

Clinical Research Update



DOCR

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September 2017

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OnCore Community News

OnCore Champion training sessions were held August 29th- 31st to provide the initial training for members of the research community who volunteered to serve as Champion “Super Users”. We are pleased to report that 7 PIs and 69 staff members representing roles as CRC’s, ARPMs, RPMs, FPMs, DOCR staff, other grants, finance and support roles completed the sessions. Three training locations were staffed and managed by DOCR representatives and taught by Forte in training environments conducive to classroom activities and question and answer discussion. This training provided the foundational immersion necessary to prepare the champions for their role in assisting the research community before, during and after OnCore launch.

Additional training will be provided through the eLearning modules and DOCR sessions to increase knowledge in the applications and workflows. In addition tasks are under way from designated workgroups to assist with configuration settings, workflows, processes and training materials for functional areas. Questions or concerns should be directed to docr-training@dm.duke.edu. Additional OnCore Champion training sessions and recordings will be available for Champions who were unable to attend the sessions.

Thank you to all participants for investing time and attention to the OnCore Champion training.

Research Community News

Email Addresses for the Office of Research Contracts

To alleviate confusion when emailing the Office of Research Contracts (ORC), ORC has created two separate email accounts to better service the School of Medicine. For all Industry Sponsored Agreement questions regarding signature status, award status, or any general questions regarding agreement processing, please contact ORC_Industry_Contracts@dm.duke.edu. For any Government or Foundation Agreement questions regarding signature status, award status, or agreement processing please contact orcfed-foundationcontracts@dm.duke.edu. For specific questions regarding negotiation or finalization of an agreement, please be sure to contact your Agreement Manager that is negotiating your agreement.

New SAP Tools for Subrecipient Management

Beginning Tuesday, September 5th, Duke's management of subrecipient invoices will transition into SAP directly. Previously, OSP has used a stand-alone database tool to track subaward budgets and subrecipient invoices; the details of this data were not available in SAP to assist grant managers (GMs) in their subrecipient monitoring responsibilities. SAP will now directly store detailed budgets for all active subawards, and subrecipient invoice payments will be displayed at the category level (e.g., Salaries & Wages, or Travel) in SAP Inception-to-Date reports. This new detailed information for the research administration community is designed to assist with management of subaward expenses. The SAP University Reporting – Sponsored Projects guide will be updated on page 63 ([Project/WBS: Inception to Date w/Plan](#)) to provide an overview of how to run the ZFR1E transaction in SAP specifically for subrecipient subcodes to view subaward budgets and cumulative invoice payments.

Two new reports providing extensive data for both subawards and individual invoices will also be available in Sponsored Research Reports on the Grants Management tab in Duke@Work. Detailed guidance for GMs for the both Duke@Work and the SAP ledger reports will be available in a [Quick Reference Guide](#) that will provide context on how to access, understand, and use report results.

Create Research Apps Using the Medable Platform

Duke is proud to offer a new tool to create Apple [ResearchKit](#) or Android [ResearchStack](#) apps through the new [CTSI Mobile App Gateway](#). Duke has contracted with [Medable](#) for researchers to create their own research apps utilizing these frameworks via the Medable platform.

Study teams, PIs interested in learning more, or teams who will be building an app can attend one of two App Creation Workshops on September 18th or an Advanced Workshop on

September 19th. Space in the workshops is limited, so please contact [Marissa Stroo](#) for approval prior to registering.

Requirement to Enroll Mobile Devices in the new Duke Health Mobile Device Manager

To address the growing risks to Duke security, anyone who connects mobile devices to the secure Duke Health wireless network will be required to enroll these devices in the new Duke Health Mobile Device Manager by December 31, 2017. Enrollment is required for any mobile device which connects to Duke systems, whether you carry a Duke-owned device, you get a stipend for use of your own device for business purposes, or you just bring your own device to work for personal use. This system will be the only way you will be able to get access to the secure wireless network, and mobile access to your Duke email. You will also have the ability to wipe Duke apps from your device remotely if it is lost without losing pictures or non-Duke apps (unless you choose to wipe these as well), and Duke will have the assurance that your device is password-protected, updated and encrypted.

