July 2015

- Regulations, Policies, and Procedures
- Training Opportunities
- Did You Know?
- CRU Corner
- Partner Resources

Regulations, Policies, and Procedures

Enrollment Log Template Available in REDCap

DOCR has created an Enrollment Log Template in REDCap to make it easier for study teams to track enrollment information. This template is not required, but rather a tool that you may use in place of Excel spreadsheets or other less secure tracking systems. This tool may be especially helpful in cases when study participants are not Duke patients. You may use this log as-is or modify to your own needs. The log can be exported into other file formats for other purposes (e.g., Excel). If you are interested in a copy of the template:

- Go to https://redcap.dtmi.duke.edu/redcap/surveys/?s=oR63f5
- Select Copy of Existing project
- Enter the name of your project in this format: Enrollment Log - Pro000####
- Complete the rest of the information on the form and submit the form.

If you have questions and need to understand how to use the tool, please contact redcap-docr@duke.edu, or visit us in Hock 9047 at 11:00am on Tuesdays, when we have open REDCap office hours. A tip sheet is also available.

Reviewing Patient Charges and Payment Routing

As you may know, an error in the RSH 005 report (used to verify patient charges and routing) was discovered. Charges that had already been billed through the system were not being pulled into this report. In order to verify charges and routing, the research community will now need to use the Research Billing Review button. A tip sheet with step by step instructions is available.
We recognize that this is a change and takes time – we are asking that coordinators review NIH and other federally-funded studies by August 1st. Other studies (those that are not NIH or federally funded) should be reviewed by October 1.

**Re-Designed DOCR Website Goes Live**

In conjunction with the re-design of the School of Medicine website, the Duke Office of Clinical Research website has been re-designed and will launch soon. The new design of the DOCR website is organized around clinical research processes and tasks that occur in each step of the clinical research life-cycle from study initiation through study close out. The site is intended to make it easy to find information and answers to questions regarding the clinical research process at Duke.

**Annual DOCR Satisfaction Survey**

We want your feedback! In our continuing efforts to refine and improve our service to the research community, 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 also will have the opportunity to be entered into a drawing to win an iPod shuffle (while still maintaining anonymity of individual survey responses)! If you have any questions or concerns, please direct them to DOCR.Help@dm.duke.edu.

**Save the Date: “It Takes a Team!” 2015 Clinical Research Appreciation Day**

The 2015 Clinical Research Appreciation Day “It Takes a Team!” will be held Tuesday, October 6th, 11:00 am – 2:00 pm, Trent Semans Center Great Hall. This year’s baseball themed event will include information tables, raffle prizes, and food and beverage. Stay tuned for additional details as the event approaches.

**Duke Human Research Training (DHRT) Update**

In mid-June, you received emails about issues with the DHRT training. As we mentioned in our communications, due to a corruption in how the course was functioning in the Learning Management System, learners who successfully passed the DHRT quiz didn’t receive credit for the course. DOCR has created a mirror course that functions correctly and has fixed all known issues. Any employees taking the DHRT course in the future will be taking the new course and should not experience difficulties. We appreciate everyone’s patience. As always, please let us know if you have issues with DHRT or have general questions – docr.help@dm.duke.edu or 681-6665.
DOCR Certified Trainer Program

DOCR is in the process of expanding its course instructor pool for the 2015/2016 calendar year. Duke Clinical Research community members are invited to apply to the DOCR Train-the-Trainer series. In addition to the series, accepted applicants will receive one-on-one content and presentation professional development and will be expected to lead 2 – 4 classes on the DOCR course calendar over the coming year. A flyer and application is available. Applications are being accepted through July 30 for the summer training session. Contact DOCR-Training@dm.duke.edu with questions.

