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What’s New?

Revision to Human Subjects Research (HSR) Education and Training Policy

A revision was made to the HSR Education and Training policy that clarifies the personnel required to take the training. The HSR policy now applies to all Duke Medicine clinical research
personnel who interact with study participants or who have access to study participant private information, as well as Duke University faculty and key personnel with active protocols managed by the Duke Medicine Institutional Review Board (IRB). The revised policy is posted on the DOCR website.

DOCR’s on the Wiki!
Please check out DOCR updates to projects on the wiki available at https://ori.duke.edu/wiki.

Institutional Signature for Industry-funded Agreements
As we continue to review the process for industry-funded clinical research at Duke, we have identified another opportunity to provide clarity and efficiency in the administrative processing of the industry-funded agreements. The current process requiring agreements to be submitted to OCRC for review and negotiation will not change. However, as of September 2, 2014, ORA will only provide institutional signature on industry-funded projects that do not require IRB review (or are deemed to be exempt by Duke’s IRB) as well as all federal and foundation-funded agreements regardless of the IRB declaration. DOCR will provide institutional signature on all industry-funded projects that involve an expedited or full board IRB protocol review, including Duke-as-a-site clinical research agreements.

For the past year, DOCR generally only signed the industry-funded, Duke-as-a-site clinical trial agreements (interventional studies). By expanding the scope to all industry-funded clinical research agreements, not just clinical trials, we hope to provide the clinical research community with a single point of contact regarding institutional signature for these types of agreements.

If you have a question as to the status or location of your agreement after this transition, please contact DOCR.Help@dm.duke.edu or 681-6665.

HIPAA-compliant Box Storage Accounts
Duke faculty, students and staff now have access to secure Box cloud-storage accounts. You can share files stored in these accounts with Duke and non-Duke users, and all files stored in Box are securely accessible anywhere, anytime and from any device connected to the Internet. Duke Medicine users are required to complete online training before being given a Box account. Once you complete the training, you will receive notification of your Box account provisioning within a few hours. If you already have a Duke Box account, you’ll be given the sensitive data folder required for use of Duke restricted data. For additional information on Box and instructions for accessing the training, please visit the DHTS site.

Access to Protocols in Maestro Care for Financial Reconcilers
In the past, financial reconcilers have been able to run the single and multi-fund code reports (RHB233 and RHB234) on any protocol regardless of the protocols they were assigned to. Effective September 2nd, FPMs, financial analysts, and grant managers will only have access to run reports they are assigned to in the RSH record. FPMs should already be assigned to all the protocols in their CRU. You can view who is assigned to a protocol by clicking on the Study
Administration Records link from the dashboard. Enter the protocol number and select the protocol. Next, click the Users and Providers link. The financial reconcilers will be listed in the “Research contacts” field. Please contact your FPM if you need to be assigned to a protocol. A FPM can assign someone to a protocol by submitting a Service Now ticket with the person’s name, dempo ID, and the list of protocols to be assigned.

Maestro Care Reports
Maestro single and multi-fund code reports saved as a favorite currently automatically rerun on a daily basis. Please remember to delete unused reports. If you will not need a report to automatically run on a daily basis, please remove the report as a favorite. Once you need to run the report, you can edit the date range in the report, if needed, make the report a favorite again, and then request the report.

Routine Costs in a Clinical Trial: NC Medicaid
The policy that defines routine and qualifying trials for the NC Division of Medical Assistance and describes when routine costs in a clinical trial may be charged to NC Medicaid/NC Health choice has been posted on the DOCR website.

DOCR Research Management Team to the Rescue
There is a great article posted on the DTMI website that highlights the benefits of using DOCR’s Research Management Team (RMT) to assist with recruitment, data management, and other research needs.

New Internal Funding Opportunity
Before leaving to head the Institute of Medicine, former Chancellor Victor J. Dzau approved a two-year pilot of a new internal funding opportunity to provide financial support to research teams at the Schools of Medicine and Nursing who are developing collaborative research programs. In this pilot phase, the new program is limited to teams intending to submit to currently active National Institutes of Health (NIH) P01, P50, U19, and/or U54 funding opportunities.

The Request for Proposals for the new Program Project Accelerator is attached; the deadline to apply is October 6.

