Duke University School of Medicine
Clinical Research Update
July 2014

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What’s New?

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

**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 15\(^{th}\) 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!

**Save the Date—Clinical Science Day**
Clinical Science Day will be held on Saturday, November 8, 2014 in the Great Hall of the Mary Duke Biddle Trent Semans Center. The goal of Clinical Science Day is to bring together faculty, staff, trainees, and students to celebrate clinical research and the vast and diverse array of activities taking place across our medical campus, and to encourage collaborations. You may register for this event [here](#).

**Process for Adding a Volunteer or Unpaid Intern to a Study Team**
The process for adding a volunteer/unpaid intern to a study team has been posted on the home page of the IRB web site. If you wish to add a volunteer to your study team, please see the current requirements for this on the [IRB Website](#). If you have questions about the process, please contact June Walker in the DUHS IRB.

**Recent Revision to Advertisement Policy**
The IRB has revised the advertisement policy to clarify that specific dollar amounts are not to be included in study advertisements. Advertisements may state “You will be compensated for your study participation” but should not state the specific amount to be paid, or use bold or enlarged print or other means to emphasize compensation. The revised policy can be found at the IRB web site on the [HRPP Policies page](#).

**New Safety Reporting System (SRS) Now Live**
The new SRS module integrates DUHS’ patient safety reporting, risk management, and visitor relations systems. The result is a comprehensive picture of patient risk and safety across the enterprise. To coincide with the implementation, and as mandated by The Joint Commission, all clinical and non-clinical DUHS and PDC employees, as well as any faculty and staff who have direct patient interface in their roles and/or duties related to education and research, are required to complete interactive training by **Tuesday, July 15**. The new SRS can be accessed the following ways:
- On PIN workstations, by clicking on the “Safety Reporting System” icon
- Outside the Duke Network on [https://awi.duhs.duke.edu](https://awi.duhs.duke.edu)
Existing connections/links to SRS sites will also re-direct to the new site

**New System to Access Duke Medicine Policies**
In an effort to centralize and standardize the development and accessibility of policies and procedures across Duke University Health System (DUHS), a new online Duke Medicine Policy Center has been launched. You can access this information the following ways:
- By visiting the Duke Medicine intranet homepage ([intranet.dm.duke.edu](http://intranet.dm.duke.edu))
- On PIN workstations under “Institutional Systems”
- On any computer with an internet connection using the URL: [https://egrc.duhs.duke.edu](https://egrc.duhs.duke.edu) and entering your Duke NetID and password

This system does not include DOCR or IRB policies which can still be found on each office’s website.

**Grant Pricing Request “Resolved” Service Now Tickets**
The request for grant pricing is now processed through a Service Now ticket, with the actual form attached to the Service Now request. Once the PRMO has processed the request, you will receive an email stating the ticket has been “resolved.” You will need to click on the hyperlink in the email, which will direct you to your submitted ticket. The completed pricing form will be attached to the ticket.

**Maestro Audit Report**
The “Patient Needing Coordinator Review” report (RPB466-CRC) has been available for a few weeks. This report enables a CRC to review patient charges and services to ensure that the right charge is directed correctly (insurance, insurance-research related, or research fund code). After a biller has reviewed, the CRC will be able to view the charges by patient and mark each service as reviewed. The information from the CRC Review report will populate a new Maestro Audit report. The Maestro Audit report will be used by financial reconcilers to confirm which charges have been reviewed by the CRC. This will be the “hand off” process between the CRC’s verification of the patient services and the charge reconciliation of Maestro to R3 by the financial reconciler. We anticipate this report to be in production by the end of July.

**EPIC 2014 Update**
With the EPIC 2014 upgrade in July, there will be a freeze on moving new protocols into production from July 8 - 12. That means that if the protocol isn’t in production by July 7th, that protocol or any changes to an existing protocol will have to wait until July 13 to move into production. Urgent and emergent requests are affected by this freeze as well. Please plan accordingly and contact DOCR with any concerns.

**Rebecca Brouwer Joins DOCR Team**
DOCR is pleased to welcome Rebecca Brouwer, MS as Associate Director, Research Operations in the Duke Office of Clinical Research (DOCR). Rebecca has been at Duke since 2000 and has had held research roles with progressive responsibilities. Her most recent experience is with the Duke Global Health Institute and Community Family Medicine where she has been a Research Project Manager.
In her new role, she will be responsible for the identification, strategic planning and development of clinical research support, development, study operations and start-up planning for grants. This position will oversee the centralization of performance metrics alignment with professional research staff (clinical research coordinators and other research personnel). Additionally, she will provide oversight as an Institutional resource for clinical research study planning activities involving grant applications and will work directly with faculty and research staff to prepare appropriate budget and operational plans for grant-funded applications. She will liaise with the School of Medicine’s Research Development office to assist with operationalizing the plans for complex grants and individual investigator submissions through departments.