If you have questions about this initiative, please contact the Duke Health IT Service Desk at 684-2243. To enroll, click on the blue "[Enroll in Duke Health Mobile Device Manager](#)" button in the upper right-hand corner of the site to start the registration process.

Modernizing the Clinical Research System: Insights from the Former FDA Commissioner

The Office of Regulatory Affairs and Quality in conjunction with Regulatory Guidance for Academic Research of Drugs and Devices (ReGARDD) will host Dr. Rob Califf on October 2nd on the UNC Campus. Dr. Califf will speak on "Modernizing the Clinical Research System: Insights from the Former FDA Commissioner." [Click for session information and to register.](#)

Privacy A-Z

The OARC Privacy Office has completed Phase I of our 'Privacy A-Z' compiling many references from across Duke and the Duke Health. Comments welcomed to privacy@duke.edu. <https://oarc.duke.edu/privacy/duke-privacy-%E2%80%94-z>

CTSI Funding Programs Open for Applications

CTSI currently has two major funding programs open for applications:

[CTSI Translational Accelerator Funding Agreement](#)

- Up to \$150,000
- Purpose: Support for cross-disciplinary scientific research addressing the development of therapies diagnostics, or devices applicable to human disease, clinical research trials (excluding Phase 2 and beyond), epidemiological studies, and/or community-based research
- Letter of Intent due Sept. 15, Application due Nov. 6

[CTSI Transformative Funding Agreement](#)

- Up to \$500,000
- Purpose: Supporting the development of mature research with the potential to attract significant interest for external partnering, thus enabling and accelerating translation of research out of the academic environment
- Letter of Intent due Sept. 15, Application due Nov. 6

CTSI Funding Accelerates Four Innovative Translational Projects through Next Stages

Four teams of researchers have received \$150,000 to pursue translational research projects through CTSI's Translational Accelerator Awards. The funding agreements last twelve months, and they are designed to help quickly move innovations through intermediary stages, such as proof-of-concept, and to develop data to support larger studies in the future.

Details on the award recipients and the funded projects are [available on the CTSI website](#).

DIHI Request for Applications (RFA 2018 Innovation Pilots)

The Duke Institute for Health Innovation (DIHI) promotes transformative innovation in health and health care by catalyzing multidisciplinary teamwork across Duke University and Duke Health.

DIHI is excited to announce the next emerging ideas and innovation funding cycle for demonstration pilots. Proposed demonstration projects should address actual and important problems encountered by care providers, patients and their loved ones and represent urgent health challenges nationally. For the upcoming funding cycle, DIHI is specifically interested in (a) Population Health and Analytics (b) Building Resilience and Well-Being (c) Novel Patient Interactions (d) Team-Based and New Care Models (e) Optimizing Patient Flow (f) Enhanced Transitions of Care.

Please visit www.dihi.org/funding for additional information and instructions. The deadline for submitting applications is October 6, 2017. All proposals are required to have a DUHS operational lead as a cosponsor to be accepted for review. If the DIHI team can be of any assistance in the formulation of ideas or connections, please contact [Suresh Balu](#).

Core Facility Voucher Program—Call for Proposals

Current submission deadline: October 20, 2017

The School of Medicine departments, institutes and centers oversee a wide range of research core facilities. To enable investigators to access these services for exciting new studies that are

not yet externally funded, we are pleased to announce the 2017 Fall Core Facility Voucher Program.

The [Core Facility Voucher Program](#) is a joint program with the School of Medicine (SoM), the Office of the Provost and Duke Research Computing/Office of Information Technology to offer vouchers in amounts ranging from \$500 to \$10,000 redeemable for provision of services at SoM core facilities/shared resources. The sources of funding are from the School of Medicine and the Office of the Vice Provost for Research (OVPR).

All data or resource generating core facilities/shared resources that provide services open to faculty members on a fee-for-service basis are eligible for participation in this program. No more than two facilities can be included in a single proposal. Research Computing may be included as a third facility, if utilizing data storage space in conjunction with data collected from another core facility.

The list of eligible core facilities can be found on the [Core Research Facilities](#) web page.

