Regulations, Policies, and Procedures

Research with Children CITI Module to Be Required for the Clinical Research Community on January 15th

Duke utilizes the Collaborative Institutional Training Initiative (CITI) program to meet the human subject’s protection training requirements for all members of the clinical research community. Starting January 15th, the Research with Children module will be required for all staff participating in human subject’s research at Duke. Because this module was previously required of clinical researchers who conducted studies with participants less than 18 years of age, many researchers may have already completed the training. DOCR will provide a notification to existing researchers who need to complete this module. As new researchers register for the CITI training, this module will be included in their required list of modules.

Simplified Renewal of Human Subjects Research Training

To make it easier for you to stay up-to-date on this annual training requirement, DOCR has simplified the process for renewal significantly reducing the number of steps you must complete. Approximately 30 days before your training is set to expire, you will be registered for the web-based version of the training in the Duke LMS. You will receive an automated email message from the Duke LMS indicating that you are registered. You can use the link in the email message to log into the Duke LMS. The Human Subjects Research at Duke training will be listed in your In-Progress Learning Activities. Just click Launch.

DOCR continues to work on the process and content behind-the-scenes to make the process less cumbersome and technologically sound. Please contact DOCR.Help@dm.duke.edu if you have any difficulties completing your training or renewal.

Revising the Research Data Security Plan (RDSP)
To revise an approved Research Data Security Plan (RDSP) completed within the eIRB, do not submit an amendment to the IRB. Please follow the instructions in the RDSP Reference Guide which is located on the eIRB website under User Guides.

Updated Closeout Process Tools

Duke’s Closeout Project Team has made enhancements to the Closeout Tasklist and FAQs. In addition, a video is now available that provides Closeout Project information from the Research Administration Symposium. Keep updated about the closeout project by visiting the Closeout Project website.

MaestroCare Will be the Registry of Record for all Duke Patients Effective February 1, 2015

To date, only patients recruited into research with research charges either going to insurance or a fund code required registering in Maestro Care. Effective February 1, all Duke Patient recruits will be registered in Maestro Care. Training for staff who are unfamiliar with Maestro Care will be available on January 14, 21, and 18 from 8:30 a.m. to 11:00 a.m. in the Seeley Mudd Computer Training Lab. This training will focus on registering subjects. You can find the class in the Duke LMS by searching for “Patient Registration.” For questions about one of your studies or assistance with registering in the class, contact DOCR.Help@dm.duke.edu.

Research Dashboard Messages Available in MaestroCare

If your research subjects have been seen in the Duke Emergency Department or admitted to the hospital, you will receive an In-Basket message in MaestroCare to notify you. You can then research the incident and link the encounter to the timeline if the incident is deemed related to the study.

New Research Patient Care Rate Agreement

An updated version (November 2014) of the Research Patient Care Rate Agreement is available on the DOCR web site under CRUs and Oversight Organizations, then CRU Resources and Tools.

Training Opportunities

Research Professionals Network Kickoff – Part 2

DOCR held its first Research Professionals Network (RPN) event on December 11 at Trent Semans with about 60 people in attendance. There was a great response to the network and we’ve had requests to hold a second, repeat, kickoff event so that more research professionals could attend. The repeat event will be held on January 21, from 1:00-2:00 p.m. Calendar invitations will be sent via our listserv. If you know of research professionals looking to enhance their careers, encourage them to take part – email docr-rpn@dm.duke.edu. This network is particularly useful for professionals such as Clinical Research Coordinators, Clinical Trials Managers, Clinical Trials Assistants, Project Managers or Coordinators for Clinical Research, Assistant Research Practice Managers, and Research Practice Managers.

Upcoming SOCRA Exam Availability
SOCRA in conjunction with the Duke Oncology Clinical Research Unit will provide the SOCRA exam on March 27, 2015 from 8:30 a.m. to 12:00 p.m. at Hock Plaza. The deadline to apply for this exam is February 13, 2015. See the SOCRA website for additional information.

Did You Miss Dr. Califf’s Presentation at Research Wednesday?

Dr. Califf spoke about the CTSA, Google, PCORnet and Clinical Research at Duke on October 22nd. However, you may have missed his presentation. When you can’t attend the Research Wednesday session, you can view the presentation and hear the voice-over by completing the web-based version in the Duke LMS. It’s almost like being there. Check out the other Research Wednesday presentations that are available for your review in the Duke LMS on the Past Presentations page of the DOCR web site. At this time, CEU credit is not provided for the online versions.

