Duke University School of Medicine
Clinical Research Update
May 2014

What’s New?

- FastTrack No Longer Offered Through the HRPP
- Heartbleed Bug and ClinicalTrials.gov
- Charge Correction Requests to PRMO
- Updated Subject Payment Form Posted
- Printing Transcripts in SABA
- REDCap Changes
- REDCap Version 5.5 Upgrade
- RDSP Language
- ResearchMatch E-mail Verification
- Geocoding and Limited Data Sets
- NIH and AHRQ Announce Updated Policy for Application Submission

Education Opportunities

- Research Wednesdays
- Upcoming DOCR Trainings

Don’t Forget

- Clinical Trials Quality Assurance FAQs Posted on Website
- Adding Personnel to Maestro Care
- NIH Public Access Policy—90 Day Requirement

Frequently Asked Questions

- How Can I Request a Study Participant to Fill Out a REDCap Survey/Questionnaire in Maestro Care?
- Where can I find information on Maestro Care to Complete a Sponsor’s Site Questionnaire?

What’s New?

FastTrack No Longer Offered Through the HRPP
The option to fast track studies through the HRPP will no longer be provided. Due to the strain on HRPP resources as well as the inability to fast track several processes required for institutional approval, the overall objective of the service could not be fully achieved. If a study needs to be moved through the system more quickly than usual, please work closely with your IRB specialist, your OCRC agreement manager, and DOCR to be sure you receive institutional approval in a timely manner.

Heartbleed Bug and ClinicalTrials.gov
Due to the Heartbleed bug, ClinicalTrials.gov is recommending that passwords be changed. You can change your password in the Main Menu of https://register.clinicaltrials.gov by using the Change Password link located under the User Account section. If you need assistance, please contact DOCR.Help@dm.duke.edu.

**Charge Correction Requests to PRMO**
Any charge correction or inquiry to the PRMO Clinical Trials Billing Office must be submitted through a Service Now ticket. The Billing team will return any request received by another method, e.g., email or phone, for resubmission. This will permit efficient evaluation, resolution and tracking of requests.

**Updated Subject Payment Form Posted**
The IRB has posted an updated Personal Data Disclosure form. This form now contains an area to record a subject’s Duke Unique ID number if the subject is a Duke employee. If the subject is not a Duke employee, then their social security number should be recorded.

**Printing Transcripts in SABA**
There is a new report available for staff to print their own transcripts in the Duke LMS system. Instructions are listed on the Home page when you log into SABA. Instructions have also been posted on the DOCR website (under HSR Training and Register for Trainings). Managers are also able to print their staff members’ transcripts in the Duke LMS system. Instructions are listed on the Manager Dashboard in SABA and also included on the DOCR website (under Clinical Research Units: CRU Resources and Tools).

**REDCap Changes**
When you log into REDCap on May 15th, you will see the following changes:

- On the REDCap Home page, there will be a new link entitled Request New Project in the blue section on the lower left. Users will use this link to request new surveys and databases. The Request New Project tab will no longer be used.
- The Request New Project link will include a REDCap Builder Agreement (RBA) section that all REDCap survey and database builders must agree to when requesting a new project. The RBA will replace the current Limited Service Agreement generated for REDCap builders, as a signed document is no longer required.
- The User Rights form will be replaced with a survey. This survey will allow you to assign predefined User Roles or create Custom Roles (User Rights Roles are project specific).
- Project team members will now be able to see a snapshot of the user rights within each project under the Project Bookmarks on the lower left side.

**REDCap Version 5.5 Upgrade**
The DOCR RMT data team is preparing for another upgrade. Version 5.5 will provide enhanced features for project builders including Piping. The Piping feature allows users to inject previously collected data into text on a data collection form or survey, thus providing greater precision and control over question wording. It can also be used in other ways, such as for customizing survey invitations (e.g. by including the respondent's name in the email) or survey
acknowledgments (e.g. thanking your respondent by name after completing a survey). Read more about Piping at [http://tinyurl.com/redcappiping](http://tinyurl.com/redcappiping) or you may view a live demo of Piping on a survey at [https://redcap.vanderbilt.edu/surveys/?s=ph9ZlB](https://redcap.vanderbilt.edu/surveys/?s=ph9ZlB). DOCR anticipates having the new version available for projects at the end of May. All REDCap builders will have access to the new version. For questions about REDCap, please contact [redcap-docr@duke.edu](mailto:redcap-docr@duke.edu), or you may speak with a programmer at our office hours (first and third Wednesdays at 11:00 A.M. in Hock 9047).