DOCR News

Clinical Research Appreciation for Faculty and Staff Tuesday, October 10th

The annual DOCR sponsored Clinical Research Appreciation Day will take place in the Trent Semans Center Great Hall. Highlights of the event include information tables from administrative offices and groups involved in clinical research at Duke, door prizes and great food. This event is a great way to network with others in the Clinical Research community, learn about groups and services available to clinical researchers, and be appreciated for the great work you do in clinical research at Duke. Please direct all questions and concerns to docr-training@dm.duke.edu.

NEW REDCap Office Hours Location/Time

REDCap weekly office hours will continue to be on Tuesdays. Starting on October 17th, office hours will be held in the Medical Library 212C conference room (Seeley G. Mudd Building) from 10am-11am. Office hours will continue to be held in Hock 9047 from 11am-12pm until October 10th.

Don't forget office hours are also held the first Thursday of the month, 10:00-11:00 in DMP 2W93.

Please contact redcap-docr@duke.edu with any questions.

Did You Know?

REDCap Features: Action Tags

Action Tags are special terms that begin with the '@' sign that can be placed inside a field's Field Annotation. Each action tag has a corresponding action that is performed for the field when displayed on data entry forms and survey pages. Such actions may include hiding or disabling a given field (either on a survey, data entry form, or both).

One of the newer action tags is @NONEOFTHEABOVE. This action tag, only available when using checkboxes (choose all that apply), will prevent multiple selections in a checkbox fields when the choice of 'none of the above' is selected. Note this feature must be manually coded into the field annotation box. If you have questions about this or any REDCap features please reach out to the REDCap admin team at redcap-docr@duke.edu.

Maestro Care: Increased Height of Research Study Section in Appointment Forms

Did you know the height of the Research Study section of the appointment form has been increased?

Outpatient Before:

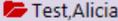
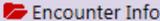
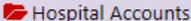
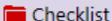
Linked	Study Code	Study	Status
<input type="checkbox"/>	PRO00035959	CoreValve Continued Access Study (Extreme Risk Pat...	Enrolled (IC obtain

Timeline: Encounter not linked to timeline

Outpatient AFTER:

Linked	Study Code	Study	Status
<input type="checkbox"/>	PRO00056651	Undiagnosed Diseases Network: Clinical Site	Enrolled (IC obtain
Timeline:		Encounter not linked to timeline	
Investigator:		Vandana Shashi, MD	
<input type="checkbox"/>	PRO00074019	SPIAM-101: Elamipretide in Subjects with Intermediat...	Enrolled (IC obtain
Timeline:		Encounter not linked to timeline	
Investigator:		Scott William Cousins, MD	
<input type="checkbox"/>	PRO00068955	SHIELD II	Enrolled (IC obtain
Timeline:		Encounter not linked to timeline	

Inpatient Before: NOTE – was small and in middle of form.

-  Test, Alicia
-  Encounter Info
- Providers/Research**
-  Hospital Accounts
-  Checklist

Provider Information

Admitting provider: Phone:

	Attending Provider	From Date	From Time	To Date	To Time
1	<input type="text" value=""/>				
2	<input type="text" value=""/>				

Current only

Outpatient PCP: Phone:

Referral source: Hospitalist needed?

Research Study

 Research Studies List is currently read-only.

There are no active research study enrollments for this encounter.

Specialty Billing

Specialty billing:

Legacy Recurring ID:

Carolina Access

CA NPI: CA Override:

Inpatient AFTER: NOTE, Increased in size **AND** moved to bottom of form.

- Research_Jennifer
- Encounter Info
- Accommodations
- Providers/Research**
- Hospital Accounts
- Inpatient - RESEARC...
- Coverage Info
- Claim Info
- Documents
- Checklist

Provider Information

Admitting provider: Phone:

	Attending Provider	From Date	From Time	To Date	To Time
1	<input type="text"/>				
2	<input type="text"/>				

Current only End Assignment Delete

Outpatient PCP: Phone:

Referral source: Hospitalist needed?

