Clinical Research Update

Duke CTSA
Clinical & Translational
Science Award
UL1TR001117

DOCR

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

February 2018

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OnCore Community News

The roll out date for the OnCore project has been set for April 9, 2018 in order to align with the deployment of the iMedRIS System. Since these two systems communicate with each other and data will move from the iMedRIS System to the OnCore System, it is desirable to roll out both initiatives simultaneously.

We are continuing the migration of information from the IRB, eResearch, and Maestro Care. Over the next 2 months, members of the research community will be asked to review data and provide information that is not located in one of the other systems, such as a study's closed to accrual date and enrollment logs for studies with subjects not in Maestro Care. If you receive a request, please take the time to review and provide the missing information. We need your assistance to make the system as accurate and robust as possible.

In preparation for the OnCore Go Live, we will conduct a Stop Light Evaluation to review the workflows and system use. This evaluation is open to all Duke Health research faculty and staff and will be similar to that conducted prior to the Maestro Care Go Live. Two sessions are scheduled:

Location: Hock Auditorium

Thursday, March 1st, 1 PM – 4 PM

Friday, March 2nd, 9 AM – Noon

More details will be communicated in the coming days.

Research Community News

Duke Health CITI Required Course Title Merge

As a follow-up step to the CITI GCP course change effective December 14, 2016, we will merge course titles for Duke Health CITI required courses. In response to the NIH Policy change https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html, GCP modules were added to the Duke Health required CITI courses. In a few days CITI will merge the *CITI GCP Good Clinical Practice course* (ID: 30546) with the *Biomedical Research - Basic/Refresher* (ID: 30541) in order to have one combined course name. This merge will not require any action from the user. The new course title is **Biomedical Research with GCP – Basic/Refresher** (ID 30541). Merging the course titles will:

- Eliminate confusion of both course titles with the same modules
- Make the transfer to LMS cleaner for applying the requirements to transcripts
- Prepare us for the iMedRIS and OnCore interfaces

We will inform Duke Health researchers when the merge is active. Should you have questions or need more information, please contact docr-training@dm.duke.edu.

Changes to Common Rule Delayed

On January 17, 2018, the Department of Health and Human Services announced a delay to the changes to the Common Rule that were scheduled to go into effect on January 19, 2018. The Interim Final Rule announced by the agency delays both the effective and compliance dates for the new Common Rule until July 19, 2018, with the option for further delay.

For investigators and study teams, this means that the new continuing review schedule, exempt categories, and other changes in the rule will not go into effect until July 19, 2018 at the earliest. The DUHS IRB will continue to review research under the guidelines of the pre-2018 rule until the new rule is implemented. However, the IRB is still requiring that study teams use the updated consent and waiver templates available on the IRB website for new studies. These include the additional elements required under the new rule and will allow for an easier transition when the rule does go into effect.

The IRB will continue to announce news via the Common Rule FAQ on its website and via the DOCR Newsletter.

The full announcement is available here: https://www.federalregister.gov/documents/2018/01/22/2018-00997/federal-policy-for-the-protection-of-human-subjects-delay-of-the-revisions-to-the-federal-policy-for.

Responsible Conduct of Research (RCR) Training Program

The School of Medicine is launching a new Responsible Conduct of Research (RCR) program for faculty and staff engaged in research. The individuals who need training are research faculty or research staff (not including Postdoctoral Scholars and Postdoctoral Associates who have their own specific RCR training with additional requirements) with primary appointments or hired by departments/institutes/centers within the School of Medicine. We are using the NIH definition of "engaged in research"- these persons, design, conduct, or report on the research results (i.e. not grant managers).

As part of this initiative:
1. All Departments/Centers/Institutes must have a Scientific Culture and Accountability Plan (SCAP) that is available on your website and actively disseminated to your faculty & staff.
2. All faculty and staff engaged in research must complete RCR training no later than June 30, 2018. Our team has been working to develop and finalize the various offerings, any of which will satisfy the RCR training requirement:

- The CITI online RCR Duke Health module is now available. The module contains 10 required and 2 elective modules including a Duke-specific scenario. Instructions for completion are available online on the RCR website.
- The first interactive workshop has been scheduled for February 23, 2018 in the Great Hall at Trent Semans from 9-11:30 am. An official announcement with agenda, speakers, and registration information is forthcoming. Workshops will be held monthly through June 2018.
- An online competency test will be available early February 2018. Successful completion will require a single-attempt high passing score.

