Duke University School of Medicine
Clinical Research Update
October 2014

What’s New?

Multi-Site Studies: Keeping the IRB Approvals from External Sites Up-to-Date
The DUHS IRB is continuing an initiative for multi-site study regulatory compliance. The IRB reminds you that if you have a multi-site study, please pay attention to keeping the IRB approvals from the external sites current. When a DUHS investigator plans to conduct research at a site or sites external to DUHS, and the site(s) will be engaged in research according to OHRP guidance (October 16, 2008), the investigator must submit to the DUHS IRB documentation of current IRB approval at all external sites in a timely manner. This documentation belongs in Section 05 of your eIRB submission. Please contact your IRB Specialist for assistance or call the IRB’s main number: 919-668-5111.

Volunteer and Unpaid Intern Policy
An updated policy regarding volunteers and unpaid interns has been posted on the Duke Human Resources site. This policy provides definitions, requirements, and procedures related to volunteers and unpaid interns.

DOCR Survey Results
Thank you all for your responses to the DOCR survey. We received 245 responses and will use these data and comments to continue to improve our services. Please see graphs below for a summary of the results.
DOCR Survey iPod Shuffle Winner
Congratulations to Laurianne Torres from the Department of Medicine who won the iPod Shuffle for completing the annual DOCR survey!

We Hear You! Future Plans for Research Wednesdays Sessions
Based on feedback received from the DOCR survey, we are working toward a solution to the overcrowding issue that sometimes occurs at our Research Wednesdays sessions. While a permanent solution will likely not be implemented until 2015 due to room schedules, we are actively working toward trying to accommodate as many people as possible while also allowing those who could not attend in-person to still receive CEU credit. We hope to pilot test an option at the upcoming session that Dr. Rob Califf will be presenting. We also plan to implement registration as part of this process. Stay tuned!

Soliciting Volunteers for DOCR Website Feedback
We received many comments on the DOCR survey letting us know that the DOCR website is difficult to navigate. In an effort to improve the content and navigability of the site, we would like to meet with a group of users willing to provide feedback on how we can enhance our site. If you would like to be a part of this group, please e-mail DOCR.Help@dm.duke.edu with the subject line “DOCR Website Focus Group”.

Maestro Care for Clinical Research Wiki
The information previously found on the Maestro Care Clinical Research site has been migrated to the School of Medicine wiki under the DOCR tab. There you will find your tip sheets and Quick Start guides on the Maestro Care for Research page.

Principal Investigator Billing Town Hall
A Research Town Hall meeting is scheduled for October 22, 2014 from 5 – 6 pm in Duke North Room 2002 that will be covering clinical trial billing basics in Maestro Care for investigators. Please mark your calendars. Momen Wahidi, MD, PRMO Medical Director & Chief Medical Officer; Mark Stacy, MD, Vice Dean for Clinical Research; Julie McCauley, Manager PRMO Clinical Trial Billing; and Terry Ainsworth, ACNP, Director of Clinical Research Operations, Education and Training will be presenting and available to answer your questions that range from the appropriate use of V70.7 to research billing calendars.

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)” or “[send 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. More information is available at: https://email.duhs.duke.edu/secureemail/

ClinicalTrials.Gov
The ClinicalTrials.Gov Entry System gets a new look. Changes to the ClinicalTrials.gov PRS entry system went live on September 17. There is no change to the actual information that needs to be entered but users will notice a new look and a new order to the modules.

This release includes:

- A new Record Summary page which contains an overview of a record's current status, actions required for finishing the registration or results submission, and a summary of the status of each module within the sections.
- Protocol Section editing pages are now organized into "modules" with fewer editing screens and easier editing of lists of items such as Secondary IDs, Conditions and Citations.
- Results Overview, Preview, and Review Comments screens have a new look and a consistent layout that is similar to the public display.
- New Help pages are available for each Protocol and Results Section module.

DOCR clinicaltrials.gov staff can be contacted at DOCR.Help@dm.duke.edu if there are any issues or questions about the new release.

**Beaker Go Live**
The laboratory EPIC module, Beaker, is going live October 4. If there are questions, please contact DOCR.help@dm.duke.edu. A tip sheet for Understanding Ambulatory Specimen Collection can be found on the Maestro Care for Research page. Additionally, there are WebEx learning modules related to Inpatient Provider Specimen Collection and Reprint Specimen Collection Labels. You will need to click on the links and provide your name, e-mail address, and NetID in order to access the modules.

**Join us for Clinical Research Appreciation Day**
Please join the Duke Office of Clinical Research for our second annual Clinical Research Appreciation Day on Wednesday, October 15th from 11:00-2:00 in the Great Hall of the Mary Duke Biddle Trent Semans Center. This is an opportunity for clinical research faculty and staff at Duke to connect with their colleagues and supporting offices. Food and drink will be provided!