A Question and Answer session about this program will be held on Monday, September 8, 3:30 – 4:30 pm, in Room 114, Chancellor’s Suite, Green Zone Duke South. This will be led by Joanna Downer, Director of Research Development for the School of Medicine and long-time manager of the Science Council.

Please contact Suzy Johnson at 919-681-8222 or suzy.johnson@duke.edu with any questions.

NIH Public Access Policy—100% Compliance Needed in the Future
Through the efforts of the Medical Center Library team working diligently with faculty, co-authors, and research staff, Duke now has a 96% compliance rate—one of the highest
compliance rates for large research institutions in the country! The Library greatly appreciates the responsiveness of faculty and research staff in helping to achieve this high compliance rate.

However, we still have about 400 non-compliant publications, with many of them published between 2008 and 2012. NIH has been clear that while they are focusing on non-competing renewals right now, they will expect 100% compliance in the future for new proposals, reports, and biosketches. While we do not expect NIH to implement this right away, Duke needs to start working on older publications since these can be the most difficult to resolve.

Here is what is being done and how you can help with these outstanding issues:

- The Library team is contacting publishers for articles published from 2008 through 2012 and asking them to submit the manuscript for Duke PIs and authors
- Watch for emails from NIHMS asking for approval of manuscripts!
- PIs and authors may be contacted by the Library if the publisher is not providing assistance or needs your authorization
- Remind your co-investigators and authors working under your grant to submit and approve manuscripts as soon as possible
- Duke PIs will be notified by email about more current publications that need to be submitted or approved.
- If you have a progress report due and have non-compliant publications, you will be notified about 6 to 8 weeks before the deadline of any problems

Contact the Library about a manuscript problem or if you need a refresher training session! We have a team of 6 librarians who can help with NIH questions: 919.660.1100, medical-librarian@duke.edu, or use our chat services at https://mclibrary.duke.edu/about/ask-librarian (9-5 M-F).

Education Opportunities

Research Wednesdays
DOCR and the Medical Center Library & Archives will be hosting several Research Wednesday sessions in the coming weeks. Erin O’Reilly will present Regulatory Affairs: Use of Mobile Medical Applications in Clinical Research on September 10th in Duke North 2001. Emily Mazure and Brandi Tuttle will present Medical Center Library Updates on September 24th 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 September and October for research staff at Duke, and registration instructions are available on the DOCR website:

1. Financial Basics for Clinical Research will be held on September 8th.
2. Study Documentation: Regulations and Best Practices will be held on September 9th and October 14th.
3. ClinicalTrials.gov Introduction will be held on September 16th.
4. **Industry Funded Clinical Research – Process for Contracts** will be held on September 16th.
5. **Human Subjects Research at Duke** will be held on September 17th and October 9th.
6. **Urine Pregnancy Screening for Research** will be held on September 18th.
7. **Recruiting Regulations and Best Practices** will be held on September 22nd.
8. **Biobanking Research Specimens at Duke** will be held on September 23rd.
9. **IRB Overview** will be held on September 23rd and October 21st.
10. **Phlebotomy Competency for Research** will be held on September 25th.
11. **Data Management 101** will be held on October 7th.
12. **Workshop: Informed Consent Writing** will be held on October 9th.
13. **Adverse Events** will be held on October 15th.
14. **Informed Consent** will be held on October 16th.
15. **ClinicalTrials.gov Reporting Practical** will be held on October 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 September and October on the following dates in the Seeley Mudd Computer Training Lab, 1st Floor:

- 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
- 10/1/2014 from 8:00-11:30am
- 10/6/2014 from 12:00-3:30pm
- 10/8/2014 from 8:00-11:30am
- 10/13/14 from 12:00-3:30pm
- 10/15/14 from 8:00-11:30am
- 10/20/14 from 12:00-3:30pm
- 10/22/14 from 8:00-11:30am
- 10/27/14 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 September on the following dates:

- 9/11/2014 from 2:00-3:00pm
- 9/18/2014 from 2:00-3:00pm
- 9/25/2014 from 2:00-3:00pm
Maestro Care Clinical Research Super User Applications Workshop will be held on the following date in the Seeley Mudd Computer Lab, 1st Floor

- 9/8/2014 from 12:30-3:00pm

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

**Financial Basics for Clinical Research**
If you are involved in the financial management of a clinical research study, you may be interested in attending the Financial Basics for Clinical Research class (next scheduled for September 8th). This class covers a variety of topics including the purpose of the CRU Management Fee and how to incorporate this fee into a budget, the concept of effort management, and the importance of financial and management reporting. You can register for this class via the [DOCR website](https://docr.gov).

