

Clinical Research Update

Duke CTSA
Center for Translational
Science and
Health
0417000117

DOCR

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June 2018

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OnCore Community News

OnCore Access Requests: Step by Step Instructions

If you or one of your employees needs access to the OnCore System, please follow the steps below:

1. The **OnCore Basic Navigation** module is a required pre-requisite for all functional roles. Once a user completes the **OnCore Basic Navigation** module, they will then take one or more additional modules for functional role access.
2. Please go to the [DOCR OnCore Support Page](#) to learn about what training is required for your function role. Select the “**My Required Training Classes**” section.
3. Once the appropriate training is complete, users will submit a request for OnCore access through the Service Now Account Access process:

- a. Go to <https://duke.service-now.com/ess/home.do>
 - b. Select Get IT > Accounts & Access > Account Access Order Guide > OnCore – CRMS
4. Access will be granted after receiving the following confirmations:
 - a. Manager’s approval of the access form in Service Now
 - b. Verification of completed training courses as required for each role
5. If you request OnCore access prior to completing the required training for your functional role, your request will be placed on hold until the above steps are completed.

Contact Your OnCore Champion!

OnCore Champions are staff members who have been trained and equipped to provide frontline end user support at Duke. Champions are your first point of contact if you have questions related to OnCore. The best part about contacting a Champion is that they are accessible and located right in your department or CRU. [Check the Champion Directory](#) to find those in your area. There is also a list of [DOCR OnCore Champions](#) available to assist a well.

If you experience issues or have questions related to your training requirements, please contact docr-training@dm.duke.edu.

For additional technical questions that cannot be answered by your local OnCore Champion, contact docr.help@dm.duke.edu.

Status Updates in OnCore: Check the Date!

When you are updating a status in OnCore, be sure to review the other dates that were migrated.

The OnCore Administrative Team is seeing errors where the consent date is after the off study date. The off-study status will not go over to Maestro Care in these cases.

Fixed! Treating Clinician Staff List

Staff who were incorrectly identified on the Staff list as “Study Coordinator (CRC/CRNC/RPL)” in OnCore have been successfully updated to their correct role of “Treating Clinician”.

iRIS Community News

Need Help with iRIS?

Chat with the DHTS Service Desk for Help (24/7): https://duke.service-now.com/ess/fix_it.do

Submit a Self-Service Ticket to the DHTS Service Desk for Help (24/7): https://duke.service-now.com/ess/fix_it.do

Phone Support: (919) 684-2243 (Press 4 for Research Support and Navigation)

Email Support: ResearchServiceDesk@duke.edu

Updated DUHS IRB Data Migration FAQ Sheet

The DUHS IRB continues to update the [Data Migration FAQ sheet](#) posted on their website. For information regarding iRIS data migration as well as answers to Frequently Asked Questions, visit the [DUHS IRB website](#).

New iRIS Module and Tip Sheets Available

The Duke Office of Clinical Research has added iRIS Module 2 “Post Approval Submission Forms in iRIS” as well as new tip sheets to the [DOCR iMedRIS Support Page](#).

To register for the online module “Post Approval Submission Forms”, [visit the Duke LMS](#).

For access to iRIS Tip Sheets, go to the [DOCR website](#) and open the “iRIS Tip Sheets and Job Aids section”. Here users will find detailed instructions for executing a variety of tasks in the iRIS System.

Research Data Storage Plan Migration Update

The Research Data Storage Plan (RDSP) migration to eGRC has been relatively successful. All existing approved RDSPs for open protocols were migrated into eGRC and are searchable. New submissions can be entered at egrc.duhs.duke.edu.

iRIS Study Approval vs. Institutional Approval

A major difference in workflows between eIRB and iRIS is that IRB approval will be issued from iRIS, but institutional approval will be issued from OnCore. Once IRB approval is issued, study

teams may initiate interim study activities as described in the [IRB policy](#), but cannot recruit or consent subjects until institutional approval has been issued. A protocol's status is displayed in the upper-right hand corner of the page in OnCore.

iRIS Training Validation Failure Notice

If you are experiencing training validation failures during the submission process, please be sure that all study team members have logged in to the iRIS system at least once. This may correct the problem. If you continue to experience difficulties, please call the help desk.

Research Community News

Social Security Number Exception Request Waiver for ClinCard

With the launch of the iRIS System, Research Data Storage Plan (RDSP) entry now occurs in eGRC. Even though the location of RDSP data entry has changed, the [Social Security Number Exception Request Waiver for ClinCard Policy](#), which outlines how to manage SSNs for ClinCard, has not changed.

Note:

- You do NOT need to file an eGRC Exception Request if you are collecting SSNs for ClinCard *and* you are adhering to the Social Security Number Exception Request Waiver for ClinCard policy.
- In order to use ClinCard, there must be an implemented ClinCard Standard Operating Procedure (SOP) in your department.
- The [IRB Personal Data Disclosure Form](#) must be uploaded into the Duke Protected Directory located on the Duke Financial Services site within 5 business days of SSN collection.
- If you are collecting Social Security Numbers for ClinCard processing, you must answer YES to paper and electronic SSN collection in your RDSP.

Transitions: Faculty and Fellows Moving On

Summer marks a time of transition – specifically, transitions for Fellows and others who may be involved in research at Duke. Remember that when departing Duke, you are obligated to leave all research materials and data with Duke, and in a state such that the project may be continued without interruption by the Principal Investigator (PI) and/or study team. Please work with your study PI if you need to take data with you when leaving Duke. Additionally, you should contact the [Office of Research Contracts \(ORC\)](#) to obtain a [Data Transfer Agreement \(DTA\)](#) and/or any other necessary documentation. Also, don't forget to report plans to remove data from Duke in advance of your departure to the [IRB](#). If you plan well, and plan in advance, your transition can be a smooth one.

