Clinical Research Update

Duke CTSA
Clinical & Translational
Science Award
UL1TR001117

DOCR

docr.som.duke.edu
docr.help@dm.duke.edu

May 2018

- [OnCore Community News](#)

- [Research Community News](#)

- [DOCR News](#)

- [Did You Know?](#)

- [Training Opportunities](#)

- [Clinical Research Employee Highlights](#)

- [Partner Resources](#)

OnCore Community News

Clinical Research at Duke is about to change!

OnCore and iRIS are going live on Monday May 21, 2018.

What is OnCore? OnCore is the Clinical Research Management System (CRMS) developed by Forte Research Systems that will support clinical research activities at Duke. OnCore will provide enhanced clinical research study management, robust reporting, enrollment tracking, and accurate clinical research billing.

What is iRIS? iRIS is the electronic IRB (eIRB) developed by iMedRIS to be used for the submission, review, assessment, and approval of all research at Duke University including human participant-based research. Submissions include new protocols, amendments, safety

events, renewals, and closure thus supporting the needs of the clinical research community within DUHS.

Information about Go Live along with detailed OnCore Training information can be found on the [DOCR OnCore Training Support page](#).

We encourage staff to complete their training modules in the LMS and start using the OnCore Training playground.

NOTE:

1. Users who complete training BEFORE Wednesday, May 16th EOB will be added to OnCore in time for Go-Live on Monday, May 21st.

2. Users who complete training AFTER Wednesday, May 16th but BEFORE Go-Live on Monday, May 21st will receive access to OnCore the week of Go-Live (but not necessarily by Monday, May 21st).

3. Users who complete training AFTER Go-Live must use the Service Now process to request OnCore access.

With the implementation of iRIS and OnCore, the research workflow was designed to limit the change that you and your staff experience.

1. New studies will start in iRIS (the new IRB submission system) much like they start in Click eIRB today.

2. The interface between iRIS and OnCore will create the new protocol in OnCore to minimize duplicate data entry.

3. Once your IRB submission is completed and sent for PI signoff, OnCore will be ready for your team to enter additional data and upload documents to facilitate the DOCR Study Start-Up process.

4. RDSP will occur in eGRC.

5. Once IRB approval occurs, the information will push into OnCore and the rest of the Institutional Approval process will happen in OnCore to allow the study to open to accrual.

If you have any questions, please reach out to DOCR.help@dm.duke.edu.

iRIS Community News

iRIS Training Opportunities

Work continues to be done building out the submission forms capacity for iRIS and the system interfaces between iRIS and OnCore in preparation for May 21st Go Live.

The May 9th Research Wednesdays session presented by the Office of Research Informatics will be dedicated to training in the iRIS system. Any end user who will be submitting studies in iRIS should plan to attend this session which will take place in Duke Hospital North Room 2002 from 1:10 PM – 2:00 PM.

End users of the system should expect additional training sessions to begin at the end of April/early May. These trainings will consist of 1 hour sessions involving recorded video and PDF documents. Face to face trainings via WebEx will be available the first two weeks of May.

IRB Members and Specialty Committees will have user specific training designed for their particular roles. These groups will be contacted individually when their training sessions will begin.

For questions regarding iRIS training, please contact the Iris team at iris@duke.edu in the Office of Research Informatics (ORI).

To assist end users, an FAQ sheet on "Data Migration from eIRB to iRIS" has been posted on the IRB website. This FAQ contains details regarding the transition from eIRB to iRIS and the migration of studies from the old system to the new. The FAQs will be updated as Go Live approaches.

Important Dates for IRB Submissions in May

This is the first in a series of updates preparing for the May 21st launch of the iRIS IRB system. This first update is to provide you with some important submission deadlines for the cutover period between our current eIRB system and iRIS.

It will be necessary to freeze data entry in eIRB prior to go-live to allow time to migrate and verify existing data. From now through the freeze, review bodies will coordinate the move of as many submissions through to final approval as possible. Submissions in progress at the time of the cutover will return to a pre-submission state in iRIS for re-entry. **Please note the following dates and plan accordingly, to ensure reviews of your protocol applications are completed in a timely manner and that information re-entry into iRIS is minimized.**

For New Protocols, PI sign-off must occur on or before **April 30th.**

- Emergency Amendments and Emergency Uses falling between May 1-21st should be submitted via email to jody.power@duke.edu with copy to minna.pak@duke.edu and david.matesanz@duke.edu. These submissions will be reviewed and completed via

email, but study teams must upload them into iRIS by May 31st (the system is live on May 21st). Emergency Amendments include: addition of new risks to the consent form, single patient exceptions, and change in study design because of immediate direct hazard to subjects.

For Continuing Review submissions and Amendments, PI sign-off must occur on or before **May 10th**

- Between May 11-21st, Continuing Reviews will need to be held until iRIS Go Live and entered on or after May 21st.

