What’s New?

Clinical Research Appreciation Event for Faculty and Staff
More than 500 attendees came to the first-ever clinical research appreciation event! Thank you to everyone who joined us on November 18th! The event provided an opportunity for clinical researchers at Duke to connect with their colleagues and supporting offices. A raffle drawing was held for a number of prizes. Congratulations to the following winners:

<table>
<thead>
<tr>
<th>Prize</th>
<th>Type</th>
<th>Winner</th>
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<tbody>
<tr>
<td>Professional Research Membership</td>
<td>Staff</td>
<td>Kenari Marks</td>
</tr>
<tr>
<td>Professional Research Membership</td>
<td>Staff</td>
<td>Catherine Cheng</td>
</tr>
<tr>
<td>Professional Research Membership</td>
<td>Faculty</td>
<td>Burde Kamath</td>
</tr>
<tr>
<td>Professional Research Membership</td>
<td>Faculty</td>
<td>Brad Kolls</td>
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<tr>
<td>DOCR Coffee Mug</td>
<td>Staff</td>
<td>Robbin Thomas</td>
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<tr>
<td>DOCR Coffee Mug</td>
<td>Staff</td>
<td>Tracey Hawkins</td>
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<tr>
<td>DOCR Coffee Mug</td>
<td>Staff</td>
<td>Marla Jordan</td>
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<td>DOCR Coffee Mug</td>
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<td>Aggie Hunter</td>
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<td>Susan Conder</td>
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<td>Angela Clayton</td>
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<td>Brad Conant</td>
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<td>DOCR Coffee Mug</td>
<td>Staff</td>
<td>Magdi Elgasim</td>
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<td>DOCR Coffee Mug</td>
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<td>Anne Kelly</td>
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**Phishing Scam Awareness**

‘Tis the season for phishing scams....and the scammers are getting smarter. Look for scams which may include electronic greeting cards, requests for charitable contributions, screensavers, seasonal mobile apps, credit card applications, online shopping ads, shipping notifications and more. Many of you participated in awareness events about scamming in October during CyberSecurity Awareness Month, but it’s not too late if you were missed. Both the DUHS ([infosec@dm.duke.edu](mailto:infosec@dm.duke.edu)) and University ([security@duke.edu](mailto:security@duke.edu)) Security Offices are interested in hearing about the security challenges faced by staff. If you have a question or want to request that a talk be given to your group about a topic that is of interest to you, please contact Shelly Epps ([shelly.epps@duke.edu](mailto:shelly.epps@duke.edu)). And on behalf of all of us, thank you! Your dedication to understanding the security issues that our organization faces is critical to protecting the assets and information that we are entrusted to manage.

**Restructuring of Compliance at Duke**

The Institutional Ethics and Compliance Program and School of Medicine Compliance Office have been combined to create one umbrella group now known as the [Duke University Ethics and Compliance Office (DECO)](mailto:). The goal of merging the offices is to streamline all university compliance efforts while protecting the institution.

The office is under the leadership of Tina R. Tyson, formerly Chief Compliance Officer of the School of Medicine and now the Chief Ethics and Compliance Officer for Duke University. Duke has also hired Ericka Kranitz as the new Director of Ethics and Compliance Monitoring. Ericka will work with compliance liaisons throughout Duke in evaluating compliance risks, monitoring key risk areas and reporting monitoring results. She previously served as Director of Internal Audit at North Carolina State University and Director of Financial Compliance Training at the University of Missouri. Margaret Groves will continue as Director of Clinical Trials Quality Assurance, and Tom Davis will also continue as Director of the Compliance Review Services Section for DECO.

**RDSP Enhancements**

Research Data Security Plan (RDSP) enhancements are coming in January 2014 to help clarify instances in which data may need to be stored on Duke University servers. Staff who need help filling out an RDSP application should contact their Research Practice Manager and additional help is available from the Duke Medicine Information Security Office as well. The key to filling
out the information is to be descriptive and to list all areas of data storage, both inside and outside of Duke. DOCR will also be holding a Q&A Research Wednesdays session in April 2014 for researchers who have questions and feedback about RDSPs.