The ASIST team will work with you to develop or revise your SCAP as well as support RCR training for your faculty and staff.

Additional information can be found on the newly launched RCR website. Questions may be directed to asistoffice@duke.edu.

myRESEARCHhome 2.0 is Coming February 8th

MRH has an updated look and feel with improved usability and enhanced functionality.

- New user roles enable content targeted to your work.

- Widget Tabs can be rearranged or removed for increased customization.
- Mobile interface updated so you can utilize MRH anytime.

Visit mrh.duke.edu to see all the improvements.

Then, tell us what else you would like to see in the portal by completing the needs survey. Participants can enter for a chance to win one of three $100 gift cards. The survey is open until March 2nd.

Requesting Maestro Care Access

For all users who require access to the electronic health record, please follow the instructions listed below:
1. The Research Practice Manager, Assistant Research Practice Manager, or Research Program Leader MUST submit the Service Now request on all users behalf, no exceptions.
2. All users must complete the required DOCR training prior to gaining access

Please visit the Maestro Care Research Concierge Wiki for important tip sheets outlining the process for submission via Service Now as well as a tip sheet which indicates the necessary course offerings required, per user role. Once these steps are completed and verified by a member of the Maestro Care support team, users will be granted access.

New Form for Radiology Protocol Review

The Department of Radiology has implemented a new form which requires a fund code be entered for all protocol reviews conducted, with the exception of protocols for federal studies. If a fund code has not yet been established for a study, please put a departmental fund code for which the review fee may be charged. The new form can be found on the Research Support page of the Duke Radiology website under **Resource Links**. Select **Request for Radiology Implementation Review**. Please note that forms submitted without a fund code will be returned for completion.

Direct all questions to Steve Shipes, Research Practice Manager, or Chelsea Penumarthy, Financial Practice Manager.

CTSI Population Health Improvement Awards now Accepting Applications through February 22, 2018

This three-tiered program is designed to identify and promote the most promising community-research collaborations.
Duke CTSI will provide approximately $200,000 for direct costs to support pilot awards that can be used to either develop new community-research partnerships or foment already existing community and research partnerships that aim to develop and test effective solutions to improve community and population health.

Learn more about the CTSI Population Health Improvement Awards.

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.](#)

2018 BIGGER Student Research Experience Accepting Applications through March 2, 2018

The Bridging the Gap to Enhance Clinical Research Program is a six-month research experience designed to attract diverse, talented students to careers in science; to foster a better understanding of clinical research and its implications; and to provide opportunities for students to gain valuable research experience in preparation for a health professions career. The 2018 program, running from June to December, will accept six recent graduates who are taking a gap year prior to applying for graduate/health professional school.

[Learn more about BIGGER and apply here.](#)

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 9 and classes begin on August 27.

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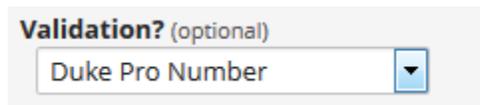
DOCR News

REDCap Validation Type

A new validation type was recently added to our REDCap instance! Users can now validate for the Duke Protocol Number. Please note, "Pro" must be typed prior to entering the 8 numbers without spaces in order to avoid receiving a warning.
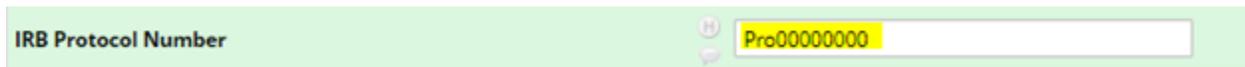
This can be selected when adding/editing a field. "Duke Pro Number" is the validation to select.

Joint DOCR Office Hours

DOCR is conducting Joint DOCR Office hours wherein representatives from multiple DOCR teams including REDCap, Maestro Care, and Outreach are on hand to answer your questions. Office hours are monthly on the first Thursday of every month from 10-11 am in the Duke Medicine Pavilion room 2W96.

New REDCap Version

REDCap will be upgraded in the coming months, a date has not been scheduled. We will notify REDCap users prior to the upgrade, including down time. Click here to see details about new features/functionality that will be available in our upcoming REDCap version (8.x.xx).

Did You Know?