**CAS/Rebudgeting Process Change Effective July 1**
The paper Rebudget Forms (Request for Rebudgeting of Funds document) and CAS Direct Cost Exception web form will no longer be accepted by ORA and ORS. The recently released online Rebudgeting/CAS Form (ReC) will be the only option for users and is accessible through Duke@WORK>Grants Management tab>eRA@Duke Management.

- Training on the use of the Rebudgeting/CAS Form (ReC) will be incorporated into RCC’s *Making Adjustments to Sponsored Projects* class. Registration is available [here](#).
- Step-By-Steps and videos are also available online on the [finance website](#) to assist users with the new Rebudgeting/CAS Form (ReC).

**Prior to using the new, online Rebudgeting/CAS Form (ReC), departments must have a Departmental Approver workflow in place.** If you are a first time user of the Rebudgeting/CAS Form and need to find out if your department has a workflow in place, please contact Meredith Woods at meredith.woods@duke.edu.

- RCC will no longer distribute monthly Non-Compliant CAS Alerts to departments. Users can now run the CAS Compliance Report at their discretion to review outstanding non-compliant CAS charges. The CAS Compliance Report provides “real time” data and is accessible through Duke@WORK>Grants Management tab>MyResearch Reports (for Grants Management Role)>CAS Compliance Report.
  - A Step-By-Step and video to assist users with the CAS Compliance Report are available online on the [finance website](#).
- RCC will continue to issue CAS Final Remediation Write-off Reports on a monthly basis to SOM departments via the Grant Management Team (GMT) and Campus departments via the Associate Deans. These reports reflect charges that must be addressed within 30 days or be written off.

**Education Opportunities**
Research Wednesdays

SRA International Conference
The Society of Research Administrators (SRA) is holding its annual meeting in San Diego, California from October 18-22. Educational credit will be offered for attending the meeting and more information about registration and the meeting agenda is available on the [SRA website](#).

MAGI 2014 West Conference
The Model Agreements & Guidelines International (MAGI) conference will be held November 9-12 in San Francisco. Over 90 sessions and workshops will offer practical tips in a coherent program for operations, regulatory compliance, contracts, and budgets. For more information and to register, please visit the [MAGI website](#).

FDA Investigator Training Course
The Sixth Annual Clinical Investigator’s course, co-sponsored by the Food and Drug Administration’s office of Medical Policy and the Duke School of Medicine is now open for registration. The dates for the course are Nov 4-6, 2014. The venue is The Holiday Inn, College Park, MD 20740.

This extensive three day course focuses on non-clinical, early clinical, and phase 3 studies, issues in the design and analysis of trials, safety and ethical considerations, and FDA's regulatory requirements related to the performance and evaluation of clinical studies. Attendees will have the unique opportunity of hearing directly from FDA’s nationally renowned experts on issues critical to successful clinical research. The course is designed for physicians, nurses, pharmacists and other health care professionals involved in clinical trials.

For more information on and to register for the course click here: [http://continuingeducation.dcriduke.edu/CITC](http://continuingeducation.dcriduke.edu/CITC). You will need to create a profile prior to registering for this course. For instructions on how to set up a profile please see the instructions on the registration page. The course fee is $150.00. Visa and Mastercard are accepted

Upcoming DOCR Trainings
The following DOCR trainings will be held in the month of July and August for research staff at Duke, and registration instructions are available on the [DOCR website](#):

1. *Study Documentation: Regulations and Best Practices* will be held on July 8th and August 14th.
2. *Human Subjects Research at Duke* will be held on July 10th and August 21st.
3. *Urine Pregnancy Screening for Research* will be held on July 17th.
4. **IRB Overview** will be held on July 22\textsuperscript{nd} and August 1\textsuperscript{st}.
5. **Adverse Events** will be held on July 22\textsuperscript{nd}.
6. **ClinicalTrials.gov Introduction** will be held on July 22\textsuperscript{nd}.
7. **Phlebotomy Competency for Research** will be held on July 24\textsuperscript{th}.
8. **ClinicalTrials.gov Reporting Practical** will be held on July 31\textsuperscript{st} and August 21\textsuperscript{st}.
9. **Research Data Integrity/Data Security** will be held on August 5\textsuperscript{th}.
10. **Investigator Responsibilities** will be held on August 11\textsuperscript{th}.
11. **Informed Consent** will be held on August 12\textsuperscript{th}.
12. **Workshop: Informed Consent Writing** will be held on August 14\textsuperscript{th}.
13. **ClinicalTrials.gov Advanced Reporting** will be held on August 21\textsuperscript{st}.