CEUs No Longer Offered for Duke Human Research Training (DHRT)

Beginning July 1, 2015, Continuing Education Units (CEUs) will no longer be offered for completion of the Duke Human Research Training (DHRT). Previously, CEUs were offered for participants taking the in-person offering of the course. It was determined that since this course is an annual training requirement it does not meet the criteria necessary to grant CEUs. Many of DOCR’s other courses continue to provide CEU credits. For a full listing of DOCR’s educational offerings, visit the website.

Research Wednesdays Moves to New Time

Beginning July 8th 2015, the Research Wednesdays education series will move to a new time, 1:00 – 2:00 pm Duke North 2002 or 2001. The time change is a result of room availability with the new academic year. Additional information about this series along with a list of upcoming dates and speakers is available on the DOCR website.

Implementation of Study Subject Payments Using a Debit Card (Greenphire)

Duke University has contracted with Greenphire to implement a debit card system for use in clinical studies. This card system is intended to replace the need for issuing checks or providing gift cards to study subjects, as well as enhancing the security around the Social Security Numbers needed to process a check.

A pilot group is expected to “go live” in late July.

As Greenphire begins to roll out, budgeters and study teams need to take into consideration the costs of the Greenphire card while developing and negotiating budgets.

At this time, the Greenphire card costs $3.50 and the load fee is $1.00. The load fee is associated with every payment, as well as every void.

Training materials, including Frequently Asked Questions (FAQs), are being developed and will be available to those involved with compensating and reimbursing study subjects.
Who Is Overseeing a FDA Regulated Protocol When the PI Is Out of the Duke Area and Unavailable?

According to the FDA Guidance for Industry: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009, section B,2: Reasonable Access to Medical Care: “Investigators should be available to subjects during the conduct of the trial for medical care related to participation in the study. Availability is particularly important when subjects are receiving a drug that has significant toxicity or abuse potential. For example, if a study drug has potentially fatal toxicity, the investigator should be readily available by phone or other electronic communication 24 hours a day and in reasonably close proximity to study subjects (e.g., not in another state or on prolonged travel). Study subjects should be clearly educated on the possible need for such contact and on precisely how to obtain it, generally by providing pertinent phone numbers, e-mail addresses, and other contact information, in writing. Prior to undertaking the conduct of a study, prospective investigators should consider whether they can be available to the extent needed given the nature of the trial.”

Therefore, in the case that the PI no longer meets the criteria above (for example on prolonged travel or FMLA), the study team must submit a personnel change request to change the PI to someone who is both knowledgeable and familiar with the study and can act as the PI in the former PI’s absence (DUHS Principal Investigator Agreement, Sections 3, 17, 18). The protocol must have plans for emergency contact by subjects in the event of a subject-related injury.

What Is the CTSA Doing for You? Learn More...

Ever wondered what the CTSA can do for you? Ebony Boulware, MD, contact PI for the Duke CTSA will host the first CTSA Virtual Town Hall on July 20 at noon. Dr. Boulware will share an overview of CTSA efforts and will conclude with an open Q&A time.

DCRU IRB Application

There are some updates to how you complete your eIRB submission for studies involving the DCRU. Section 15.1 (DCRU application) includes the section: Clinical Trial Charge Assignment Grids. In the past, this section required a response to move forward with the application, but with the last eIRB software update the requirement (red asterisk) was removed. This section is no longer relevant since MaestroCare billing calendars have replaced the charge assignment grid.

*Clinical Trial Charge Assignment Grids

Please submit Clinical Trials Charge Assignment Grids for Duke as a Site (“Duke Office of Clinical Research Grid” or “DOCR Grid”):

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Date Created</th>
<th>Last Modified</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There are no items to display
Additionally, below this section is the Appendices section. Study teams should attach a completed DCRU service request form in this section. Without the form, the DCRU specialty committee will not be able to complete its review of the project. For more detailed information please either click on the link DCRU Application Packet or contact Donna Hamel.

