Clinical Research Update

Duke CTSA
DOCR
docr.som.duke.edu
docr.help@dm.duke.edu

April 2018

- [OnCore Community News](#)

- [Research Community News](#)

- [DOCR News](#)

- [Did You Know?](#)

- [Training Opportunities](#)

- [Clinical Research Employee Highlights](#)

- [Partner Resources](#)

OnCore Community News

OnCore and iRIS/iMedRIS Go Live Moved to May 21st

As a result of gathering requirements for the interface between iRIS/iMedRIS and OnCore, two things became apparent:

1. The interface between iRIS/iMedRIS and OnCore is more complicated than initially anticipated. As a consequence, the testing of the application and the workflows has extended the timeline.

2. In order to keep the data in iRIS/iMedRIS and OnCore in synch there would need to be a way to identify data fields that change on a daily basis. There is no easy way to identify data fields that change daily in the current eIRB that would permit a manual update in OnCore.

After discussions between the project teams and business owners, it was agreed that the interface is vital to the successful implementation of both systems. It is not feasible to complete the testing process with an acceptable level of confidence without extending the Go-live date. (April 9th).

After discussion with leaders, stakeholders and the vendors it was determined that moving the Go Live date of both OnCore and iRIS to May 21, 2018 made the most sense.

The OnCore and iRIS Executive Leadership Teams (ELT) and the IT Governance Committee (formerly SIGC) approved this plan.

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 be coordinating to move 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 review of your protocol applications are completed in a timely manner and that information re-entry into iRIS is minimized.**

For New Protocols and Amendments, 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, after 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, 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.

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.

Training and Communication Review for iRIS (iMedRIS)

Training for the iRIS System will roll out to members of the Duke Health community sequentially during the months of April and May. This training will be a combination of recorded WebEx sessions, PDF documentation, Office Hours, and live demos of the system. Additionally, the test system will be available for end users to explore/play in before the system goes live on May 21st.

End users of the system should expect 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.

Research Community News

Recruiting Students, Employees (Including Study Team Members), Friends, & Family Members

The HRPP policy on recruitment of students, employees, friends, and family members as research participants has been updated to clarify the expectations when study teams seek to enroll work colleagues, friends, and family members as participants in research. This policy describes the responsibilities of the DUHS IRB and Duke Investigators when recruiting and enrolling students, employees (including study team members), friends and family members as participants in research. Please visit the IRB web site to read the updated policy:

https://irb.duhs.duke.edu/policies-and-regulations/policies/recruiting-students-employees-including-study-team-members-friends

Contact the IRB Specialist for your Department/CRU if you have questions: https://irb.duhs.duke.edu/about-us/staff-and-chairs

e-Consent Now Available in REDCap

e-Consent is available via REDCap, giving study teams a new tool to use as part of the informed consent process for minimal risk studies. This functionality provides the ability to consent remote participants or participants in clinic via tablets or touchscreen device. Participants will have the capability to sign electronically with a stylus, mouse, or finger. Once the consent form

is submitted, participants will receive an email that includes a PDF attachment with a copy of the signed consent form.

Information about the process can be found on the DOCR website. While this is a great new tool, it may not be appropriate for all study populations. If you would like receive consultations about best practices and tools for your study's recruitment, please reach out to the Recruitment Innovation Center, supported by the Duke Clinical & Translational Science Institute.

Conflicting CITI Expiration Date Resolution

An issue has been identified where some Duke Health CITI members may encounter a difference in expiration dates as a result of the Biomedical Basics with GCP and the GCP stand-alone module in CITI. In general, CITI modules are listed as either a "Basic" module or a "Refresher" module. The initial time a user registers for a subject module, they are enrolled into the Basics module. Once completed or at expiration, the user is guided to the refresher selection. Refreshers are generally a subset of the course modules or an abbreviated version of the module content. Module content is managed by CITI even if some contribution to the modules is submitted by the user institution in a user specific module.

When the GCP and the Biomedical Basics/Refresher courses recently merged, those members who were in refresher state were subjected to the database logic, which determined that there were refresher courses involved as a course separate from the basics module course. This meant the system dates for the refresher were not carried over to the course completion date. As a result, some members show the original basics course date expiration and that date was applied to the merge.

After working with CITI programmers, we were informed that the best strategy was to update each instance on a one by one basis. DOCR will work with the CITI programmers to resolve the issues.

