Clinical Research Update

DOCR
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March 2018

OnCore Community News

Stop Light Evaluations

In preparation for the OnCore Go Live, we will conduct Stop Light Evaluations to review the workflows and system use.

These sessions are structured similar to those conducted for Maestro Care.

Location: Hock Auditorium

Thursday, March 8th, 1:30 PM – 4:30 PM

Friday, March 9th, 9 AM - Noon.

Training and Communication Review for OnCore

As we approach the Go-Live for OnCore, DOCR Training and Communications will communicate the training and preparations necessary for your role and function. Each employee whose job duties require access to OnCore must complete the designated training for their functional role before access is granted to the OnCore system.

Employees who have duties with multiple functional roles must complete training for the additional roles also (for example a CRC who also functions as a Regulatory Coordinator must complete training for both roles). Functional Roles in OnCore are:

Functional Role	**Abbreviation or Title**
Research View Only	CRA
Clinical Research Coordinator	CRC
Regulatory Coordinator	RC
Financial Staff	FPM, Financial Analyst
Principal Investigator	PI
CRU Leadership	ARPM, RPM, CRU Directors
Administrative Leadership	Executive Leadership (Deans, Assistant Deans, Chairmen, Business Managers)

On March 12th you will receive a detailed communication regarding the training and support for OnCore. Training sessions for both E-Learning and Instructor-led sessions will be included. We will also provide important links and instructions for support should you encounter problems during the training period. As we move forward you may also find all communications available on the OnCore page of the DOCR website.

OnCore is the Clinical Research Management System (CRMS) purchased by Duke Health to support research activities and compliance. The system will allow for enhanced research study management, robust reporting, enrollment tracking, and accurate clinical research billing. For additional information contact the DOCR website.

Publishing Study Information to a Website

One of the features of OnCore is the ability to publish current study information to a website. The plan at Duke is to use the OnCore data to display all approved study information on the Dukehealth.org website. So, for the first time at Duke, all studies Open to Accrual and Approved for public posting will be available on a central website easily accessible by patients and others seeking information about research opportunities at Duke.

DCI will also post their studies to their existing website, but the information on both websites will be the same.

To accomplish this for current studies, surveys were sent to all study teams in order to gather study specific data for the OnCore Study Information Pages (SIP). The Recruitment Innovation

Center (RIC) will assist study teams and ensuring the study information is consistent, standardized, and contains lay-friendly language.

The OnCore team, RIC, and the Duke Health Marketing team are working closely to build out this functionality. A goal of June 2018 is projected for site go-live.

Research Community News

Enrollment of Study Team Members on Their Own Study

Investigators must have specific IRB approval to enroll their study team members, family members, or anyone with a supervisory relationship to a study team member on a clinical research study at Duke Health. Please submit an Amendment to the IRB to request permission for this kind of enrollment. On rare occasions, the IRB will approve such an enrollment, usually if the study team can demonstrate either possible direct benefit to the subject, or the fact that valuable scientific information could be gained from the enrollee (such as the case of a rare genetic mutation). An example of an approvable enrollment would be enrolling a study team member who suffers from chronic migraines onto a study involving a new migraine drug. Please contact your IRB Specialist for further assistance: https://irb.duhs.duke.edu/about-us/staff-and-chairs

Missing Signature Line on Minor Consent Forms

For studies involving a population of minors and currently open to enrollment, please check the study's consent forms to verify there is a signature line at the end for the person obtaining consent. If your consent form lacks that signature line, please submit an amendment to the IRB as soon as possible to add the signature line (and date and time). If you have already consented subjects using a minor consent form that does not have the signature line for the person obtaining consent, re-consent is not required. Study teams may use *a note to file* as documentation of the discrepancy. The signature line for the person obtaining consent was inadvertently left out of the Minor Consent Template, but the omission has been corrected. Please contact the IRB if you have any questions: https://irb.duhs.duke.edu/about-us/staff-and-chairs

Research Ads That Do Not Require IRB Approval

In keeping with OHRP and FDA Guidance, DUHS IRB review and approval for brief online advertisements, and for television ads shown on Duke TV, are not necessary **provided that the information is limited to:**

- study title
- purpose of the study

- protocol summary
- basic eligibility criteria
- study site location(s), and
- how to contact the study site for further information

When information posted on a clinical trial website goes beyond directory listings with the basic descriptive information given above, such information is considered part of the informed consent process and therefore requires IRB review and approval. Information exceeding such basic listing information includes descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information from potential research subjects.