Training Opportunities

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 June and July 2015:

<table>
<thead>
<tr>
<th>Title</th>
<th>Dates</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Wednesdays:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- DOCR Website Launch and the Wiki</td>
<td>July 8</td>
<td>1 PM – 2PM</td>
</tr>
<tr>
<td>- Demystifying the Contracts Process</td>
<td>July 22</td>
<td></td>
</tr>
<tr>
<td>- Office of Research Informatics—Project Updates and New Initiatives</td>
<td>August 26</td>
<td></td>
</tr>
<tr>
<td>MC Clinical Research 100</td>
<td>July 1, 8, 15, 22, 29</td>
<td>8:30 AM-Noon</td>
</tr>
<tr>
<td></td>
<td>August 5, 12, 19, 26</td>
<td></td>
</tr>
<tr>
<td>MC Clinical Research 100</td>
<td>July 13, 20, 27</td>
<td>Noon-3:30 PM</td>
</tr>
<tr>
<td></td>
<td>August 3, 10, 17, 24, 31</td>
<td></td>
</tr>
<tr>
<td>Duke Human Research Training (DHRT)</td>
<td>August 17</td>
<td>Noon – 2 PM</td>
</tr>
<tr>
<td>IRB Overview</td>
<td>July 21, August 18</td>
<td>10 AM - Noon</td>
</tr>
<tr>
<td>Phlebotomy Competency for Research</td>
<td>July 23</td>
<td>9 AM – 11 AM</td>
</tr>
<tr>
<td>Phlebotomy RENEWAL Competency for Research</td>
<td>July 23</td>
<td>11 AM – 11:30 AM</td>
</tr>
</tbody>
</table>
Clinical Research Training Program (CRTP) Accepting Applications

The CRTP program of the Duke University School of Medicine provides academic training in the quantitative and methodological principles of clinical research. Designed primarily for clinical fellows who are training for academic careers, the program offers formal courses in research design, research management, medical genetics, comparative effectiveness, translational methodologies, and statistical analysis.

A degree option in the program leads to a Master of Health Sciences in Clinical Research, a professional degree awarded by the School of Medicine. An advanced degree in a clinical science from an accredited institution is a prerequisite for admission either as a degree candidate or as a non-degree participant.

The program is now accepting applications for the academic year 2015-16. For a detailed description of the program, the course offerings, and a link to the online application, visit the CRTP website. For more information, contact Gail Ladd, CRTP Program Coordinator, 681-4560.

Duke AHEAD Hosts Tips and Tricks for Effective Posters & Presentations

This hour-long session will feature a series of mini-presentations by experts in poster creation and oral presentation. Participants will be able to:

- Effectively plan your message, deliver the presentation, and handle questions.
- Describe components of integrating video within a poster presentation.
- Describe the steps for formatting and designing an academic poster.
- Discuss the creation of appropriate poster content.

The session is held on July 15, 2015, 12:00-1:00 pm in room 1026 DUSON Pearson. Lunch will be served. Please RSVP to dukeahead@duke.edu.

Did You Know?

Did you know there is a way to link a Maestro Care appointment to a study protocol and timeline for the scheduling view? A tip sheet is available for step by step instructions.
CRU Corner

DCRU would like to congratulate Zongyao Sophie Wang on her completion of the graduate program at Elon. She obtained her MBA this May.

DCRU would also like to congratulate Charlene Carver for her recent promotion to CTA II and Byron Hauser for his promotion to CRC I.

Congratulations to Nichole McNeil, CRC 1, who recently joined the Lumberton Cluster of the Heart Center Research Team.

Congratulations to Dr. Brett Atwater and the rest of the Electrophysiology (EP) research team. Please view the WRAL spotlight to see the exciting research going on in EP.

Partner Resources

DUHS Compliance Office Newsletter

Catch up on news from the DUHS Compliance Quarterly Newsletter.

CTSA Updates

Catch up on the news about the Clinical and Translational Science Award (CTSA) in the latest Newsletters.

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.