ClinicalTrials.gov
Serious Adverse Event (SAE) and Adverse Event (AE) data can now be uploaded to Clinicaltrials.gov using an Excel spreadsheet. The Arms/Groups in the spreadsheet file must exactly match the current Clinicaltrials.gov entry for your study in order to be successful. To obtain the necessary Excel spreadsheets, click “Download/Upload” in the menu located on the “Results: Adverse Events Overview” screen. Download one Excel spreadsheet for SAEs and one for other AEs. For questions, please contact Susan Natoli at 919-684-9425 or send an e-mail to docr.help@dm.duke.edu.

Providing Notice of Privacy Practices to Subjects
If your study recruits subject who are not patients, then the study team is responsible for providing these subjects a Notice of Privacy Practices (NPP) form at the time of first study contact and getting the acknowledgement of receipt. The NPP changed on September 20, 2013, and the most recent copy of the form is available on DukeHealth.org. If you have current study subjects that received the old form, you will need to provide the new one to them at their next study visit. Subjects who have completed their participation do not need the revised NPP. Information about ordering NPP brochures through Staples Advantage is available on the DOCR website.

Education Opportunities

Speed Science Event
Duke Translational Research Institute (DTRI), the Office of Biostatistics and Bioinformatics, and the Duke Office of Clinical Research will be holding a Speed Science Event on January 23, 2014 from 3:00pm-6:00pm in the Searle Center Lecture Hall. This event is aimed at the many clinical and translational investigators at Duke who would like to incorporate "omic" methods into their research, but lack the quantitative expertise to properly analyze the data, as well as computational researchers who develop advanced analytic methods, but lack high quality datasets to which to apply them. The event will be divided into three sessions:

- **Hour 1**: Each participating *in vitro/vivo* researcher will give several 7-minute interactive presentations of his/her research interests, scientific questions, biospecimens, and data types to small groups of quantitative researchers.
- **Hour 2**: Each participating *in silico* researcher will give several 7-minute interactive presentations of his/her research, desired data types, and analytic expertise to small groups of clinical and translational researchers.
- **Hour 3**: Networking and posters over food and drink.
Registration and additional details about the event are available online.

**DTMI Biostatistics Core**
Funded by the Duke CTSA, the Duke Translational Medicine Institute (DTMI) Biostatistics Core offers consultation on statistical issues in the design and analysis of research projects. Staff members are available to provide advice and support to study teams needing assistance in this area, and they offer walk-in office hours every Monday from 8:00am-10:00am in Hock Plaza (Room 11016) or scheduled consultations through the DTMI website. More information about the DTMI Biostatistics Core services is available on the [DTMI website](#).

**Tech Expo 2014**
The Tech Expo 2014 collaboration will be held on January 9th at the Washington Duke Inn. The full-day event, funded by the University and Health System IT departments, is free to participants. The event will offer the opportunity to hear from diverse teams of IT staff at Duke working across boundaries to build a better, stronger, and more secure IT environment. More information about the event is available on the [Duke website](#).

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting the next Research Wednesdays session on December 11, 2013 featuring a presentation on *DOCR Study Initiation Meeting: What is it? Do I need one? What should I expect?* by Patrick Barrera and Angie Padget. The session will be held from 12:00pm-1:00pm in Duke North 2001, and more information is available on the [DOCR website](#).

**Upcoming DOCR Trainings**
The following DOCR trainings will be held in the month of January for research staff at Duke, and registration instructions are available on the [DOCR website](#):
1. *Research Data Integrity/Data Security* will be held on January 7th.
2. *Human Subjects Research at Duke* will be held on January 7th.
3. *IRB Overview* will be held on January 28th.
4. *Informed Consent* will be held on January 16th.
5. *Study Documentation: Regulations and Best Practices* will be held on January 21st.
6. *Phlebotomy Competency for Research* will be held on January 9th.
7. *Workshop: Consenting a Subject to a Research Study* will be held on January 14th.
8. *Urine Pregnancy Screening for Research* will be held on January 23rd.
9. *Financial Basics for Clinical Research* will be held on January 13th.
10. *ClinicalTrials.gov* will be held on January 30th.

