhere to the Duke University Health System flu vaccination policy. Faculty and staff leased in any amount to the PDC should adhere to the PDC’s vaccination policy.

Students in the School of Medicine should adhere to the flu vaccination policy specific to students.

**Vaccinations will be available for free beginning September 18, 2014. Those required to be vaccinated must do so by November 17, 2014.**

To read the School of Medicine’s Employee Influenza Vaccination Policy or to access a Frequently Asked Questions document and flu vaccination exemption forms, visit medschool.duke.edu/fluvacinepolicy. If you have questions regarding the School of Medicine’s Employee Influenza Vaccination Policy, please contact your supervisor or department/center/institute business or HR manager.

**EPIC 2014 Update**

The EPIC 2014 upgrade was postponed until August and the new dates for the freeze on moving new protocols into production is now August 4 - 10. That means that if the protocol isn’t in production by August 4th, that protocol or any changes to an existing protocol will have to wait
at least until August 10th to move into production. Urgent and emergent requests are affected by this freeze as well. Please plan accordingly and contact DOCR with any concerns.

**Maestro Care Release to Inspector Functionality**

We were notified last week that a monitor could edit the Maestro Care record. This issue had been reported previously and HIM believed that it had been resolved. The issue is not resolved and will not be resolved prior to the 2014 upgrade on August 10th. Study teams are responsible for supervising monitors to ensure that they only review records in Maestro Care. Alternatively, if you can postpone the monitoring visit until a later date, we are working with the Maestro Care team on implementing Duke Med Link as a replacement to Release to Inspector. The target build for Duke Med Link for research is slated for end of September.

**Using “Box” for Cloud Storage and Content Collaboration**

Earlier this year, Duke entered into a Business Associate Agreement with Box that enables HIPAA-compliant cloud-based sharing and collaboration. Over the next few weeks, all active faculty, staff, students, and affiliates at Duke University and Duke Medicine will be automatically given a Duke Box account. Users can access, share and collaborate on files (up to 50GB) securely with Duke and authorized non-Duke users. All Duke Medicine users and Duke University (Campus) users who are conducting research under the guidance of the DUHS IRB will be required to complete an online training module, which is currently under development by Duke Medicine Information Security Office (ISO). While Box is already available to Duke University, the date for the roll-out of Box to the Duke Medicine community has not been determined. For more information about Box, please contact security@duke.edu.

**Using “Send Secure” With Outlook 365**

When using the web access version of Outlook 365 to compose an e-mail, there is no send-secure button. If you are sending sensitive electronic information (SEI) via e-mail, simply type “(secure)”, no quotes, at the beginning of the subject line in order to encrypt the message. Do not include any SEI in the subject line. Additionally, communications with patients should generally be done within Epic/MyChart. Additional information is available at: https://email.duhs.duke.edu/secureemail/

**New Education Research Projects Template**

To improve institutional oversight of health professions education research projects and to aid the health professions education researcher at Duke University in study design and submission to the IRB, the Duke IRB has developed a research template specifically for health professions education research projects.

The goal of this template is to help researchers conduct a careful review of study plans and later to develop precise descriptions of research methodologies (both quantitative and qualitative), any risk to study subjects, and data management/security in their research summary documents. This will help the Duke IRB provide a complete and timely review of health professions education research proposals. The template can be found online on the IRB website (under Submission Forms) and eIRB website (under Other Templates).
New IRB Templates for DCRI Submissions

New research summary templates for DCRI coordinating centers and DCRI data/specimens repository protocol submissions have been posted on the IRB web site under (Forms/Standard Language page) and on the eIRB web site (Download Forms page):

1) Coordinating Center Regular Study Application Research Summary Template for eIRB submission of a multi-site clinical research protocol, regular study application in which Duke is “engaged in research” and serves as a Coordinating Center (e.g., central clinical coordinating center, statistical coordinating center) or provides a central resource (e.g., Data Coordinating Center, Health Economics and Quality of Life (EQOL) coordinating center, Clinical Events Committee, Central Imaging, etc.) for the study.

2) Coordinating Center Request for Exemption Research Summary Template for eIRB submission of a multi-site Coordinating Center Study Application research protocol (e.g., central clinical coordinating center, statistical coordinating center, or a central resource such as Data Coordinating Center, Health Economics and Quality of Life (EQOL) coordinating center, Clinical Events Committee, Central Imaging, etc.) in which Duke may be considered “not engaged in human subjects research.”

3) Database and Specimens Repository Research Summary Template for eIRB submission of a data and/or specimens repository protocol from DCRI under which samples and/or private information are collected and stored for future research.

Note that to obtain an authoritative determination of whether an activity is exempt from further IRB review, the Faculty/Staff Member must request confirmation from the IRB that an activity does or does not constitute research with human subjects, and whether the project involving research with human subjects qualifies for exemption from further IRB review or meets the definition of “not engaged in research”. If you think your project may qualify for exemption, please submit the project to the IRB and choose the option ‘Application for exemption from IRB Review’ in section 03 of the submission form in eIRB. If you are unsure about how to submit your study, contact the IRB at 919-668-5111 and ask to speak with a Chair.