To learn more about privacy at Duke, visit <https://oarc.duke.edu/privacy>.

2018 CTSI Population Health Improvement Award Recipients Announced

CTSI has awarded up to \$25,000 each to seven community-academic research partnership teams to examine issues like mental health, HIV, and smoking cessation, as well as local initiatives to address these issues and health disparities. 2018 is the second year of CTSI [Population Health Improvement Awards](#), which are designed to foster community-engaged research collaborations aimed at improving local health.

Digital Health Devices: Exploring Data Integrity and Clinical Use

Sponsored by the Clinical & Translational Science Institute & Mobile App Gateway

With hundreds of 'health' devices on the market, how do you choose which fitness tracker/sensor/bluetooth-enabled product to use for your research and patient monitoring? Join Ryan Shaw, PhD, RN, Faculty Director for the Mobile App Gateway and Associate Professor of the Schools of Nursing and Medicine explain the pros and cons of different choices, which tools integrate with Epic, and best practices for effective data capture.

- Date: Thursday, June 7th, 2018
- Time: 11:30am-1:00pm
- Location: Duke Medical Pavilion, Room DMP.2W96

Lunch will be provided.

Please [register here](#).

Translating Duke Health Cardiovascular Disease Initiative: Request for Proposals

The Translating Duke Health Cardiovascular Disease Initiative is pleased to announce a call for proposals to identify areas for investment that will accelerate research in the area of Cardiovascular Resistance, Resilience and Rejuvenation. Our goal is to build on existing Duke expertise and resources to create a small number of research 'force multipliers' or platforms for multidisciplinary work addressing important areas of unmet needs. We are looking for proposals across the continuum of bench to bedside to population health. Successful ideas will greatly enhance our environment for discovery and will have potential for both scientific and public health impact.

Deadline: Proposals must be received by 5 PM EST, August 1, 2018

Full details on this initiative [can be found on the School of Medicine website](#).

Questions and completed applications should be submitted as one combined pdf file to: translatingdukehealth@duke.edu.

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 was 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.

Save the Date: Keeping the Heart Young: The Science of Cardiovascular Resistance, Resilience and Rejuvenation

Translating Duke Health will be hosting this daylong event Saturday, October 6, 2018, 8 AM – 3:30 PM. The event will bring together national experts in Cardiovascular Disease to address the science of keeping the heart young. For more information and to register, [visit the School of Medicine website](#).

DOCR News

Research Professional Network: Professional Development and Certification Opportunities through SOCRA and ACRP

Thursday, June 7, 1:00 PM - 2:00 PM in Trent Semans Great Hall

Representatives from the Society of Clinical Research Associates (SOCRA) and the Association of Clinical Research Professionals (ACRP) will provide information to the RPN about certifications and local professional development opportunities available through their organizations. Light refreshments will be served.

[Use this link to register!](#)

Did You Know?

REDCap Remote Office Hours

The DOCR REDCap team has added **NEW Remote Office Hours**; this is a great time to get help with your REDCap project if you are not able to attend our weekly office hours in person. Every Thursday at 2 PM, you can join the call via WebEx to get answers to any REDCap questions. Join us via WebEx by [clicking here](#) to join the call.

Don't forget the REDCap in-person weekly office hours, held every Tuesday from in the Medical Center Library & Archives [Seeley G. Mudd Building](#) conference room [212C](#) and the first Thursday of the month in DMP 2W96, both are from 10 AM – 11 AM.

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: - Mobile Applications	June 13	1:10 PM – 2 PM

- Vice Dean of Clinical Research Annual Updates	June 27	
- ORI Annual Updates	July 11	
- School of Medicine Finance Updates	July 25	
Research Professionals Network:		
- 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	June 26 July 3, 10, 24, 31	9 AM – 11:30 AM
OnCore Training for the Regulatory Coordinator	June 13, 27 July 11, 25	9 AM – 11:30 AM
PC Console Overview for OnCore Financials	July 19, 26	Noon – 4 PM
Industry Funded Clinical Research: Process for Contracts	July 23	10 AM - Noon
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: Building in the Data Dictionary	July 20	11 AM - Noon
REDCap: Exporting/Importing and Reports	June 15	11 AM - Noon
Research Database Design Principles	July 6	11 AM - Noon
Screening and Consenting Subjects	June 11	2 PM – 4 PM
Study Documentation Regulations and Best	June 21	1 PM – 3 PM

Practices	July 10	Noon – 2 PM
Urine Pregnancy Screening for Research	June 12 July 12	2 PM – 3 PM
Workshop: Start Building in REDCap	June 8 July 13	10 AM - Noon

Clinical Research Employee Highlights

- The Heart Center welcomes Caroline Phan-Le to their Clinical Research Unit. Caroline recently graduated with an MPH from ECU, and joins the Central team as a CRC. Welcome, Caroline!
- The Heart Center would like to welcome Jessica Ashworth as a Clinical Research Coordinator to the Cath Lab Research Cluster. Congratulations Jessie!
- The Heart Center would like to welcome Jennifer Andrews as a Clinical Research Nurse Coordinator to the Cath Lab Research Cluster. Congratulations Jennifer!
- The Medicine CRU welcomes Dawn Dempsey as our new co- Finance Practice Manager.

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>.

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