We ask that anyone who encounters a difference in CITI expiration dates or who has a question with resolving a CITI issue, please contact us at docr-training@dm.duke.edu.

Maintaining Maestro Care's Security

Maintaining Maestro Care's security is a critical component of caring for our patients and their loved ones. It is also essential that staff's access within Maestro Care accurately aligns with their credentials and role. To ensure proper access, the current user provisioning requirements for transferring staff will be applied. When a staff member transfers to a new position, current Maestro Care access will be disabled in accordance with the SAP transfer date. The staff's new manager will be required to request Maestro Care access applicable to the new position.

This change will be implemented immediately.

myRESEARCHnavigators Hotline and Onboarding Services

Not sure where to look next for the answers to your research questions? Know of a researcher who might be interested in getting oriented to research at Duke? Let the myRESEARCHnavigators team help you identify relevant resources, connect with experts and understand processes and best practices for performing research at Duke. This service is supported by the Clinical & Translational Science Institute. To reach the team:

- Use the online "Need Help" widget in myRESEARCHhome

- Call (919)684-2243, option 4

- Email myresearchnavigators@duke.edu

Encrypted Audio Recorders Available for Loan

Do you run focus groups or interviews as part of a research project? Are you in short-term need of an encrypted voice recorder? If so, visit the Duke Office of Research Initiatives website, to access the lending library request form. These recorders, paid for by Duke's CTSA, are currently available at no cost (a small rental fee may apply in the future). Please provide as much notice as possible so that we can coordinate loans across the institution. Email researchinitiatives@duke.edu with any questions.

Cleaning Old Data and Devices

Spring Cleaning? Remember to clean up your old data and devices at work, too. Review your files to see if you can delete or archive old data and e-mails – both paper and electronic. Don't forget about your old devices – forgotten thumb drives and old laptops or other devices which contain sensitive or restricted data exposes Duke to risks. Take a few minutes each day to clean up not only your physical but your digital dumping ground by appropriately deleting or destroying old files – you will feel relieved to reduce your clutter!

Visit Duke Privacy at https://oarc.duke.edu/privacy

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](#).

Workshop: Creating Engaging Mobile Apps

Have you ever noticed that some apps are super simple to use and delightful? And others feel clunky and frustrating? Join the Mobile App Gateway and a local development partner for this workshop to learn best practices for creating engaging mobile apps that will bring your users back for more. Join us on Thursday, April 26th at Erwin Mill, A103 from 9am-1pm. Lunch will be provided. Register here: [bit.ly/MAGUserEngagement](#)

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.

Events and Funding Opportunities from CTSI

Funding Opportunities

[Announcing: Duke CTSA TL1 physician research fellowship](#)

A new 2-year training program aiming to provide two years of funded time to support the research training of physician-scientists. We have particular interest in applicants looking to obtain training in data science methodology, and applicants interested in broadening their previous training to include a new category of research methodology. The Duke CTSA TL1 will provide tailored professional development support, a stipend, and training-related expenses.

Applications will be considered on a rolling basis. Priority deadline: May 1, 2018

[Announcing: Duke CTSA TL1 post-doctoral training program](#)

A new 2-year training program aiming to provide two years of funded time to support the research training of outstanding junior scientists with a PhD and no more than 2 prior years on a federal postdoctoral training grant. We have particular interest in applicants who are interested in broadening their previous training to include a new category of research methodology, and applicants looking to obtain training in data science methodology. The Duke CTSA TL1 will provide tailored professional development support, a stipend, and training-related expenses.

Applications will be considered on a rolling basis. Priority deadline: May 1, 2018

[Children's Health & Discovery Initiative and MEDx Pilot Research Grant](#)

Up to $50,000 to one research team that includes one PI from the School of Medicine and one PI from 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 life-long health. [View the RFP](#).

Application deadline: June 5, 2018.

Events

[2018 K Day (NIH career development awards)](#)

For early career investigators interested in NIH career development awards.

Wednesday, April 4, 8:00 a.m.-3:00 p.m.

[CTSI Virtual Grand Rounds: What's new in myRESEARCHhome and myRESEARCHnavigators?](#)

Presented by Rebecca Brouwer, Director of Research Initiatives, and Derek Jones, myRESEARCHhome Product Manager

Friday, April 27, 10:00-11:00 a.m.

[2018 Duke CTSA Career Development Symposium](#)

Featuring presentations from Duke, UNC, and Wake Forest K Scholars.