For more information please see the DUHS IRB policy on Advertisement of Research: https://irb.duhs.duke.edu/policies-and-regulations/policies/advertisement-research

CrowdStrike Replacing Symantec

The Office of Information Technology and Duke Health Technology Solutions will kick off an effort in February to remove the Symantec product from Duke systems by May 1, 2018. Symantec will be replaced by CrowdStrike for Duke systems, as well as several options for personal use (more below). OIT and DHTS staff are working with University and Health System departments to identify systems that need the Symantec client removed, as well as providing the tools to uninstall Symantec and replace it with CrowdStrike.

The Campus and Duke Health IT groups will have slightly different implementation processes, so please check with security@duke.edu if you have any questions about your particular area.

Duke Health (DUHS, School of Medicine, School of Nursing) enterprise systems

For Duke Health systems, CrowdStrike is already installed and no further action is needed. DHTS and departmental IT support personnel are continuing to identify and address any gaps in the CrowdStrike deployment, and will be using automated mechanisms to uninstall Symantec from systems over the next few months.

Note that mechanisms are already in place to ensure CrowdStrike is automatically installed on all Duke Health systems. The CrowdStrike agent is being included in the default Duke Health Windows 10 image, and is also deployed via BigFix if not already installed on Windows, Mac, and Linux systems. IT staff who have questions about this or have systems for which these methods are not sufficient should contact security@duke.edu for further assistance.

Also, Duke has officially licensed Malwarebytes for malware remediation. It is now available via software.duke.edu for DHTS and Duke Health departmental IT staff to download. Note that this version of Malwarebytes is only useful as a remediation tool,

and should not be considered a full endpoint protection solution. Also, please remember that all malware infections need to be reported to security@duke.edu *__before__* taking steps to remediate the issue, as our Computer and Security Incident Response Team (CSIRT) may need to take additional steps to ensure compliance with the HIPAA Security and Privacy Rules, as well as other legal and regulatory breach notification requirements.

Duke University (excluding Schools of Medicine and Nursing) enterprise systems

OIT will be making the CrowdStrike installer and SEPM uninstaller available no later than Monday, February 19th via the endpoint management tools and at software.duke.edu. For University machines where the CrowdStrike agent has already been deployed, CrowdStrike will need to be uninstalled first and OIT will coordinate with departments to perform a silent uninstall. This must be done first so that the updated installer correctly connects to the University CrowdStrike instance. Afterwards, OIT will work with the departments to test and deploy the new CrowdStrike agent and remove the Symantec client by May 1st. More information will be forthcoming in February for campus IT groups.

Malwarebytes is also now available via the software.duke.edu site for campus IT staff to download and use for malware remediation.

Personal-use Antivirus

Communications to the end users who have downloaded Symantec from software.duke.edu will offer them suggestions for their personal machines and share that on Windows 8.1/10 systems. Note that the removal of Symantec automatically enables Windows Defender.

Symantec will be replaced on software.duke.edu with 3 free options:

- Windows Defender
- Bit Defender
- Avast

More information is forthcoming from OIT and DHTS to the respective campus and health system groups in the coming weeks. Should you have any questions, please contact service desks. OIT: 919-684-2200 or DHTS: 919-684-2243 or the security teams at security@duke.edu.

OHRP Releases Listing of Social-Behavioral Research Standards Now Available

A new listing of 27 social-behavioral research (SBR) laws, regulations, and guidelines around the world is now available on the OHRP website.

