Clinical Research Update

DOCR
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January 2018

OnCore Community News

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.

Research Community News

Maestro Care: Research Active Banner and Active Research Schedule Column

The Research Active Banner and Active Research Schedule Column will now appear for all studies, regardless of billing designation (DUHS Billing or No-DUHS Billing). Please remember to manage patient statuses throughout the course of the study to ensure that these flags appear correctly. Patients should be moved to the "off study" status upon study completion. Please note that simply entering a study end date in Maestro Care does not turn off the Research Active Banner or the Active Research Schedule Column. A Research Wednesdays session on January 10th will provide workflow training for managing patient statuses in Maestro Care.

Maestro Care: Unused Research Orders

Any unused research orders must be managed in a timely fashion to prevent them from being utilized erroneously. If research orders are not used as planned, they should be discontinued promptly. Failure to discontinue unused orders may result in medical errors and billing issues. If you have questions about how to manage orders throughout the course of the study, please contact Research Support Services at 919-684-2243, option 4. A portion of the Research Wednesday session on January 10th will be devoted to workflow training on order management.

Inaugural Design Workshop: Request for Questions

Duke Forge seeks to leverage data and expertise at Duke to improve outcomes. The first Forge Design Workshop will teach us what works, what is helpful to teams with problems or ideas that might benefit from access to inter-disciplinary data science expertise. We hope that clinical and quantitative scientists will meet around these ideas in a way that moves them closer to an actionable state. Success would mean we initiated a creative process that fuels teams at Duke to work outside limits and silos – toward learning health.

We are seeking applications from members of the entire Duke Community who have ideas, data, quantitative methods, and/or needs that could contribute to actionable approaches in health or healthcare.

Interested applicants should submit a one-page application to THEFORGE@duke.edu by 5pm Tuesday, January 23, 2018. The application should include:

- The title (stated as a question)
- A list of potential team members
- A brief description of the health or healthcare problem you seek to address
- Any currently existing data resources or other resources available to address the question
- Any perceived gaps in expertise

Up to ten applicants will be invited to participate in the first design workshop on February 27, 2018 from 4:00 pm - 7:00 pm; invited applicants unavailable to participate will be assigned to a subsequent design workshop. The design workshop will provide opportunities to engage with health system clinicians, quantitative experts, operations experts, and students to refine ideas.

Subsequent to the workshop, Duke Forge will recommend next steps to further advance and refine ideas as applicable. A subset of questions will be selected for further refinement and consideration for inclusion in the portfolio of Forge demonstration projects.

Send questions and to Victoria.christian@duke.edu or to Forge@Duke.edu.

Office Hours to Assist Teams with NIH and AHRQ Human Subjects Proposals Due on or after January 25, 2018

NIH is implementing significant changes to the application process for all research with human subjects and broadening the definition of what is considered a clinical trial. These changes will apply to all NIH and AHRQ submissions (both grants and contracts) with due dates on or after January 25, 2018. To help the Duke research community meet these new requirements, several teams and offices at Duke are offering comprehensive office hours twice per week from mid-December through mid-February. [Visit the ORA website for specific dates and times](#) and email researchinitiatives@duke.edu with any questions.

The CTSI Population Health Improvement Awards 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](#)

DOCR News

Research Professionals Network (RPN) Relaunch Event "Networking 2.0" with Keynote Speaker Kris McGuigan

Thursday, January 18 1:00-2:00 pm in Trent Seman's Great Hall

Learn about the exciting new opportunities as the network moves towards a more community owned model and refocuses on the mission to strengthen members' roles in their study teams through educational and networking opportunities.

Our Keynote Speaker at this event will be Kris McGuigan, CEO of Professional Courage in Cleveland, Ohio. During this session members will look at the building blocks of networking, share tips for building relationships and expanding your prospects, and craft a personalized action plan for incorporating networking into everyday activities to enhance your position in the marketplace.

[Use this link to register for the Relaunch Event](#).

Joint DOCR Office Hours

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

Research Wednesdays: January 10th Topic Change

We have had a topic change for the Research Wednesdays session scheduled January 10, 2018, beginning at 1:10pm. The new session will be titled "Research Wednesday: Managing Maestro Care Statuses and Order Management".

This session will provide workflow as well as address frequently asked questions for handling status changes and order management.

You do not need to register to attend. Your registration will be added to the LMS after you have attended the session.

Did You Know?