**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 July and August on the following dates in the Seeley Mudd Computer Training Lab, 1\textsuperscript{st} Floor:
- 7/7/2014 from 12:00-3:30pm
- 7/9/2014 from 8:00-11:30am
- 7/14/2014 from 12:00-3:30pm
- 7/16/2014 from 8:00-11:30am
- 7/21/2014 from 12:00-3:30pm
- 7/23/2014 from 8:00-11:30am
- 7/28/2014 from 12:00-3:30pm
- 7/30/2014 from 8:00-11:30am
- 8/4/2014 from 12:00-3:30pm
- 8/6/2014 from 8:00-11:30am
- 8/11/2014 from 12:00-3:30pm
- 8/13/2014 from 8:00-11:30am
- 8/18/2014 from 12:00-3:30pm
- 8/20/2014 from 8:00-11:30am
- 8/25/2014 from 12:00-3:30pm
- 8/27/2014 from 8:00-11:30am

**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 July on the following dates:
- 7/10/2014 from 2:00-4:00pm in Duke North 2001
- 7/24/2014 from 2:00-4:00pm location TBD

**Don’t Forget!**
July 1 Price Increases
As a reminder, the first of the new fiscal year is here and the annual price increase for patient care charges is in effect. You may notice some differences as your study is billed for subjects seen after June 30th. If you would like to know specific charge increases, please contact the PRMO with a revised pricing request via a Service Now ticket.

REDCap Reminders
Completing User Rights Requests in REDCap
When creating a Custom Role, do not use any of the predefined custom role names. Please limit 1 project per request.

REDCap Tuesdays
REDCap Tuesdays is now every Tuesday from 11:00-12:00 in Hock 9047.

I was in REDCap earlier and now I’m unable to log back in. Can my password be reset?
Your password likely does not need to be reset. Try using another browser such as Firefox or Chrome to log in. Internet Explorer (IE) is not the preferred browser for REDCap and it will sometimes lock you out. Restarting IE will sometimes works as well.

REDCap Requests
Please remember to e-mail your requests to redcap-docr@duke.edu.

Duke University International Travel Registry
If you are planning an international trip that is sponsored or funded by Duke University, you are encouraged to register your plans on the Duke University International Travel Registry so that you may be located abroad should a natural disaster or crisis associated with civil and/or political unrest occur at your destination.

Record Retention
Per DUHS policy, all research records must be retained for at least six years beyond completion of all data collection, analysis, and submission of the IRB closing progress report. Research records involving minor subjects must be retained until the youngest child on the study is 21 years old or six years following completion of the study, whichever is longer. However, please always review your contracts to make sure you are retaining records for the amount of time agreed upon in the contract. The retention obligation in the contract may extend beyond the six year period required by DUHS policy.

Reminder about ResearchMatch at Duke
Study teams wanting feasibility access to ResearchMatch need only be affiliated with Duke to gain access to the site. Feasibility access allows you to view and search aggregate data within ResearchMatch, but you may not contact volunteers. Study teams wanting recruitment access to ResearchMatch, giving them the ability to locate and potentially contact participants for their research, must list ResearchMatch as a recruitment tool in their Research Summary submitted to the IRB. An amendment can also be submitted to the IRB adding Research Match as a
recruitment tool if it wasn’t previously listed in the Research Summary for your study. We’ve already had a number of researchers register and begin recruitment efforts through ResearchMatch, and if you would like to register your study, visit our ResearchMatch page for more information or contact docr.help@dm.duke.edu with any questions.

Frequently Asked Questions

Which Data Capture Survey Programs Can I Use at Duke?
If you are interested in collecting research data using a web survey, Duke has two survey tools already reviewed and approved for this type of data collection: Qualtrics and REDCap Survey. Qualtrics is a robust, vendor-supported survey tool available through OIT, in which Duke has established a Business Associate Agreement (BAA). Information regarding the use of Qualtrics can be found on the OIT website. REDCap Survey is another survey tool that is designed for web-based data capture. This survey tool is supported through the Duke Office of Clinical Research and all data is stored on servers located behind the Duke firewall. REDCap Survey is academically licensed with Vanderbilt University through the Clinical and Translational Science Awards (CTSA). Information regarding the use of REDCap can be found by visiting the REDCap Training website or by contacting the Duke Office of Clinical Research REDCap team.

CRU Corner

Heart Center CRU
Congratulations to Dana Schrantz from the Heart Center CRU Cath Lab Cluster. Dana has recently been promoted to CRC II RN. Keep up the great work Dana!

The Heart Center CRU would like to welcome Matt Baum, CRC I to the team. Matt will be working with HC CRU Imaging Cluster. Welcome Matt!

Oncology CRU
Congratulations Melody Torain who achieved her CCRP certification!

Congratulations Kelly Mundy, new Assistant Research Practice Manager for the GU Oncology team!

Psychiatry CRU
Sue Hunter, M.P.H. has joined the Psychiatry CRU as an Assistant Research Practice Manager. Welcome, Sue!

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