The page lists SBR standards from the following countries (some countries have issued more than one standard):

Australia	Botswana	Brazil
Canada	Finland	France
India	Kyrgyz Republic	Malawi
Nigeria	Norway	Philippines
Saudi Arabia	South Africa	Sweden
Taiwan	United Kingdom	United States

In addition, one SBR standard was issued by UNESCO.

The information is presented in two tables. Table 1 consists of a 16-page Description of each standard that is organized into the following sections:
Title, year, and URL link
Description/summary of the standard

Table 2 features a 4-page Analysis containing the following information:

- Title of standard
- Length in pages
- Free-standing or subsumed as part of a larger document: primary purpose, legal status, broad or specific topic focus (if applicable), addresses humanities (history, languages, etc.), exempt or expedited review allowed

Prepared by the Office for Human Research Protections of the Department of Health and Human Services, the listing is designed for use by IRBs, researchers, sponsors, and others involved in human subjects research around the world.

Carrying Sensitive Research Information with You?

The DUHS Policy titled Privacy Safeguards for all forms of patient information outlines minimum safeguards that must be implemented by the DHE to protect the confidentiality of PHI. For example, if you take study data (CRF's, etc.) or other Sensitive Information with you in your car, you must keep the car locked and the information hidden from view when the car is not occupied. This is true for your own personal and sensitive information. Remember to lock your financial documents and records in a safe place at home, and lock your wallet or purse in a safe place at work. Protecting Sensitive Information is everyone's responsibility!

myRESEARCHhome Needs Survey

We wish to thank everyone who completed the myRESEARCHhome Needs Survey. Your responses are critical in helping us understand and prioritize the needs of the research community as we develop new features for MRH. Congratulations to our drawing winners: Josephine Lee, Asheley Skinner, and John Stanifer. If you have any other ideas or suggestions, you can always send them to us using the Feedback form in myRESEARCHhome. We are always happy to hear from you!

BLS Blitz Enrollment Update

Some of you may have received a message that your BLS registration was cancelled for the BLS Blitz. If you received this information, DOCR is working with the Clinical Educational Professional Department (CEPD) to get all research staff who require BLS scheduled again around their expiration date. Our first priority is to reschedule the RNs who have interactions with patients before it expires. We will work with all other research professionals who interact with patients to make certain that they can complete the training around their expiration date. If you have any questions or need further assistance, please contact us at docr-training@dm.duke.edu.

Coulter Translational Partnership Accepting Proposals for 2017-2018 Funding Cycle through March 9, 2018

Accelerating the development of promising bioengineering research

This partnership supports collaborative translational research projects that involve co-investigators from the Duke University Department of Biomedical Engineering and a clinical department in the Duke University Health System. Examples of desirable outcomes include inventions, patents, improved diagnosis and treatment of disease, follow-on funding (e.g., grants, SBIR, angel investment) commercial products, licenses, commercial partnerships and/or start-up companies.

Learn more about the Duke-Coulter Translational Partnership or read the 2017 call for proposals.

Digital Health Rules & Regs: An Overview of FDA Guidelines

Join the Mobile App Gateway and the Office of Regulatory Affairs and Quality for a seminar on **Digital Health Rules & Regs: An Overview of FDA Guidelines** on **March 20th, 9:00 AM-10:00 AM**. This seminar will give an overview of FDA's approach to regulating mobile medical apps and software. Types of mobile apps/software that are not subject to FDA regulation will be reviewed. Guidance will be provided on how to determine the risk level of your mobile app/software, and an overview of the regulatory requirements for testing mobile apps in human subjects will be provided. Participants are encouraged to bring a mobile device to participate in case scenarios.

For more information sign up here: http://bit.ly/MAGmobilehealthguidelines. Light breakfast will be served.