**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!**

**Save the Date—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!

“To Secure Protected Information...Encryption is Key” – October is Security Awareness Month

**Protect It** – Store or sync files containing PHI – Only use Duke’s shared network or Duke Box secure cloud storage.

**Encrypt It** – All portable devices storing PHI should be configured for encryption: thumb drives, USB hard drives, cell phones, tablets, etc.

**Sync It** – 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: [security.duke.edu/secure-your-devices/mobile-devices](https://security.duke.edu/secure-your-devices/mobile-devices)

**Funding Opportunities**
Duke provides a search tool for various funding opportunities (Institutional, non-profit, and Federal) at [https://researchfunding.duke.edu/](https://researchfunding.duke.edu/).
Open Payments (Sunshine Act) Review Process
Due to a technical glitch that caused the Open Payments system to be offline for several days, CMS has now extended the review period to September 8th (previously August 27th). This limited review period will allow physicians and representatives from teaching hospitals to review and dispute any payments that manufacturers of pharmaceuticals or devices reported to CMS in the last five months of 2013.

Sponsored Travel Reporting Reminder
In August 2012 federal regulations relating to conflict of interest were put in place for individuals who receive Public Health Service funding for research (e.g. NIH, CDC, FDA). These rules will require active steps on your part. We would also like to reiterate, these are federal rules, not Duke specific rules, that institutions like Duke are being asked to enforce.

Sponsored Travel Reporting
Any individual who receives and/or is paid on a PHS-funded research grant is now required to disclose all reimbursed or sponsored travel (i.e., that which is paid on behalf of the individual) if the travel meets the following criteria:

- The travel is reimbursed or sponsored by an external entity (including non-profit foundations, professional societies, and for-profit drug and device manufacturers);
- The sponsored travel is related to your institutional responsibilities at Duke (e.g., as a physician scientist, you are being sponsored to attend a corporate scientific advisory board meeting to discuss your science, or as a hematologist you are asked to attend a meeting of the American Board of Hematology).

You do not need to report travel if it is reimbursed or sponsored by any of the following:

- An Institution of higher education;
- Federal, state, or local government agency;
- An Academic teaching hospital;
- A research institute affiliated with an institution of higher education.

Otherwise, travel supported by all other sponsors must be reported, including foundations, professional associations, societies, professional boards, corporations, etc.

See this link for examples of qualifying travel. If your travel requires reporting, you should enter it into a new web application. You will need your NetID and NetID password to access the site. The web address is: https://radapps.duke.edu/phs_travel

Conflict of Interest Reporting Form
Should you have a significant change in any external financial relationships, you are required to update your conflict of interest reporting form within 30 days of the change in status. Examples of a “significant change” include new consulting relationships with a pharmaceutical or device company, a newly licensed intellectual property, or joining a scientific advisory board for a company that does business with Duke. To update your conflict of interest form, the web site is: https://radapps.duke.edu/coi_form
Frequently Asked Questions

How do I Consent Mothers and Their Babies?
The process for consenting a mother and her unborn child to participate in a research protocol in which the participation period extends beyond the birth of the child is as follows:

- A mother consents to a research study for herself and her unborn child
- The study team sends a copy of this signed research consent to medical records, if clinically relevant, for inclusion in the mother’s electronic medical record
- Once baby is born, the study team will send another copy of mother’s signed consent with a single strike through the maternal identifiers on the consent (initialed and dated) and affix the baby’s Maestro label next to the maternal info to be uploaded in infant’s electronic medical record.

CRU Corner

School of Nursing CRU
Please welcome Rebecca Ellis, RN to the School of Nursing research staff as a CRC II. Initially she will be working with Karin Reuter-Rice on her TBI in Pediatrics Research Study. Rebecca comes to us from DUHS.

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