For Safety Events, PI sign-off must occur on or before **May 10th.**

- Between May 11-21st, Emergency Safety Events should be processed via email to jody.power@duke.edu with copy to minna.pak@duke.edu and david.matesanz@duke.edu. For the period of May 11-21st, normal timelines for reporting of safety events will be suspended. However, Emergency Safety Events (deaths, hospitalization, emergence of new risks) should continue to be reported according to IRB timelines and will be processed via email.

May 18 – 21st, Data Migration begins; both systems down

Additional information including training resources and schedule for iRIS activities will be communicated using the IRB Website (https://irb.duhs.duke.edu) and in eIRB on the Homepage.

Research Community News

Privacy and Sensitive Information in Research

Every day at Duke world-class research occurs that will impact the future of healthcare. Sometimes this research involves sensitive information. Take a moment to think about the sensitivity of the information with which you work and be mindful of easy steps to protect your information and Duke. Limit what information you use and store to only that which you need. Limit data access to only those individuals with a need to know (i.e., Minimum Necessary). Recognize and report emails that look fishy (i.e., phishy) to security@duke.edu. ([This NC federal case highlights why!](#)) Use a VPN or a secure wireless network (e.g., https://) for any transactions outside the office. Create strong passwords for your electronic devices. Secure information that contains personally identifiable information (e.g., name, address, and phone numbers) or protected health information from unauthorized use or disclosure. Use Duke Box at https://box.duke.edu to safely share files with authorized recipients.

To learn more, visit Duke Privacy at https://oarc.duke.edu/privacy.

Do you know your research impact?

Have you recently checked to see the research impact you, your team, department, or other group has made? The Duke Medical Center Library & Archives can help you gather and interpret publication metrics. You have likely heard of an H-Index, but there are many ways to demonstrate the value of your work. Metrics like the NIH Relative Citation Ratio or 'altmetrics', like mentions in social media and news, can build a better overall picture of the impact you have had.

Contact the library today for assistance in demonstrating the impact of your work!

Clinical Research Day at Duke May 17th

The School of Medicine's Clinical Research Day brings together faculty, staff, trainees, and students to celebrate clinical research and the vast and diverse array of activities taking place across our campus, and to encourage collaborations. This year's event will feature the Innovation Keynote Speaker Tom Insel, MD, Co-founder and President, Mindstrong Health, speaking on "How Will Digital Technologies Transform Health Care." The event will take place Thursday, May 17th, 4:00 PM - 7:30 PM, Great Hall, Trent Semans Center.

All faculty, clinical research staff, trainees, and students welcome!

For additional information and to register, visit the Clinical Research Day site.

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.

Information about the program can be found at http://crtp.mc.duke.edu. The application deadline for priority review is May 15, 2018. All applicants in this pool will be notified of admission decisions no later than July 1, 2018. Regular applications, space permitting, will be accepted up until the start of the fall term. Registration for fall term courses begins on July 9th and classes begin on August 27th.

For more information, contact Gail Ladd, CRTP Program Coordinator, at 681-4560 or gail.ladd@duke.edu.

Funding Opportunities from CTSI

New funding opportunity announced:

Duke/NC State Translational Research Agreement (Deadline: May 15, 2018)

- Up to $25,000 per institution (Up to $50,000 total, divided equally)

- Purpose: Develop inter-institutional collaborations for new investigator teams conducting novel clinical and translational research that applies or accelerates discovery into testing in clinical or population settings.

- More information and RFA

Reminder that the following funding opportunities are open from CTSI:

Children's Health & Discovery Initiative/MEDx Pilot Research Grant (Deadline: June 5, 2018)

- Up to $50,000 to one research team that includes a PI from the School of Medicine and a PI from the Pratt School of Engineering

- Purpose: To support pilot studies that lead to the development of diagnostics, prognostics, or biomarkers for early-life risk factors for disease or biological processes associated with diseases that initiate early in life, or methods/technologies to detect exposures that influence childhood or lifelong health

- More information and RFP

DOCR News

Maestro Care Research Ordering Changes

In an effort to improve patient safety, DHTS is making the following changes to orders.

1. Signed and Held orders entered by **CRCs** from a Research SmartSet have no expiration date currently. After May 8th, these orders will expire after 15 months. Any signed and held order placed by a CRC **before** February 1, 2017 will expire on May 8, 2018.

2. Signed and held Orders that **providers** enter require a Context. After May 8th, unreleased signed and held orders with a context will be discontinued in 60 days. Any signed and held order placed by a provider prior to March 10, 2018 will expire on May 8, 2018.

		Signed and Held Expiration	
Ordering User	**Context Required**	**Current**	**After 5-8-2018**
CRC	No	None	15 months
Provider (MD, NP, PA)	Yes	180 days	60 days

New REDCap Functionality: External Modules

External Modules are add-on packages of software that can extend REDCap's current functionality, as well as provide customizations and enhancements for REDCap's existing behavior and appearance, at either the system level or project level.