Bridging Population Health at Duke Symposium

The Bridging Population Health at Duke Symposium sponsored by Duke Health Population Health Coordinating Group aims to coalesce the Duke University community around a shared vision of improving health through innovative research and advanced care. The symposium will

be held Tuesday, April 3, 2018 from Noon till 5 PM in the Trent Semans Center Great Hall. For More Information and to Register go to: http://populationhealthsymposium.duke.edu

Register for K Day

Are you an early career investigator thinking about an NIH career development award? Join us as we discuss aspects of writing and preparing a career development award. The session will take place Wednesday, April 4, 2018, 8:00 AM – 3:00 PM in the Searle Center. This event is sponsored by the Duke School of Medicine Office of Faculty Mentoring. For more information and to register: https://www.ctsi.duke.edu/news/events/2018-k-day

Best Practices for the Preparation, Submission, and Maintenance of Sponsor-Investigator INDs and IDEs

The Office of Regulatory Affairs and Quality (ORAQ) will sponsor two workshops outlining best practices for the preparation, submission, and maintenance of Sponsor-Investigator INDs and IDEs.

- The Investigational New Drug (IND) Workshop, April 10, 2018, 1:00 PM – 4:00 PM
- The Investigational Device Exemption (IDE) Workshop, April 11, 2018, 9:00 AM – Noon

For more information regarding these workshops and to register, visit the ORAQ website.

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.

Workforce Engagement and Resilience (WER) Tier Advancement

Workforce Engagement and Resilience (WER) has successfully completed the first tier advancement cycle. We want to thank the clinical research professionals who participated in our first round of tier advancement. We are sincerely grateful for all of the effort that you have put into this important initiative.

Congratulations are in order for the following Clinical Research Coordinators, Clinical Research Nurse Coordinators, and Regulatory Coordinators for their professional advancement to tier 2.

Omowunmi Olaleye from Anesthesiology

Ashley Burke from Anesthesiology

Nicole Scott from Heart Center

Juliann Gilchrist from Heart Center

Megan Eure from Heart Center

Alicia Nelson from Medicine

Melissa Hurdle from Medicine

Alexia Bwensa from Neurosurgery

Julia Hurrelbrink from Oncology

Erin Arbuckle from Pediatrics

Hai Huang from Pediatrics

Tiara Stanley from Pediatrics

Stephen Gazda from Radiology

Sarah Lowe from Surgery

Sarah Casalinova from Surgery

Congratulations are in order for the following Clinical Research Coordinators, Clinical Research Nurse Coordinators, and Regulatory Coordinators for their professional advancement to tier 3.

Katherine Sweeney from Anesthesiology

Shayna Clancy from Community and Family Medicine

Leanne Stanton from Heart Center

Gayle Challinor from Heart Center

Mariko Kopping from Medicine

Jennifer Korzekwinski from Radiology

Samantha Womack from Radiology

Congratulations are in order for the following Research Program Leaders for their professional advancement to tier 2.

Brooke Heidenfelder from CTSI

Sunita Patil from DOCR

Johanna Johnson from Medicine

Molly McFatrich from Population Health Sciences

Courtney Mann from Population Health Sciences

DOCR News

Research Professionals Network (RPN) Spring Journal Club

This three-part series will focus on research ethics, with each installation centered on its own tenet of the Belmont Report. The goal is to engage fellow research coordinators in the science of research practice and develop implementation strategies for our renewed collective values. The first event scheduled for March 21, 2018 from 2:00-3:00 PM in Duke North 2253, will focus on "respect for persons." The current literature will function as a guide in examining issues surrounding vulnerable populations, conferring agency within the recruitment process, and the boundaries between researcher and participant. This is a drop-in event and registration is not required. Email DOCR-RPN@dm.duke.edu for more information.