**Education Opportunities**

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting several Research Wednesday sessions in the coming weeks. Shelly Epps will present Duke Medicine Information Security Office on October 8th in Duke North 2001. Rob Califf will present CTSA Grant and Future of Clinical Research at Duke on October 22nd in Duke North 2001. More information about the sessions is available on the DOCR website.

**Upcoming DOCR Trainings**
The following DOCR trainings will be held in the months of October and November for research staff at Duke, and registration instructions are available on the DOCR website:

1. **Data Management 101** will be held on October 7th.
2. **Human Subjects Research at Duke** will be held on October 9th and November 11th.
3. **Workshop: Informed Consent Writing** will be held on October 9th.
4. **Study Documentation: Regulations and Best Practices** will be held on October 14th and November 13th.
5. **Adverse Events** will be held on October 15th.
6. **Informed Consent** will be held on October 16th.
7. **ClinicalTrials.gov Reporting Practical** will be held on October 20th.
8. **IRB Overview** will be held on October 21st and November 18th.
9. **Budget Development and Negotiating Training** will be held on November 3rd.
10. **Workshop: Consenting a Subject to a Research Study** will be held on November 5th.
11. **Research Data Security Plan** will be held on November 6th.
12. **Investigator Responsibilities** will be held on November 18th.
13. **Phlebotomy Competency for Research** will be held on November 20th.

**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 October and November on the following dates in the Seeley Mudd Computer Training Lab, 1st Floor:

- 10/6/2014 from 12:00-3:30pm
- 10/8/2014 from 8:30-11:30am
- 10/13/14 from 12:00-3:30pm
- 10/15/14 from 8:30-11:30am
- 10/20/14 from 12:00-3:30pm
- 10/22/14 from 8:30-11:30am
- 10/27/14 from 12:00-3:30pm
- 10/29/14 from 8:30 – 11:30am
- 11/3/14 from 12:00 – 3:30pm
- 11/5/14 from 8:30 – 11:30am
- 11/10/14 from 12:00 – 3:30pm
- 11/12/14 from 8:30 – 11:30am
- 11/17/14 from 1200 – 3:30pm
- 11/19/14 from 8:30 – 11:30am
- 11/24/14 from 12:00 – 3:30pm
- 11/26/14 from 8:30- 11:30pm
**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 October and November on the following dates in Duke North 2003:

- 10/16/2014 from 2:00-3:00pm
- 11/6/2014 from 2:00-3:00pm

Please visit the [DOCR Calendar of Events](http://www.duke.edu) or [LMS system](http://www.duke.edu) to see future classes and dates.

**Don’t Forget!**

**Mandatory Flu Vaccination**
Annual vaccination against influenza is the best protection for our patients and study subjects against flu transmission during a research-related encounter. Influenza vaccination also protects those who work in and visit our facilities and their families.

Flu vaccines will be available free of charge to all SoM faculty and staff. Times and locations for obtaining the vaccination are available online at [http://www.duke.edu/flu/shots/](http://www.duke.edu/flu/shots/)

According to the School of Medicine 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 including DCRI)
- 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. You may request a medical or religious exemption from vaccination. Exemption forms and instructions for completing the forms are available at [medschool.duke.edu/fluvacinepolicy](http://medschool.duke.edu/fluvacinepolicy).

In order to ensure timely processing of your exemption request, medical or religious exemption requests should be submitted by October 17, 2014.
For those staff required to be vaccinated, flu vaccination is a condition of employment. For faculty required to be vaccinated, non-compliance could result in denied access to Duke Medicine EMR and clinical facilities and/or an impact on performance evaluations.

Department/Center/Institute managers will be provided access to a list of employees in their units who require vaccination. Department, Center, and Institute business and HR managers will be able to track employee compliance with the vaccination policy using reporting tools available from OESO. If you have any questions about your inclusion in the cohort to be vaccinated, please contact your Department, Center, Institute business or HR manager.

To read the School of Medicine’s flu vaccination policy or to access a Frequently Asked Questions document and flu vaccination exemption forms, visit medschool.duke.edu/fluvaccinepolicy.