New Vendor Relationship for Research/Laboratory Equipment and Supplies

Duke University has negotiated a new partnership with VWR International as its strategic partner for supplying laboratory equipment, research supplies, and design and renovation casework, effective July 1, 2014. This is an enhanced supplier relationship for the Duke Research Community with VWR offering a high usage list of products at exceptional discounts, which will enable all of us to do more with the research funding available to us.

This new partnership supports our ongoing efforts in the School and across Duke to reduce and control the costs of supplies and equipment. By more efficiently and effectively utilizing our financial resources through such relationships, we will focus the maximum share of those resources directly on our efforts to create life-changing innovations through your research.

Additional details about the new agreement can be found at: http://finance.duke.edu/procurement/programs/storeroom/index.php
**Patient Needing Coordinator Review Report**

Great News! The Patient Needing Coordinator Review report is now functional. Please note the following changes:

Old name: RPB466       **NEW NAME:** RSH005

Professional and Technical charges should be visible. You run the report exactly like you did the previous report, just remember to put in the updated name. You may see professional charges before May 1, 2014, but all technical charges should be after that. If you don’t see your technical or hospital-based charges at first, scroll down to make sure that they are not at the bottom of the page. Contact Terry.Ainsworth@dm.duke.edu if you do not see your charges that should have been reviewed by the biller.

**Education Opportunities**

**Research Wednesdays**


**Upcoming DOCR Trainings**

The following DOCR trainings will be held in the month of August and September for research staff at Duke, and registration instructions are available on the [DOCR website](#):

1. *Investigator Responsibilities* will be held on August 11th.
2. *Informed Consent* will be held on August 12th.
3. *Workshop: Informed Consent Writing* will be held on August 14th.
4. *ClinicalTrials.gov Advanced Reporting* will be held on August 21st.
5. *Study Documentation: Regulations and Best Practices* will be held on August 14th and September 9th.
6. *ClinicalTrials.gov Reporting Practical* will be held on August 21st.
7. *Human Subjects Research at Duke* will be held on August 21st and September 17th.
8. *Workshop: Consenting a Subject to a Research Study* will be held on September 4th.
9. *Financial Basics for Clinical Research* will be held on September 8th.
10. *ClinicalTrials.gov Introduction* will be held on September 16th.
11. *Industry Funded Clinical Research – Process for Contracts* will be held on September 16th.
12. *Urine Pregnancy Screening for Research* will be held on September 18th.
13. *Recruiting Regulations and Best Practices* will be held on September 22nd.
14. *Biobanking Research Specimens at Duke* will be held on September 23rd.
15. *IRB Overview* will be held on September 23rd.
16. *Phlebotomy Competency for Research* will be held on September 25th.

**Maestro Care Training**
An updated *New to Duke: DOCR MC Clinical Research 100* research training for licensed and unlicensed CRCs is still available for staff who are new to research or Duke, or who just want a refresher. The course is being offered in July and August on the following dates in the Seeley Mudd Computer Training Lab, 1st Floor:

- 8/11/2014 from 12:00-3:30pm
- 8/13/2014 from 8:00-11:30am
- 8/18/2014 from 12:00-3:30pm
- 8/20/2014 from 8:00-11:30am
- 8/25/2014 from 12:00-3:30pm
- 8/27/2014 from 8:00-11:30am
- 9/1/2014 from 12:00-3:30pm
- 9/3/2014 from 8:00-11:30am
- 9/8/2014 from 12:00-3:30pm
- 9/10/2014 from 8:00-11:30am
- 9/15/2014 from 12:00-3:30pm
- 9/17/2014 from 8:00-11:30am
- 9/22/2014 from 12:00-3:30pm
- 9/24/2014 from 8:00-11:30am
- 9/29/2014 from 12:00-3:30pm

**Maestro Care Patient Verification & Financial Reconciliation** training for CRCs and financial research staff to gain skills needed for the verification and reconciliation of research patient charges will be offered in August on the following dates:

- 8/7/2014 from 2:00-3:30pm in Duke North 2001
- 8/14/2014 from 2:00-3:30pm in Duke North 2003

Please visit the [DOCR Calendar of Events](#) or [LMS system](#) to see future classes and dates.

**eIRB Training Available by Request**
The IRB offers free one-on-one eIRB training to help study teams prepare protocol submissions. IRB staff will help you learn to navigate eIRB more efficiently, and to better understand the questions the IRB asks on eIRB submission forms. For a training session at a time convenient for you, please contact Minna Pak in the IRB: minna.pak@duke.edu.

**Don’t Forget!**
**Open Payments (Sunshine Act) Review Process**
The Centers for Medicare and Medicaid Services (CMS) recently announced that on June 1, physicians and teaching hospitals can register to review data submitted on payments made to them by drug and device manufacturers. Registration in the CMS Enterprise Portal is the first of a two-step process that must be completed to access information in the CMS’ “Open Payments” database, established under what is commonly known as the “Physician Payments Sunshine Act.” Manufacturers have submitted information to CMS on all payments or transfers of value made to physicians or teaching hospitals between August 1 and December 31, 2013. After establishing their identity in the portal, physicians and teaching hospital delegates still will need to register in the Open Payments (Sunshine Act) system for the review and dispute process. A limited review period from July 14 to August 27 will allow physicians and representatives from teaching hospitals to access the data and dispute any entry that manufacturers of pharmaceuticals or devices reported to CMS in the last five months of 2013. The resulting database is scheduled to be made publicly available by September 30, 2014.