Research Re-Consent

Common reasons for research re-consent are:

- Revisions to the consent form contain new information that may affect the subject's willingness to continue (such as additional risks, study procedures and additional visits)

- A subject who is a minor turns 18 years old while on the study and must be re-consented as an adult

- A subject regains decision-making capacity as a result of change in medical status

Research re-consent is not required simply because there is a 30+ day time period between the date the subject signed the consent document and the initiation of study activities. If one or more of the scenarios above occur during that time period, then re-consents would be required. It's not related to the number of days that have passed. Previously, DOCR consent classes included that re-consent was required/best practice if the time period between the consent date and the research activity was 30 days or more. That's not true. What is required: at each visit, the study team should confirm and document that the subject is still willing to participate in the research study before beginning study interventions. This information is documented in Maestro Care for Duke patients (see Smart Text below) and the subject's study record for non-Duke patient participants.
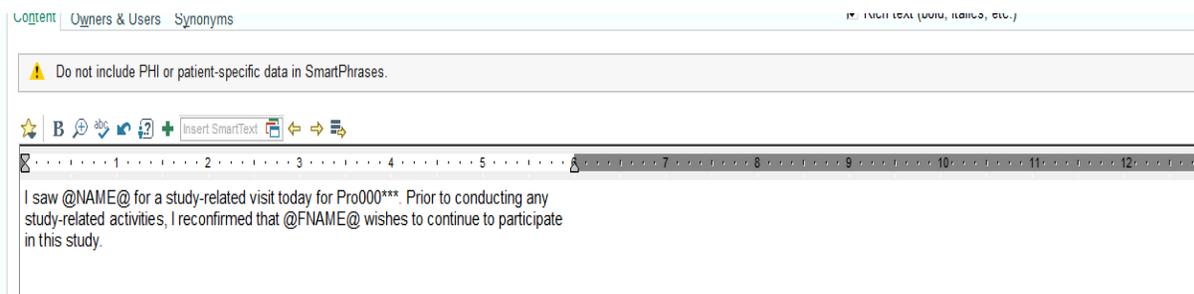
To access this Smart Text:

Within a patient's chart> Open blank progress note> place cursor in [Insert SmartText] and type rsh>select phrase by double clicking or choosing accept> Phrase will populate in body of note.

Updating Maestro Care: Deceased Patients

Maestro Care is updated weekly to identify deceased patients. If you become aware of a deceased patient who is not listed as such in the medical record, please notify HIM via their new email address: himdataintegrity@dm.duke.edu.

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 Community Updates - Research Integrity Office: Conflict of Interest Reporting - University Counsel - Trial Innovation Network, cIRB Processes, and Duke Trial and Recruitment Innovation Center	February 14 February 28 March 14 March 28	1:10 PM – 2 PM
Research Professionals Network: - Speed Dating networking event	February 22	1 PM – 2 PM
MC Clinical Research 100	February 13, 20, 27 March 6, 13, 20, 27	9 AM - Noon
ClinicalTrials.gov Introduction	February 19	1 PM – 3 PM
IRB Overview	February 20 March 20	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	February 19 March 8	10 AM – Noon 9 AM – 11 AM
Phlebotomy RENEWAL Competency for Research	February 19 March 8	Noon – 12:30 PM 11 AM – 11:30 AM
REDCap: Exporting/Importing and Reports	March 16	11 AM - Noon
REDCap: Learning to Manage Surveys	February 16	11 AM - Noon
Research Database Design Principles	March 2	11 AM - Noon

Screening and Consenting Subjects	February 12	10 AM - Noon
Study Documentation Regulations and Best Practices	February 8 March 22	1 PM – 3 PM 10 AM - Noon
Urine Pregnancy Screening for Research	February 13 March 12	2 PM – 3 PM
Workshop: Start Building in REDCap	February 9 March 9	10 AM - Noon

Clinical Research Employee Highlights

- The School of Nursing welcomes Maralis Mercado Emerson as a Clinical Research Coordinator!
- The School of Nursing welcomes Ebony Burns as a Clinical Research Coordinator. Ebony started in this role on January 2nd.
- The Oncology Clinical Research Unit welcomes Jessica Pennell, RN to Endocrine Oncology.
- The Oncology Clinical Research Unit welcomes Meredith Carter, Regulatory Coordinator joining the Gynecologic Oncology clinical research team.
- The Oncology Clinical Research Unit welcomes Linda Kaltenbach and Francis Murigi as Regulatory Coordinators in Hematologic Malignancies and Cellular Therapy.
- The School of Nursing welcomes Michelle Carreño as a Clinical Research Specialist, Sr.

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**.