Upcoming DOCR Training Offerings

DOCR training offerings are available in the Duke LMS. You have 2 easy ways to find all DOCR classes: Enter “DOCR” in the search field and click Search, or click the Category link, and then click the DOCR link. The results display all the offerings currently available from DOCR. Hint: If you want to bookmark the Duke LMS in your browser, edit the bookmark to this address:

https://vmw-lmsweb.duhs.duke.edu/SabaLogin

Detailed information about each offering and direct links to the offering are also available on the DOCR website. Following are the upcoming instructor-led DOCR Offerings for January and February 2015:

<table>
<thead>
<tr>
<th>Title</th>
<th>Start Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>MC Clinical Research 100</td>
<td>1/5/2015</td>
<td>Mon (12P-3:30P)</td>
</tr>
<tr>
<td>Human Subjects Research at Duke</td>
<td>1/6/2015</td>
<td>Tue (10A-12P)</td>
</tr>
<tr>
<td>Study Documentation Regulations and Best Practices</td>
<td>1/6/2015</td>
<td>Tue (12P-2P)</td>
</tr>
<tr>
<td>MC Clinical Research 100</td>
<td>1/7/2015</td>
<td>Wed (8:30A-12P)</td>
</tr>
<tr>
<td>The Informed Consent Process</td>
<td>1/7/2015</td>
<td>Wed (10A-12P)</td>
</tr>
<tr>
<td>MC Clinical Research 100</td>
<td>1/12/2015</td>
<td>Mon (12P-3:30P)</td>
</tr>
<tr>
<td>IRB Overview</td>
<td>1/13/2015</td>
<td>Tue (10A-12P)</td>
</tr>
<tr>
<td>MC Clinical Research Patient Registration</td>
<td>1/14/2015</td>
<td>Wed (8:30A-11P)</td>
</tr>
<tr>
<td>Research Wednesdays: The Duke LMS - What Can It Do for Me?</td>
<td>1/14/2015</td>
<td>Wed (12P-1P)</td>
</tr>
<tr>
<td>Phlebotomy Competency for Research</td>
<td>1/15/2015</td>
<td>Thu (9:00A-11:30A)</td>
</tr>
<tr>
<td>Phlebotomy RENEWAL Competency for Research</td>
<td>1/15/2015</td>
<td>Thu (11:30A-12:00P)</td>
</tr>
</tbody>
</table>
Frequently Asked Questions

**Question:** How do I pay employees who are research participants without gathering the Social Security Number which is protected information?

**Answer:** Because income from research participation is potentially taxable, the income must be reported to the IRS. The Personal Data Disclosure Form, available on the [eIRB site](https://eirb.duke.edu) and the [IRB main site](https://irb.duke.edu) includes fields for both the Social Security Number and the
Duke Unique ID. However, only one of the identifying numbers is required. For employees, list the Duke Unique ID so that the Social Security Number is not needed.

**CRU Corner**

Congratulations to both Megan Arthur who was recently promoted to a Clinical Research Coordinator II with the Heart Center CRU Cath Cluster. Keep up the great work Megan!

Congratulations to Connor Drake who has been reclassified to a Clinical Research Coordinator I in the School of Nursing. Thank Connor for your hard work!

Congratulations to Anita Brantley on her new position as a Clinical Trials Coordinator I with DTMI. She will be a “Research Navigator” helping connect the research community to resources within the institution to help perform research. Her last day at DOCR will be January 28.

The HC CRU would like to welcome Sharon Chavis, RN to the Heart Failure Cluster. Sharon, a new CRC I, previously worked as a Clinical Nurse II on the Clinical Transport Team. Welcome Sharon!

Congratulations to Jessica Hester! Jessica has been working with our Heart Failure cluster as part Duke temps. She has recently accepted a permanent position as a CTA I. Congratulations Jessica!

Welcome Andrea McGovern, a CRC I, to the Cath Cluster in the HC CRU. Andrea joins us from PMG Research in Raleigh and Wake Research Associates. We are so excited to have Andrea join our team!

**Partner Resources**

**DTMI Newsletter**

The Duke Translational Medicine Institute (DTMI) has launched a new website (www.dtmi.duke.edu). Help us improve it by giving it a test run and providing feedback to DTMI_Info@dm.duke.edu.

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