Specialty Billing

Specialty billing:

Legacy Recurring ID:

Carolina Access

CA NPI: CA Override:

Research Study

Linked	Study Code	Study	Status
<input type="checkbox"/>	PRO00056651	Undiagnosed Diseases Network Clinical Site	Enrolled (IC obtaine
	Timeline:	Encounter not linked to timeline	
	Investigator:	Vandana Shashi, MD	
<input type="checkbox"/>	PRO00074019	SPIAM-101: Elamipretide in Subjects with Intermediat...	Enrolled (IC obtaine
	Timeline:	Encounter not linked to timeline	
	Investigator:	Scott William Cousins, MD	
<input type="checkbox"/>	PRO00068955	SHIELD II	Enrolled (IC obtaine
	Timeline:	Encounter not linked to timeline	

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:		
- ACE/DEDUCE	September 13	1:10 PM – 2 PM
- Research Data Visualization	September 27	
- Information Security Office	October 11	

- Epic Upgrade	October 25	
Research Professionals Network:		
- Conversation Café: Shaping the Future of the RPN	September 28	1 PM – 2 PM
- Clinical Research Appreciation for Faculty and Staff	October 10	11 AM – 1:30 PM
MC Clinical Research 100	September 12, 19, 26 October 2, 17, 24, 31	9 AM - Noon
MC Clinical Research Oncology (Beacon)	September 14 October 12, 24	1 PM – 4 PM
MC Clinical Research Oncology (Beacon)	September 20	10 AM – 1 PM
MC Clinical Research Oncology (Beacon) Refresher: Deep Dive	September 7 October 5	1 PM – 4 PM
MC Clinical Research Personalization	September 19, 26 October 17	1 PM – 4 PM
MC Clinical Research Personalization	October 25	9 AM - Noon
ClinicalTrials.gov Introduction	September 25	10 AM - Noon
IRB Overview	September 19 October 24	10 AM - Noon
Phlebotomy Competency for Research	September 14 October 12	9 AM – 11 AM
Phlebotomy RENEWAL Competency for Research	September 14 October 12	11 AM – 11:30 AM
REDCap: Building in the Data Dictionary	September 22	9 AM – 10 AM
REDCap: Learning to Manage Surveys	October 20	11 AM - Noon
Recruiting Regulations and Best Practices	October 5	1 PM – 3 PM
Research Database Design Principles	September 8 October 6	11 AM - Noon
Screening and Consenting Subjects	October 30	1 PM – 3 PM

Study Documentation Regulations and Best Practices	September 21 October 17	9 AM – 11 AM 10 AM - Noon
Urine Pregnancy Screening for Research	September 12 October 17	1 PM – 2 PM
Workshop: Start Building in REDCap	September 15 October 13	10 AM - Noon

Clinical Research Employee Highlights

The Office of Research Contracts is happy to welcome Mitch Yelverton to the staff of the Duke Site Based Research group. Mitch is a 2005 Duke alumnus, joining the staff of the Duke Office of Alumni Affairs immediately following graduation. Mitch left Duke in 2010 to attend law school, and following graduation from Campbell University in 2013, has been in private practice as a litigator and small business advisor in the pharmaceutical industry.

Mandy Kelley joins the Office of Research Contracts from the corporate office of The YMCA of the Triangle where she worked in their Financial Development Department. Prior to that, Ms. Kelley practiced law for over a dozen years and brings her valuable experience in legal issues and contracts to the ORC team. Mandy is a proud wife, mom to 3 boys, and is excited to join our Duke ORC family.

The Department of Medicine welcomes the following people on its research team: Allison Johnson, CRS Sr. with DHVI, Erika Coleman, CRS Sr. in Pulmonary, and Meredith Mock, CRC in ID.

The Children’s Clinical Research Unit welcomes Lynn Rodgers, CRC to the Division of Nephrology and Nicole Baisden, CRC to the Division of Critical Care Medicine.

The School of Nursing welcomes Caroline Bishop as a CRC, Sr.

The Heart Center CRU welcomes Lacey Taylor as a CRS, Sr. to a full time position in the Heart Failure Cluster.

Congratulations to Pooja Parmar, clinical research coordinator at the Duke Center for Autism and Brain Development, who passed the SOCRA exam and received CCRP credentials.

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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