Clinical Research Update

Duke CTSA

DOCR

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July 2017

OnCore Community News

Thank you for the great attendance at our OnCore Community Kickoffs. We had a total of 630 people attend the 3 sessions either in person or over the livestream! The recording of the 3rd day is available by clicking this link http://bit.ly/2sJDqj9 and the PowerPoint slide deck is available on the DOCR website. Thank you for submitting questions during the sessions both over the web and in the room. We will compile a document of FAQs for posting on the DOCR website and the ORI Project Wiki page (https://ori.duke.edu/wiki/display/ON/Oncore+Implementation) in the coming weeks.

As we mentioned in the kickoff meeting, we are still looking for YOU, the Duke Research community to assist with the project implementation by: Serving as OnCore Champions to the Research Community or by joining a workgroup. To volunteer for these critical success roles for the OnCore rollout, please contact Lorna Dula or Terry Ainsworth.

An OnCore Champion Introductory meeting will be held Friday July 18th from 2:30 – 3:30 pm in Hock 9047. OnCore Champion training will be held in the late August to early September time frame. More details about training dates, times and location will follow.

OnCore workgroups will assist with configurations settings, workflows, processes, and training material for OnCore functional areas. They will generally meet every 3-4 weeks for one hour starting in July or August.

An OnCore update will be presented on August 9th at Research Wednesdays. We look forward to seeing you there and we appreciate your service as OnCore Champions and workgroup volunteers.

Research Community News

Change to Confidentiality Language in DUHS IRB Sample Consent Template

The IRB has updated the consent template confidentiality language. Updated consent templates can be found on the IRB website and in eIRB. The reason for this change is to provide language that better reflects how data is shared. As with all template language, it is meant to be edited as appropriate to fit the parameters of each study. All new protocols submitted to the IRB should contain the new language. Study teams may elect to amend existing protocols if re-consent is planned.

NIH Single IRB Policy—New Effective Date of January 25, 2018

The National Institutes of Health has pushed back the effective date of its single IRB policy. The original effective date was May 25, however several delays have resulted in a new effective date of January 25, 2018. The single IRB policy, which came out almost a year ago, requires that a research protocol subject to federal human subject protection regulations (45 CFR 46) that takes place in multiple locations must use the same IRB to review the protocol for each site. If you have questions please contact Minna Pak in the IRB Office.

Call for Applications—DASHE Voucher Program

Health Professions Educators often lack resources needed to advance educational research and scholarship. In recognition of this challenge, Duke AHEAD is proud to announce the Duke AHEAD Supports Health Professions Educators (DASHE) voucher program. DASHE vouchers are available to all Duke AHEAD general members. The program will offer $2500 vouchers for the following programs/services: Executive coaching, DOCR services (e.g., REDCap build, project management assistance, poster/presentation design, and qualitative analysis support), biostatistical support, editorial services, library services, and travel support. Visit the DASHE website for more information.

Clinical Research Training Program Accepting Applications

The Clinical Research Training Program (CRTP) of the Duke University School of Medicine/Biostatistics and Bioinformatics Department provides academic training in the quantitative and methodological principles of clinical research. CRTP is designed primarily for faculty, fellows, and other health professionals. The program offers formal courses in research design, research management, medical genetics, comparative effectiveness, translational methodologies, and statistical analysis.

Advanced education in a clinical health science (or two years of medical school) from an accredited institution is a prerequisite for admission either as a degree candidate or as an auditing participant. The degree option leads to a Master of Health Sciences in Clinical Research, which is awarded by the School of Medicine. Additionally, CRTP offers an auditing option for individuals interested in taking one or more courses.

The program is now accepting applications for the academic year 2017-2018. For a detailed description of the program, the course offerings, and a link to the online application, please visit the CRTP website at http://crtp.mc.duke.edu. The application deadline for priority review was May 15, 2017. Applications will be accepted through August 1, 2017. On-line registration for fall term courses begin on July 10 and classes begin on August 28.

New Features for MyResearchHome

Have you, your research colleagues, and faculty seen what's new in MyResearchHome?