October is National Cybersecurity Awareness Month
As part of National Cybersecurity Awareness Month in October, Duke University's IT Security Office and Duke Medicine's Information Security Office are sponsoring multiple events. Details for all activities can be found at security.duke.edu but check out the highlights here:

- **GoPhish Quiz** - contest to help Duke faculty, staff and students learn to detect phishing attempts. Enter after October 1st for a chance to win a Google Chromecast or a pair of Duke men's basketball tickets.
- **LiveForLife events** at all three hospitals (DRH cafeteria October 1, DUH Searle Center basement October 15, DRaH cafeteria October 29).
- **Research Events** - Duke Office of Clinical Research Staff appreciation event (October 15, Trent Semans 11-2) and Research Wednesday (October 8, Duke North 2001, 12-1).
- **Departmental Meetings** - contact us if you would like us to present to your group.
- **Learn IT@Lunch Wednesdays** - October 8, 15, 22 at 217 Perkins. Register at security.duke.edu. Windows basics, Bitcoin, LastPass and Multifactor authentication.

**Encryption is the Key to Secure Protected Health Information (PHI)**
Store or Sync files containing PHI
- Only use Duke’s shared network or Duke Box secure cloud
- All portable devices storing PHI should be **configured for encryption**: thumb drives, USB hard drives, cell phones, tablets.
- All smartphones & tablets accessing PHI **must** sync with Duke's Exchange email service to ensure encryption.

For information on securely configuring mobile devices:
- Email: iso@mc.duke.edu
- Visit: http://security.duke.edu/secure-your-devices/mobile-devices
2014 Fall Faculty Flex Voucher Program

Faculty Flex Voucher Pilot Program: Call for Applications

Junior faculty members are often faced with the critical challenge of jump-starting their careers at the same time that family/childcare obligations are least flexible. In recognition of this challenge, the School of Medicine is pleased to announce the Faculty Flex Voucher Pilot Program. Faculty Flex Vouchers are designed to be used in a wide variety of ways by connecting junior faculty members with high quality academic services that facilitate their engagement in scholarly work. Vouchers can be used for institutional services available through the Duke Office of Clinical Research (DOCR), the Communications Publications Services group at the Duke Clinical Research Institute (DCRI), and the Medical Center Library. Vouchers will be awarded for services up to $2,500.

Important dates for the fall 2014 Faculty Flex Voucher Pilot Program:
- Deadline for pre-application meetings with service providers: October 24
- Applications Close: October 31
- Voucher Start: January 1, 2015
- Voucher End: June 30, 2015

CLICK HERE FOR COMPLETE APPLICATION AND PROGRAM INFORMATION

For questions please contact the Office for Faculty Development (facdev@dm.duke.edu or 919-684-4139).

Pilot and Feasibility Grant Program: Duke Skin Disease Research Center

The Duke Skin Disease Research Center (SDRC) Pilot and Feasibility Grant Program will be awarding up to four grants annually to Duke University faculty members. The program is open to both new and established investigators with a goal of fostering research into skin biology and diseases. Awards are made annually after review by the SDRC Pilot and Feasibility Grant committee. Awards may be renewed one time if significant scientific progress is made and a need is demonstrated for further studies before external funding can be obtained. Grants will provide up to $35,000 for new investigators (Instructor or Assistant Professor) in skin biology and/or disease and $25,000 for established investigators (Associate Professor or higher).

The goals of the Pilot and Feasibility Grant Program are:
- Encourage and develop research in skin biology and skin diseases leading to federal and other external funded proposals
- Attract investigators to pursue research in skin biology and disease
- Encourage collaboration between members of the Department of Dermatology and other departments within Duke School of Medicine and the University

Grant awardees will become members of the Duke SDRC during the grant period and remain members if they continue research in skin biology and disease. Preference will be given to projects which utilizes one or more of the SDRC Core laboratories (Cell and Gene modification Core; Animal Models and Tissue Engineering Core; Tissue Procurement and Analysis Core).
Proposals should be submitted electronically to Russell.Hall@duke.edu no later than October 19, 2014, for funding to begin November 2014.

Proposals should include:

1. Abstract of proposed project (PHS 398, page 2)
2. NIH biosketch (PHS 398 /2590)
3. Budget for project period (personal, supplies)
4. Research Plan (Specific Aims, Relevance to skin biology or disease, Research Design and Methods) (3 Pages)
5. References
6. Description of how this award will be used to obtain future funding, including plans for future funding (i.e. R01, K award, VA funding etc.). (1 paragraph)

Questions regarding proposals can be directed to Russell Hall MD, Director, Duke Skin Disease Research Center (Russell.Hall@duke.edu).

Frequently Asked Questions

When is the next DUH BLS Blitz?
The DUH BLS November Blitz registration is now open. The sessions will be held November 10-14 in Hock Plaza, Suite G07. For information regarding session times and registration instructions, please see the informational flyer.

CRU Corner

Oncology CRU
CONGRATULATIONS ANNIE TSUI, RN who has been promoted to CRNC III for the Thoracic Oncology Research Team AND has achieved the coveted Oncology Certification in Nursing (OCN) certification!!!!

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