Maestro Care Event Notices for Status Change

In advance of the OnCore CRMS implementation scheduled for Early 2018, the list of available study enrollment statuses was updated.   All patients that had a status of Completed Study now have an Off Study status. The configuration for the Admit event notice has a 30 day lookback for any status changes. As a result you may see Admit Event notifications for patients that are no longer actively enrolled on a study. We realize that these notices may be an inconvenience, but they will cease after January 7th.
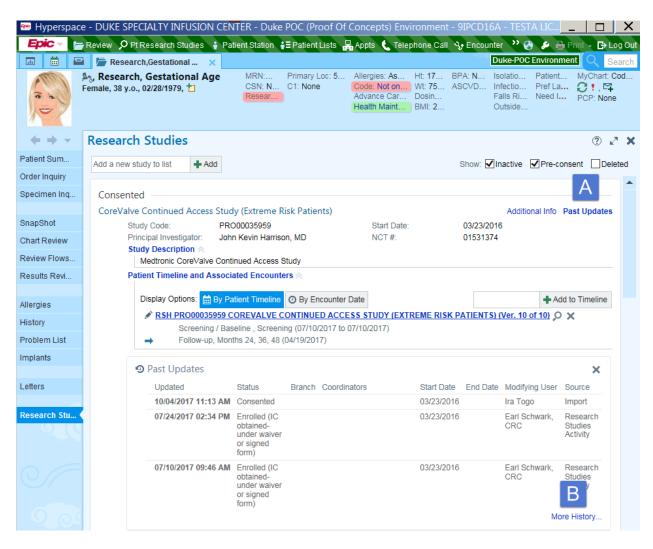
Maestro Care: Adding Key Personnel

As a reminder, whenever there are changes to key personnel that need to be reflected in Maestro Care, it is best to submit a ServiceNow ticket (https://duke.service-now.com/ess/home.do) as follows:

Get IT → Research → Maestro Care Research Request → Subcategory: Changes to Users and Providers on RSH record

Maestro Care: Viewing an Audit Trail

Did you know that you can view an audit trail of all research status changes for your patients in Maestro Care? First click "**Past Updates**" (labelled with an A below) and then click "**More History**" (labelled with a B below). Note that the "More History" option will only be available if there are more than 3 past updates.

Validating Fields in REDCap

Validating fields in REDCap is important for data entry and data analysis. By taking a few minutes to validate while building the database, it will allow for cleaner data collection allowing the analysis to start sooner. Validation can only be used with text boxes; some validation options include numeric, date, email addresses, and zip codes. Minimum and maximum values can also be set for certain validated fields.

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: - Maestro Care Updates - Duke Office of Clinical Research Annual Updates - IRB Updates - Research Integrity Office: Conflict of Interest Reporting	January 10 January 24 February 14 February 28	1:10 PM – 2 PM
Research Professionals Network: - Networking 2.0 - Speed Dating networking event	January 18 February 22	1 PM – 2 PM
MC Clinical Research 100	January 9, 16, 23, 30 February 6, 13, 20, 27	9 AM - Noon
ClinicalTrials.gov Introduction	February 19	1 PM – 3 PM
IRB Overview	January 23 February 20	10 AM - Noon
Phlebotomy Competency for Research	January 11 February 19	9 AM – 11 AM 10 AM - Noon

Phlebotomy RENEWAL Competency for Research	January 11	11 AM – 11:30 AM
	February 19	Noon – 12:30 PM
REDCap: Building in the Data Dictionary	January 19	11 AM - Noon
REDCap: Learning to Manage Surveys	February 16	11 AM - Noon
Research Database Design Principles	January 5 February 2	11 AM - Noon
Screening and Consenting Subjects	February 12	10 AM - Noon
Study Documentation Regulations and Best Practices	January 11 February 8	1 PM – 3 PM
Urine Pregnancy Screening for Research	January 9 February 13	2 PM – 3 PM
Workshop: Start Building in REDCap	January 12 February 9	10 AM - Noon

Clinical Research Employee Highlights

- The Medicine CRU would like to congratulate Charlene Carver, Regulatory Coordinator, who graduated with a BAS degree in Clinical Research.

- The School of Nursing welcomes Camilla Sanders as a CRS, Sr.

- The Heart Center would like to welcome Meghan Ronn as a Clinical Research Nurse Coordinator to the Cath Lab Research Cluster. Congratulations Meghan!

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**.