**Don’t Forget!**

**Flu Vaccination Deadline: December 9, 2013**
School of Medicine faculty and staff who work as key personnel on clinical protocols and have in-person interaction with patients or study subjects are required to receive a flu vaccination as a condition of employment. The School of Medicine is sending weekly reminders to all employees who are required but have not yet received a vaccination or an approved exemption. Lists of employees are also being supplied to RPMs, HR managers and/or business managers and CRU directors. If you have questions about the policy, please consult your supervisor.

**eBrowser Retiring on December 14th**
The implementation of Maestro Care as the primary source for documenting healthcare records at Duke is leading to the retirement of the eBrowser system on December 14, 2013. The historical data located in eBrowser has been migrated, and no new data has been added to the system since Maestro Care went live in June 2013. Additional information and resources for using Maestro Care in the clinical research setting is available on the [Duke Intranet](#).

**Adjunct Faculty Serving on a Study**
Adjunct faculty members who are serving on a study should be listed on the Outside Key Personnel list (Section 02. Study Personnel Outside Duke) in your IRB submission. Please note that adjunct faculty members do not meet the requirements for serving in the Principal Investigator (PI) role on a study, as specified in the [HRPP policy](#). If you have any questions concerning adjunct faculty on your study, please contact your IRB specialist.

**DTRI Funding Opportunities**
The Duke Translational Research Institute (DTRI) supports the development of novel methods and proof of concept evaluation of therapeutic agents, biomedical devices, diagnostic tests and technologies through various funding opportunities. More information about the DTRI funding opportunities ranging from $25,000 to $500,000 for Duke Investigators is available on the [DTRI website](#), or you can send questions to dtripilots@dm.duke.edu.

**Frequently Asked Questions**

**Can the offline functionality available in Qualtrics be used in Duke Medicine?**
The Information Security Office (ISO) has posted an article on its website concerning the offline usage of Qualtrics at Duke Medicine. The article highlights the fact that Qualtrics may only be used on Duke-owned devices that are encrypted, and it also provides instructions for how to use the system properly. The full article is available on the [ISO website](#).

**How should I enter the budget for my industry-funded clinical trial into SPS?**
DOCR encourages you to only use the included and excluded direct cost categories when entering industry-funded clinical trial budgets in SPS. All other categories should have $0 and
all costs should be reflected as either included or excluded direct costs. Further details on how to enter these budgets are available on the [DOCR website](http://www.docr.gov). Please keep in mind that this only applies to industry-funded clinical trial budgets. All other budgets (clinical research, federal, etc.) must still use the detailed budget format. If you have questions about how to enter the budget, please contact us at [DOCR.Help@dm.duke.edu](mailto:DOCR.Help@dm.duke.edu).

**I've sent DOCR my fully executed clinical trial agreement. Why is DOCR approval still pending in the eIRB?**
When DOCR receives a fully executed industry-funded clinical trial agreement from the CRU, we provide the Office of Research Administration (ORA) approval in the eIRB system. Receiving DOCR approval in the eIRB is based on several other items: the need for a Maestro Care order set or Beacon build, CT.gov registration, and compliance of all key personnel with required training (CITI, HSR, etc.) Questions related to the approval process can be directed to [DOCR.Help@dm.duke.edu](mailto:DOCR.Help@dm.duke.edu).

**CRU Corner**

**Heart Center CRU**
The Heart Center CRU would like to welcome Hillary Hood to our team. Hillary will be working with the Cath Cluster as a Clinical Trials Assistant II. Welcome, Hillary!

**Radiology CRU**
The Radiology CRU would like to thank Melissa Jenkins Chesney for her invaluable work as CRC over the last 13 years. She is resigning to pursue her education full time. Thank you, Melissa!

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