- **Find a Collaborator widget** integrates with Scholars@Duke to search for faculty with common research interests
- **Active Award information from SPS in myProjects** including the project period, associated fund code, and a direct link to the NOA
- **Need Help? widget** provides enhanced access to the Research Navigators via live chat and targeted help requests

These additions join a host of tools designed to meet your research needs including single sign-on across many Duke systems, due dates with links to your required training, and snapshots of your project balances, IRB protocols, and agreements.

Go to mrh.duke.edu to utilize all these features and more!

Contact us at MyResearchHome@duke.edu at any time to schedule a demo!

Support for Physicians Requesting Access to Investigational Drugs for Treatment Purposes

When a patient has a serious or immediately life-threatening condition and their physician believes he or she may benefit from a drug that is not FDA approved, a physician must request approval from the drug company, the FDA, and the IRB to treat the patient outside of participation in a clinical trial. These treatment requests, known as expanded access, require the submission of an individual patient Investigational New Drug (IND) application to the FDA.

To support Duke physicians requesting access to investigational drugs for treatment purposes, Duke University Health System (DUHS) and Duke University School of Medicine (SOM) have teamed up to provide a resource for the preparation and submission of regulatory applications, including IND and IRB submissions. Regulatory work will be performed by a select group of experienced staff and both emergency and non-emergency use situations will be supported.

Interested in utilizing this resource? Please visit https://medschool.duke.edu/oraq and click on "Individual Patient IND Request." Complete the survey of required information and key team members and staff will be notified of your request. The Office of Regulatory and Quality (ORAQ) will assist with obtaining approval from the drug company and submitting the IND, while a core of regulatory coordinators will process the IRB application. As a means to organize and expedite the workflow, the requesting physician will be informed of progress via email notifications.

We plan to go live with this service by August 1, 2017. For questions or more information, please contact ORAQ (ORAQ@duke.edu) or DOCR (DOCR-jobs@duke.edu).

Save the Date: CTSI Virtual Town Hall with Dr. Rob Califf

Please join the Clinical and Translational Science Institute (CTSI) for a Virtual Town Hall on July 21 featuring Dr. Rob Califf, former commissioner of the U.S. Food and Drug Administration, current Vice Chancellor for Health Data Science at Duke Health, and a member of the senior leadership team at Verily Life Sciences.

The CTSI Virtual Town Hall is hosted by Dr. Ebony Boulware, director of the CTSI, Vice Dean for Translational Sciences, and Associate Vice Chancellor for Translational Research.

Add this to your calendar or view WebEx login information online here.

DOCR News

Reminder: Annual DOCR Satisfaction Survey

We need your feedback! In our continuing efforts to refine and improve our service to the research community, we would like to receive your feedback in our annual DOCR Satisfaction Survey. You can access the survey here and all responses will be anonymous (you will be given the option to provide your name). Respondents also have the opportunity to be entered into a drawing to win an iPad mini (while still maintaining anonymity of individual survey responses)! If you have any questions or concerns, please direct them to DOCR.Help@dm.duke.edu.

Research Data

REDCap: Automatic Approval Feature

The automatic approval feature in REDCap has now been enabled! This is a procedural feature that will allow for automatic approval of post-production changes that will make the approval process quicker for users. As a result of this feature, no Service Now ticket will be generated.

Automatic approvals require the project to:

- Have no records or no critical issues if there are records
- No new fields have labels or variables with matching keywords from the 'Check For Identifiers' keyword list.

It is recommended that changes are reviewed before submitting them by clicking on "*View detailed summary of all drafted changes*." Under this tab, REDCap will indicate an automatic approval. One of the following will be displayed:

- Will these changes be automatically approved? *Yes*
- Will these changes be automatically approved? *No*, an admin will have to review these changes

ClinicalTrials.gov

New Requirements from International Committee of Medical Journal Editors (ICMJE)

The ICMJE has announced the following new requirements for data sharing statements that must be included in reports of clinical trials:

1. As of July 1st, 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement
2. Clinical trials that begin enrolling participants on or after January 1st, 2019 must include a data sharing plan in the trial's registration