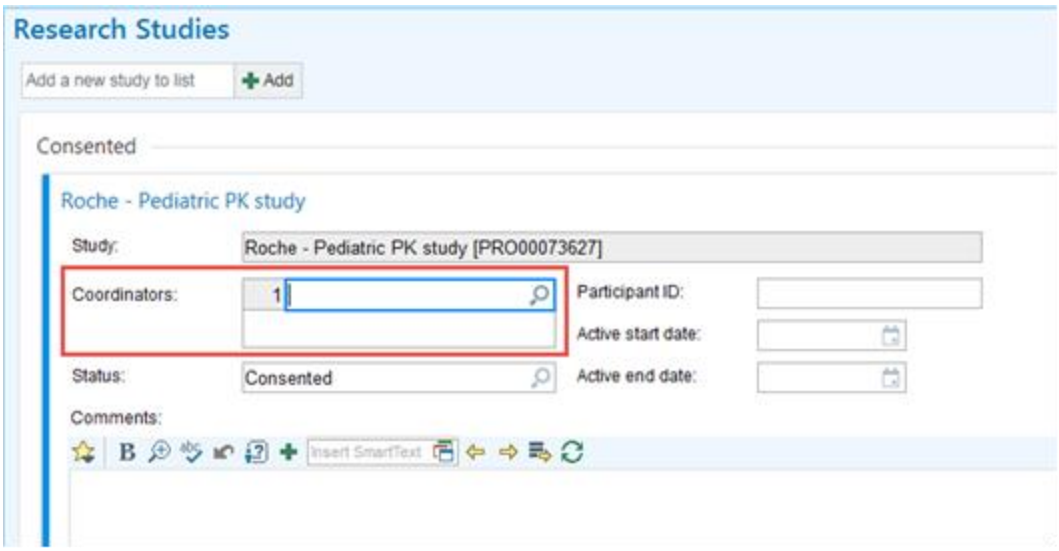
REDCap Upgrade

The REDCap system was upgraded to version 8.1. A full list of new features, changes, and improvements found in this version can be found here.

Did You Know?

Maestro Care Research Association

When associating patients with a study in Maestro Care, be sure to leave the Coordinators field blank. Entering names in this field will restrict research event notifications from being sent to all relevant individuals who have access to the study.



REDCap Pre-Built Data Collection Instruments

There are pre-built data collection instruments! The REDCap Shared Library is a repository for REDCap data collection instruments and forms that can be downloaded and used by researchers at REDCap partner institutions. Curated instruments highlighted with a star ★ have been approved for inclusion by the REDCap Library Oversight Committee (REDLOC) after review for research relevance, accuracy in function, coding, and copyright issues. Other instruments and forms are shared by individuals or groups from consortium institutions on "as-is" basis. To search for data collection instruments, go to the Online Designer tab and click on Import for the REDCap Shared Library.

Always check the library before building a form!

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: - Medical Center Library and Archives and OnCore Training Updates - Trial Innovation Network, cIRB Processes, and Duke Trial and Recruitment Innovation Center - 3-D Printing - Regulatory Affairs	March 14 March 28 April 11 April 25	1:10 PM – 2 PM
Research Professionals Network: - Making the Most of Your Performance Review - Spring Journal Club: Research Ethics	March 14 March 21	4 PM – 5 PM 2 PM – 3 PM
MC Clinical Research 100	March 13, 20, 27	9 AM - Noon
IRB Overview	March 20 April 17	10 AM - Noon
Industry Funded Clinical Research Process for Contracts	March 15	9 AM – 11 AM
Information Security for Research Staff	March 19	2 PM – 3 PM
Phlebotomy Competency for Research	March 8	9 AM – 11 AM
Phlebotomy RENEWAL Competency for Research	March 8	11 AM – 11:30 AM
REDCap: Building in the Data Dictionary	April 20	11 AM - Noon
REDCap: Exporting/Importing and Reports	March 16	11 AM - Noon
Research Database Design Principles	April 6	11 AM - Noon
Screening and Consenting Subjects	April 16	2 PM – 4 PM
Study Documentation Regulations and Best Practices	March 22 April 10	10 AM - Noon

Urine Pregnancy Screening for Research	March 12 April 16	2 PM – 3 PM
Workshop: Start Building in REDCap	March 9 April 13	10 AM - Noon

Clinical Research Employee Highlights

- The Medicine Clinical Research Unit Rheumatology Division welcomes Karissa Grier as a CRC.
- The Medicine Clinical Research Unit Nephrology Division welcomes Cindy Redd, CRC Sr.
- The Medicine Clinical Research Unit General Internal Medicine Division welcomes new CRC, Cassie Bowman.

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**.