**Reminder about the DUHS HRPP “No Cold Contacts” Policy in the Recruitment of Study Participants**
Please familiarize yourself with the HRPP policy prohibiting “cold contacts” of potential study participants. A “cold contact” in this setting is defined as a planned contact (such as a face-to-face contact, telephone call, letter, or email) with a potential research participant by the investigator or a member of the investigator’s key personnel when neither the investigator nor the contacting person is known to the potential participant as having a reason to know his/her medical diagnosis or other identifiable private information such as protected health information (PHI). Only a caregiver known to the potential participant as having a reason to know his/her medical diagnosis or other PHI may initially introduce a study to a patient. We require this to protect the privacy of potential participants. The DUHS IRB can help you devise a recruitment strategy in compliance with this policy.

**REDCap User Rights**
**Report Builder Access**
Please be aware that when you request access for another user to your REDCap project, requesting Reports and Report Builder access will also give the user access to deidentified data. Reports and Report Builder access should only be given to study team members who have permission to view deidentified records.

**User Rights Requests**
To avoid delays when requesting user rights access, it is best if the user has registered their REDCap account and completed the Secure Use Agreement before the access request is submitted.

**Holland-Trice Scholars Award**
The Duke University School of Medicine announced a call for proposals for high risk/high impact research in the area of brain and disease. This RFP is focused on discovery science, and priority will be given to School of Medicine investigators researching the basic biology underlying brain
disease, including (but not limited to) Alzheimer’s and other neurodegenerative disorders, stroke, and behavioral disorders.

Up to $50,000 for one year will be provided for pilot research projects on brain and disease based on the following criteria:

- Originality
- Scientific rational
- Potential for scientific impact
- Clear articulation of the way in which the proposed research differs from other funded projects of the Principal Investigator
- Clarity of plans for obtaining subsequent extramural funding to extend or complete the project

We expect to fund four projects during the present academic year. Grants funded during the last cycle of this award mechanism are not eligible for renewal, though previously funded investigators may apply for projects with distinct research objectives.

Please include the following in your proposal:

- Title page and contact information
- Abstract of 150 words or less describing the project
- Project summary in 3 pages or less (11 point Arial font, inclusive of figures but not including citations), addressing the selection criteria listed above.
- Biographical sketches for participating faculty, including current and pending sources of support. Please use the “NIH Biosketch Form” http://grants.nih.gov/grants/funding/phs398/phs398.html

Deadline: Proposals must be received by 5 PM EST, August 15, 2014

Selection Process for New Awards – Proposals will be peer-reviewed, and awards announced by October 1, 2014. Selection of peer reviewers and final funding decisions will be made by the Dean of the School of Medicine. Applicants will be notified of funding decisions but will not otherwise receive feedback from the evaluation process. Awardees will be required to submit a year-end progress report and will be expected to present their accomplishments at an informal meeting towards the end of their year of funding.

Applications should be submitted as pdf files to: anne.meska@duke.edu

Frequently Asked Questions

Can you approach a potential clinical research subject again after an initial refusal?
You cannot approach a potential study subject to recruit them for a research study if they have already refused to consent for that same study in the past. It does not matter how long ago they may have refused to consent—if they said “no”, you may not re-approach. However, you may recruit this potential subject for a different research study if you believe they may qualify. If you have any questions about this scenario, please contact your IRB Specialist or contact the IRB at 919-668-5111.

**CRU Corner**

**Dermatology CRU**

Congratulations to Kim Scoggins for her recent promotion to CRC III RN!
Congratulations to Kristina Hines for her recent promotion to CRC I!

**Heart Center CRU**

Welcome Rashmi Chandra, PhD and Katie Voss to the Heart Center CRU, Cardiac Cath Cluster. Rashmi joins us as a Clinical Research Coordinator I and Katie Voss joins us as Clinical Trials Assistant I. We are so excited to have you join the CRU. Welcome to the team!

Congratulations to Patti Adams, RN and ARPM for the Heart Center CRU, who was recently awarded the Friends of Nursing Research Mentor Award. The Friends of Nursing Program mission is to recognize and reward excellence in nursing in Duke Medicine. Congratulations Patti, we are so proud of you!

**Oncology CRU**

Welcome Toya Hobbs, RN, ARPM for Women’s Cancer Care.
Welcome April Seward, RN, CRC RN III for Breast Oncology Team.
Congratulations Carey Hobbs, PhD on her promotion to Regulatory Coordinator III for the GU Oncology Team.

**Pediatrics CRU**

Anita Cherry has been named Financial Practice Manager for the Children’s CRU. Welcome, Anita!

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