Vanderbilt did not create the modules provided; instead, they were submitted by software developers at various REDCap institutions around the world, Vanderbilt does test and vet the modules and local REDCap Administrators do additional testing.

The following is a partial list of External modules currently available in Production.

Shazam - allows you to define an html template to rearrange the fields on a REDCap form or survey instrument. This can be used to place fields side by side instead of below each other.

Form Render Skip Logic - Hides and shows instruments based on the value of a single field on a single form. It's like branching logic for instruments.

DAG Switcher - Enables project users to switch between any number of Data Access Groups (and/or "No Assignment").

Image Map - This module replaces an input, radio, or checkbox field with an image that users can interact with to select one or more options. Specific applications include a body map (the over 70 body regions) and a smile scale from 1-7 with facial expressions. Future versions will allow admins and users to add additional maps via the module configuration. The module is

tied to questions via the @IMAGEMAP action tag and the name of one of the pre-defined image maps. e.g. @IMAGEMAP=PAINMAP_FEMALE.

Sticky Matrix Headers - Makes the matrix header for a matrix of fields always visible (as long as the matrix is visible) - for *surveys only*.

Other External Modules and descriptions can be viewed here. Weekly Office hours is a great time to learn more about External Modules and see a demo.

*** Please note: Not all External Modules are available in Production at this time. Please contact us at redcap-docr@duke.edu if your study team has a specific use case wherein an External Module will help.***

Did You Know?

REDCap: Branching Logic

Branching logic can be applied to a field to specify whether or not it will be displayed, depending on values in previous fields. For example, a question pertaining to pregnancy should only be displayed for female subjects. To provide these conditions in the Branching Logic section in the Online Designer (shown by the double green arrow icon), or the Branching Logic column in the Data Dictionary. For basic branching, you can simply drag and drop field names as needed in the Branching Logic dialog box.

DOCR Outreach Services

The **DOCR Outreach Team** includes a Project Management Resource for clinical research. Research Program Leaders can be enlisted on a percent effort basis to provide an array of services for program- or project-level management and support. Individual RPLs support program leadership and individual teams by working to develop plans and processes, facilitate communications, and coordinate stakeholders both internal and external. They will ensure that your project stays on schedule, within budget, and that goals are met.

Available services include:

- Consultations for planning study logistics and resources (free!)

- Protocol development and study management
- Research program and portfolio management (e.g., U01, P50, etc.)
- Research program communication management (e.g., newsletters, website, etc.)
- Manuscript development
- Coordination of clinical research grant development, packaging, and editing
- Development and management of research colloquia, symposia, and consortia
- SOP development
- Other project related needs

Please contact docr.help@dm.duke.edu for more information.

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://lms.duhs.duke.edu/Saba/Web/Cloud

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: - iRIS/iMedRIS Training - School of Medicine Finance Updates - Mobile Applications - Vice Dean of Clinical Research Annual Updates	May 9 May 23 June 13 June 27	1:10 PM – 2 PM
Research Professionals Network:	May 16	2 PM – 3 PM

- Research Ethics Journal Club - Professional Development and Certification Opportunities through SOCRA and ACRP	June 7	1 PM – 2 PM
MC Clinical Research 100	Now Available Online!	
OnCore Training for the Clinical Research Coordinator	May 8, 15, 22, 29 June 5, 26	9 AM – 11:30 AM
OnCore Training for the Regulatory Coordinator	May 1, 9, 16, 30 June 13, 27	9 AM – 11:30 AM
IRB Overview	June 19	10 AM - Noon
Phlebotomy Competency for Research	June 20	9 AM – 11:30 AM
Phlebotomy RENEWAL Competency for Research	June 20	11 AM – 11:30 AM
REDCap: Exporting/Importing and Reports	June 15	11 AM - Noon
REDCap: Learning to Manage Surveys	May 18	11 AM - Noon
Research Database Design Principles	May 4 June 1	11 AM - Noon
Screening and Consenting Subjects	June 11	2 PM – 4 PM
Study Documentation Regulations and Best Practices	May 22 June 21	1 PM – 3 PM
Urine Pregnancy Screening for Research	June 12	2 PM – 3 PM
Workshop: Start Building in REDCap	May 11 June 8	10 AM - Noon

Clinical Research Employee Highlights

The Medicine Clinical Research Unit Geriatrics Division welcomes Cheryl Miller as an RPL beginning on April 16th.

The Medicine Clinical Research Unit Pulmonary Division is pleased to announce the following promotions within their group:

- Allie Frear to Clinical Research Coordinator, Sr.

- Brittany McDowell to Clinical Research Coordinator, Tier 1

- Erika Bush to Clinical Research Specialist, Sr.

The Heart Center Clinical Research Unit announces Aubrie Coburn, Exercise Physiologist in the Duke Cardiac Diagnostic Unit (CDU) since 2015, has joined the CDU Cluster in the Heart Center CRU. We are excited to have her join our group!!

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**.