**RDSP Language**

For anyone building in REDCap, the following wording should be used to supplement the Research Data Security Plan (section 12.1 of IRB):

REDCap software is a tool that does not require client local software and can be accessed from anywhere on the Internet secured on a Duke Health Technology Services (DHTS) server. This database will be developed and maintenance performed with support of the School of Medicine (SOM) Duke Office of Clinical Research (DOCR). SOM’s DOCR has partnered with the School of Medicine (SOM) to implement REDCap (developed by Vanderbilt’s CTSA and currently used and supported by more than 1000 consortium partners). REDCap provides: 1) a streamlined process for rapidly building a database; 2) an intuitive interface for collecting data (with data validation and audit trail); 3) automated export procedures for seamless data downloads to common statistical packages (SAS, SPSS, etc.); 4) branching logic, file uploading, and calculated fields; and 5) a quick and easy protocol set-up.

REDCap accounts are stored within the DTMI LDAP server hosted by the Duke Office of Information Technology (OIT). Authentication occurs via the OIT implementation of Kerberos. All connections to the system, both external and internal, occur over encrypted channels. Access to components of the system is role-based and can only be granted by administrators of the system. All collected information is stored on a standalone database server hosted by Duke Health Technology Services (DHTS). The database server resides behind the DHTS internal firewall and access to the server is controlled via firewall rules. All collected data is backed up daily, both on the local server and by the DHTS enterprise backup system. Sal Munguia (919-668-2372) is responsible for managing the server for REDCap. The Duke Office of Clinical Research (Ceci Chamorro, 919-668-9262) is responsible for managing the database platform for REDCap. At the time of this submission, REDCap is on version 5.0.20.

Server location:
Fitz-East Data Center (Fitzpatrick) The directory is: /var/lib/mysql_backup/
Server support: Sal Munguia, ORI – DHTS hosts servers (919-668-2372);
[Salvador.munguia@duke.edu](mailto:Salvador.munguia@duke.edu)
Operational support: Ceci Chamorro, DOCR (919-668-9262); [ceci.chamorro@duke.edu](mailto:ceci.chamorro@duke.edu)

**ResearchMatch E-mail Verification**

ResearchMatch is improving their researcher registration and verification process to ensure that they continue to uphold the highest standards of privacy protection for researchers and
volunteers. As such, they are asking all researchers to login and complete a quick e-mail verification process. If a PI's current e-mail address on file is not a valid e-mail address for their institution, they will be prompted to change their e-mail address. A valid institutional e-mail address is one that has been issued by their institution. As of April 15th, researchers will not be able to access their dashboard until their e-mail address is valid and the verification process has been completed. Moving forward, they will need to periodically verify their e-mail address every 90 days. This small step is intended to help maintain the integrity of the ResearchMatch database by ensuring all registered researchers are from participating ResearchMatch institutions.

**Geocoding and Limited Data Sets**
The IRB has recently seen requests to send research data to external colleagues for geocoding. Each request included a Data Use Agreement (DUA) for a Limited Data Set (LDS), but the data included street addresses. As a reminder, the LDS/DUA combination cannot be used for data containing street addresses. If you need street addresses, then you must either include the disclosure in your research consent/authorization or request a separate waiver of consent and authorization. Alternatively, the LDS/DUA can be used for geocoding using the ZIP+4 if the recipient of the data can analyze the information using this method.

**NIH and AHRQ Announce Updated Policy for Application Submission**
The National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ) have announced a change in policy on application submissions. Effective immediately, for application due dates after April 16, 2014, following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate due date. The NIH and AHRQ will not assess the similarity of the science in the new (A0) application to any previously reviewed submission when accepting an application for review. Although a new (A0) application does not allow an introduction or responses to the previous reviews, the NIH and AHRQ encourage applicants to refine and strengthen all application submissions. To read the complete guidelines: [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html)

**Education Opportunities**

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting two Research Wednesdays sessions in the month of May. Brandi Tuttle and Emily Mazure will present *Sharing and Promoting Your Research* on May 14th in Markee 224. Denise Snyder and Cory Ennis will present *It’s a Marathon, Not a Sprint—Changing Support for Clinical Research and Lessons Learned from Maestro Care Implementation* on May 28th in Duke North 2003. More information about the sessions is available on the [DOCR website](http://www.divm.wisc.edu/DOCR).
**Upcoming DOCR Trainings**
The following DOCR trainings will be held in the month of June for research staff at Duke, and registration instructions are available on the DOCR website:

1. **Investigator Responsibilities** will be held June 2\(^\text{nd}\).
2. **Research Data Integrity/Data Security** will be held on June 4\(^\text{th}\).
3. **Human Subjects Research at Duke** will be held on June 4\(^\text{th}\).
4. **Recruiting Regulations and Best Practices** will be held on June 5\(^\text{th}\).
5. **Financial Basics for Clinical Research** will be held on June 10\(^\text{th}\).
6. **Informed Consent** will be held on June 12\(^\text{th}\).
7. **IRB Overview** will be held on June 17\(^\text{th}\).
8. **Study Documentation: Regulations and Best Practices** will be held on June 17\(^\text{th}\).
9. **Creating SOPs Workshop** will be held on June 18\(^\text{th}\).
10. **Biobanking Research Specimens at Duke** will be held on June 19\(^\text{th}\).
11. **Industry-funded Clinical Research—Process for Contracts** will be held June 24\(^\text{th}\).

**Don’t Forget!**

**Clinical Trials Quality Assurance (CTQA) FAQs Posted on Website**
A helpful set of FAQs regarding CTQA reviews is posted on the Compliance website. This document answers questions including the types of reviews, how protocol selections are made, what information CTQA reviews, and what happens at closing meetings. The CTQA site also has a number of other helpful documents that study teams can reference in preparation for a CTQA review.

**Adding Personnel to Maestro Care**
It generally takes two business days to get key personnel added to the RSH record. If you need personnel added more quickly, it should be indicated on the Service Now request. In the body of the Service Now request, identify your issue as “Adding personnel to RSH record” so that it may be acted upon more quickly.

**NIH Public Access Policy—90 Day Requirement**
NIH requires compliance with the Public Access policy within 90-days of an article being published AND they use the e-pub date as a starting date. True compliance is only accomplished when a PMCID (PubMed Central ID) has been assigned.

This policy became effective in 2009 when the use of the temporary NIHMS manuscript ID number was no longer accepted after 3 months. Here is the exact wording of NOT-OD-09-136:

> Effective August 21, 2009, an NIHMSID may be used to indicate compliance with the Public Access Policy for up to three months after a paper is published. After that period, a PMCID **must** be provided in order to indicate compliance.
While we have been focusing on compliance for non-competing renewals over the last several months, this applies to ALL applications, proposals or progress reports to the NIH. When a PI cites a paper funded by his/her NIH grant in an application, report, etc., NIH checks to make sure the paper is compliant with the policy. The PI does not need to be the author of the article, but will be responsible for ensuring the manuscript is compliant. If the PI is claiming the work as part of prior or current funding, it must be compliant if accepted for publication on or after April 7, 2008.

Unfortunately, even if a journal states that it will submit on an author’s behalf, the manuscript submission is not always completed within the 90-day period. PIs are suddenly discovering they have non-compliant manuscripts!

Best practice – deposit the manuscript files at nihms.nih.gov as soon as the article is accepted (use your NIH ID and password!), track compliance in this system, and add the citation to My Bibliography when it is published. By then it should have a PMCID and PubMed ID number!

Great tip -- Set up a saved search in PubMed in the PI’s or author’s name so you are notified when an article appears in PubMed and NIH knows about its existence. You can also create a search using the grant number.

Reminder -- Tell trainees and other authors receiving funds that they should let the PI know about article submissions and be compliant with the policy!

Help -- Contact the Medical Center Library & Archives for assistance with any of these systems or issues! 919.660.1100 or medical-librarian@dm.duke.edu

Frequently Asked Questions

How can I request a study participant to fill out a RedCAP survey/questionnaire in Maestro?

If you would like your study participant to complete a RedCap questionnaire/survey in Maestro, you can simply copy and paste the URL link to the survey in the provider’s notes section. The participant will be required to open “My Chart” and click on the link to complete the questionnaire. This will enable you to collect research data that can be collected securely and stored directly behind the Duke firewall.

Where can I find information on Maestro Care to Complete a Sponsor’s Site Questionnaire?

Please consult the FAQ document on DOCR’s website to see if it can help answer questions about Maestro Care contained on many sponsor site questionnaires. We have compiled questions asked on multiple sponsor forms and provided answers. In the event there’s a
question not answered by the FAQ document, please e-mail it to DOCR.Help@dm.duke.edu and we will work with the Information Security Office to provide an answer. Additionally, please do not share the FAQ document with sponsors—it is meant to be an internal document for reference purposes only.

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