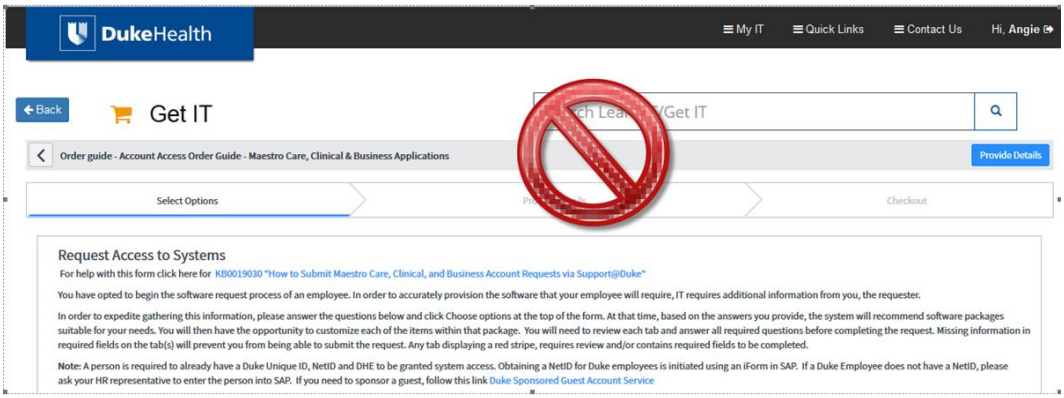
The new requirements do not mandate data sharing, but editors may take data sharing statements into account when making editorial decisions. ClinicalTrials.gov provides a field for data sharing statements that meets the ICMJE's requirements. Read the full editorial here. Contact DOCR-CTgov@dm.duke.edu for questions regarding registration or results reporting in ClinicalTrials.gov.

Did You Know?

ServiceNow Tickets for Adding Key Personnel to Studies in Maestro Care: The Right Way vs. The Wrong Way

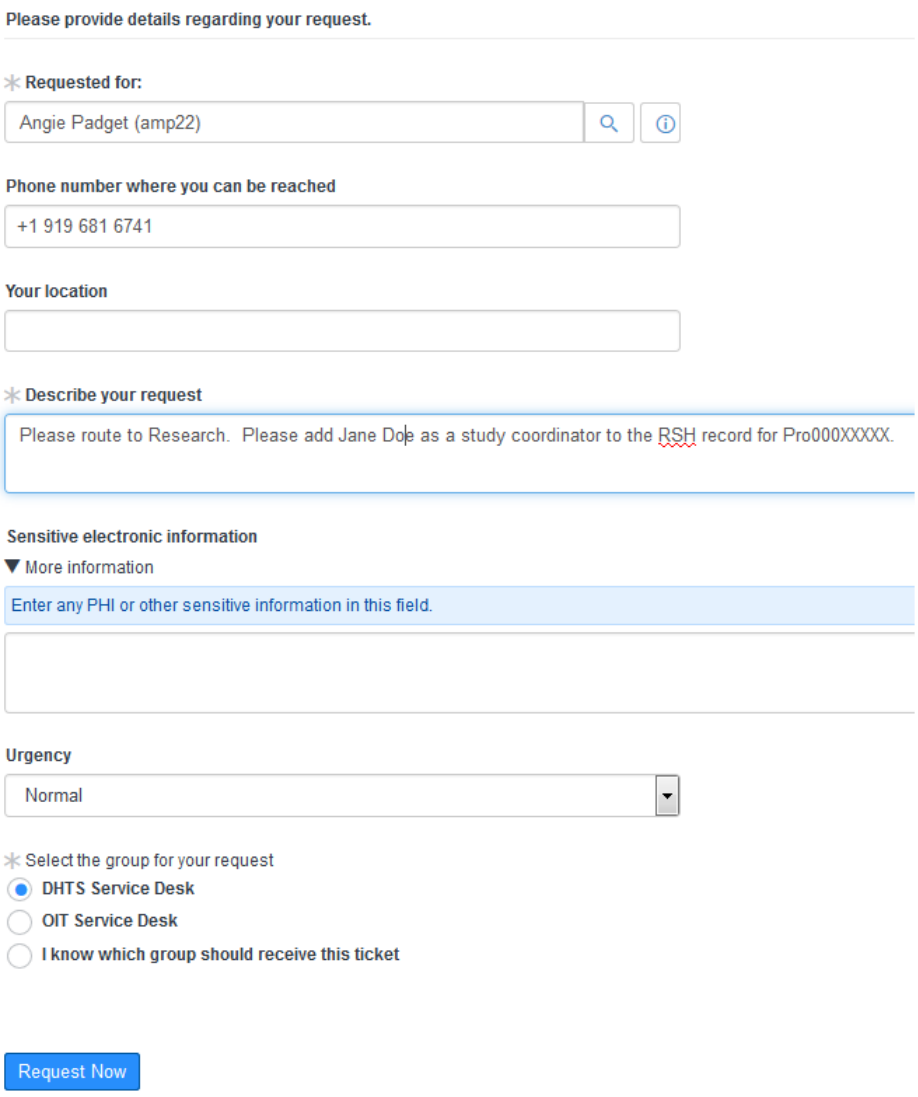
As previously mentioned in this newsletter, eIRB does not "talk" to Maestro Care, therefore it is necessary to submit a ServiceNow request whenever a user needs to be added to the coordinator or provider "bucket" of the study administration record. What you may not realize is that there is a right way and a wrong way to make this request in ServiceNow.