Tuesday, May 1, 8:30 a.m.–3:30 p.m.

DOCR News

Maestro Care 100 Online Course Available

The Maestro Care 100 class is available as an eLearning course. This training consists of navigating and practicing basic research workflow and processes in Maestro Care. The course is also the required course for obtaining access to Maestro Care. Upon completion of the online course, employees who have questions or would like an instructor led review session should email a request to DOCR-Training@duke.edu.

The instructor led session will no longer be available as an option in LMS. The online course offers the employee flexibility and convenience. The course can also be taken as a refresher for existing staff at any time. To find the course, login to the LMS and search for "MC Clinical Research 100 Online - DOCR" or [follow this link](#) to enroll in the course now.

Did You Know?

Clinical Research Progress Notes

When documenting a Progress Note in Maestro Care for participants in clinical research studies, documentation should include the following information at each visit.

- Time point within the protocol (which cycle/visit)

- Agreement by the patient to continue to participate in research

- Documentation of any adverse events experienced

- Labs and imaging done or omitted-noting any abnormal values

- Intervention delivered (if applicable)

- Instructions to the patient of signs and symptoms related to the research drug/device to watch for

- Verification that the patient knows who to contact for questions or concerns

- Appointments for the next research clinic visit and research related labs, imaging, procedures

This documentation should be entered by the CRC at research visits-do not rely on provider documentation to capture research values. Do not use "cloned" notes and "cut and paste" functionality which is available in Maestro Care. The notes in Maestro Care are available to all care providers for the patient. These notes should provide an accurate, complete account of the treatment and care given to the study participant.

REDCap: The Codebook

The Codebook is a read-only version of the project's Data Dictionary and serves as a quick reference for viewing the attributes of any given field in the project without having to download and interpret the Data Dictionary. Be mindful that checkbox fields have their coded values displayed both in the format defined by users in the Online Designer/Data Dictionary as well as in the extended format seen in data imports and exports (i.e., field___code). To access the Codebook, click the Project Home tab

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: - 3-D Printing - Regulatory Affairs: FDA Oversight of In Vitro	April 11 April 25	1:10 PM – 2 PM

Diagnostic Devices - iRIS/iMedRIS Training - School of Medicine Finance Updates	May 9 May 23	
Research Professionals Network: - Understanding Generational Differences and How They Impact the Workplace - Research Ethics Journal Club	 April 19 April 23, May 16	 12:30 – 1:45 PM 2 PM – 3 PM
MC Clinical Research 100	Now Available Online!	
OnCore Training for the Clinical Research Coordinator	May 8, 15, 22, 29	9 AM – 11:30 AM
OnCore Training for the Clinical Research Coordinator	April 23, 30	12:30 PM – 3 PM
OnCore Training for the Regulatory Coordinator	April 25 May 1, 9, 16, 30	9 AM – 11:30 AM
OnCore Training for the Regulatory Coordinator	April 19 May 3	12:30 PM – 3 PM
IRB Overview	April 17	10 AM - Noon
Phlebotomy Competency for Research	April 18	11 AM - 2 PM
Phlebotomy RENEWAL Competency for Research	April 18	1:30 PM – 2 PM
REDCap: Building in the Data Dictionary	April 20	11 AM - Noon
REDCap: Learning to Manage Surveys	May 18	11 AM - Noon
Research Database Design Principles	April 6 May 4	11 AM - Noon

Screening and Consenting Subjects	April 16	2 PM – 4 PM
Study Documentation Regulations and Best Practices	April 10 May 22	10 AM – Noon 1 PM – 3 PM
Urine Pregnancy Screening for Research	April 16	2 PM – 3 PM
Workshop: Start Building in REDCap	April 13 May 11	10 AM - Noon

Clinical Research Employee Highlights

- The Children's Clinical Research Unit welcomes to the:

    o   Division of Medical Genetics: Sybil Wilmont CRNC; Nicole Daniels CRS Sr. and Emily Jackson Regulatory Coordinator.

    o   Division of Pulmonary and Sleep Medicine: Heidi Tiedge CRC.

    o   Division of Neonatology: Anne Baez CRS, Sr.

    o   Division of Primary Care: Jennifer Talbert CRC.

    o   Obesity Prevention and Treatment Research Center: Alexandra Zizzi CRC and Tiara Stanley CRC.

- The Medicine Clinical Research Unit-Infectious Diseases welcomes Ally Odom as a CRC.

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**.