Beware of the “Request Access to Systems” request shown below! This is a general request for Maestro Care access, the kind that you submit for new employees or employees whose Maestro Care template needs to be changed. This function should not be used for key personnel changes that need to be reflected in the study administration record. (It is also very time-consuming to complete!)



Instead, <u>for key personnel changes</u>, simply click the “Get IT” button, then “Create a New Request.”

The request should be phrased as follows:



Much easier!

Training Opportunities

Upcoming DOCR Training Offerings

DOCR training offerings are available in the Duke LMS. There are 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:

Title	Dates	Time
Research Wednesdays: - Office of Research Informatics Updates - New Emergency IND/Single IND and Single IRB - OnCore Update - Office of Research Contracts	July 12 July 26 August 9 August 23	1:10 PM – 2 PM
Research Professionals Network: - How to Introspectively Reset When Your Buttons are Pushed in the Workplace	August 17	1 PM – 2 PM
MC Clinical Research 100	July 11, 18, 25 August 1, 15, 22, 29	9 AM - Noon
MC Clinical Research Oncology (Beacon)	July 11, 27 August 3, 22	1 PM – 4 PM
MC Clinical Research Oncology (Beacon)	August 16	9 AM - Noon
MC Clinical Research Oncology (Beacon) Refresher: Deep Dive	July 5	1 PM – 4 PM
MC Clinical Research Personalization	July 6, 25 August 17, 31	1 PM – 4 PM
Budget Development and Negotiation Training	July 17	10 AM - Noon
IRB Overview	July 18 August 22	10 AM - Noon
Phlebotomy Competency for Research	July 13	9 AM – 11:30 AM
Phlebotomy RENEWAL Competency for Research	July 13	11 AM – 11:30 AM
REDCap: Exporting/Importing and Reports	August 18	11 AM - Noon
REDCap: Learning to Manage Surveys	July 28	9 AM – 10 AM

Recruiting Regulations and Best Practices	July 10	10 AM - Noon
Research Database Design Principles	July 13 August 4	3 PM – 4 PM 11 AM - Noon
Urine Pregnancy Screening for Research	July 18 August 15	1 PM – 2 PM
Workshop: Start Building in REDCap	July 21 August 11	10 AM - Noon

Clinical Research Employee Highlights

Congratulations to Allison Spell, CRS with the Department of Neurosurgery, who recently was certified as CCRP after passing the SOCRA exam.

Jennifer Wilson has joined the Heart Center as the Heart Failure CRC Senior. Welcome to the Heart Center. We are happy to have you!

Congratulations Wendy Bloomer, PhD who was promoted to join Bonnie Vernarelli as the RPMs for Oncology Clinical Research Unit.

Partner Resources

DUHS Compliance Office Newsletter

Catch up on news from the DUHS Compliance Quarterly Newsletter.

Subscribe to the Clinical and Translational Science Institute (CTSI) Bi-Weekly Newsletter

Stay up to date on news, funding, and education opportunities in translational science at Duke by subscribing to CTSI UPDATES. Read past newsletters and subscribe at https://www.ctsi.duke.edu/news/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**.