

Clinical Research Update

Duke CTSA
Center for Translational
Science and
Education

DOCR

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docr.help@dm.duke.edu

October 2017

- [OnCore Community News](#)
- [Research Community News](#)
- [DOCR News](#)
- [Did You Know?](#)
- [Training Opportunities](#)
- [Clinical Research Employee Highlights](#)
- [Partner Resources](#)

OnCore Community News

We continue to make progress on many fronts of the OnCore Project. Key areas of activity include:

- Testing the interfaces with Epic
- Discussions with Forte and OIT for the SAP interface
- Discussions between iMedRIS and Duke regarding the API between OnCore and iMedRIS
- Reviewing current reports and comparing them to OnCore reports
- Documenting the current finance workflows
- Reviewing the calendars to build for go live and verifying and updating system configuration settings
- Preparations for the 2nd iteration of data migration

We will need our OnCore Champions for the upcoming validation of the data for the 2nd data migration in mid-October. Once migration is complete, we will pull data reports for Champions to validate that data is correct. We will create checklists for protocols, subjects, and reviews and forward them for review.

OnCore is the clinical research management system focusing on protocol, financial, and enrollment data of your protocols. iMedRIS is the new system that will replace Click eIRB. The two systems will be able to pass data back and forth to minimize duplicate data entry.

Research Community News

Changes to the Common Rule

Changes to the Common Rule, the primary rule regulating human subjects research, are scheduled to go into effect on January 19, 2018. Beginning November 1, 2017, the Duke Health IRB will require that new protocol submissions use updated consent and waiver templates that contain new required elements. All new studies initially submitted in eIRB on November 1, 2017 or later must use the new templates. These documents are available on the IRB website and are simply updates to the previous forms.

Investigators will see a number of changes required under the new rule:

- Consent forms will require a concise summary of study activities, major risks, and benefits presented to research participants in advance of the body of the consent document – the IRB will provide examples on the IRB website.
- Additional elements of informed consent are required in consent forms – these are included in the Duke-sample consent template document.
- The IRB will not require re-consent, except when other significant changes are made.
- In requests for waivers to use identifiable data and specimens, the IRB must find that it would be impracticable to use de-identified data. The waiver request form reflects this change.
- Minimal Risk studies reviewed via the expedited procedure after the new rule goes into effect will no longer require annual continuing review under the new rule, but will require a brief check-in with the IRB every two years. Remember that the requirement to submit amendments and reportable safety events to the IRB has not changed.
- The Common Rule regulations are separate from FDA regulations. The FDA regulations have NOT changed; FDA still requires annual continuing review for FDA-regulated studies, even those relatively rare Minimal Risk FDA-regulated studies.

More details and documents are available at: <https://irb.duhs.duke.edu/about-us/irb-news/faqs-common-rule-changes>

The IRB will host Research Wednesday presentations on changes to the Common Rule:

November 15, 2017, December 13, 2017, and February 14, 2018 at 1:10 PM Duke North Room 2002.

NIH Announces New Forms-E Grant Application Forms & Instructions, Effective January 25, 2018

The NIH has announced significant changes to its grant application forms (Forms-E) and application guide instructions for all human subjects research proposals with due dates on or after January 25, 2018. A high-level summary of these changes is available on the [NIH website](#).

This may be of importance to you if you are a faculty member or help faculty develop their NIH research proposals. Faculty and their staff who help develop proposals are invited to attend one of three 60-minute sessions. No registration is required.

November 16th at 7:30 AM and November 20th at 4:30 pm in Duke North Room 2003

November 17th at 9:00 AM in Perkins Room 217

If you have any questions, please contact researchinitiatives@duke.edu.

New Facilities and Administrative Rate

Effective as of August 22, 2017, new F&A rates should be used for grant and contract submissions. Proposals already initiated in SPS will require manual update of the F&A rate for out years. Departments should carefully review proposals for correct F&A rate applications, as the pre-award offices will return proposals that do not include the current rates (unless an alternate rate is applicable). New F&A rates were loaded into SPS on September 6, 2017. All future proposals will automatically have the new rates. Please verify the rates beginning on this date to confirm that the update has occurred.

Although F&A rates are increasing in future years, this increase will not adversely impact direct funding on existing awards or already submitted proposals. The pre-award offices will work directly with sponsors, and will only increase future year rates if additional funding is made available for this purpose.

New to the recent negotiation, an F&A rate for Other Sponsored Activities (OSA) was established. OSA activities include those activities currently in the 309-xxxx through 389-xxxx series of accounts. These activities are sponsored activities for purposes other than research or instruction. Some examples of these types of activities include public service, conference grants, or symposiums. Please note that Clinical Trials are NOT included in our OSA rate. In the weeks to come, we will provide guidance and training on how to identify these types of projects so that the new OSA rate can be appropriately applied. Management Centers will communicate any impact this new rate will have to the F&A waiver policy. A link to the official announcement [can be found here](#).

Please contact your pre-award office if you have any questions regarding the rollout of the new F&A rates.

Advertising for Studies

As a reminder, the DUHS IRB must review and approve recruitment methods and content of advertising materials to ensure adequate subject protection. The IRB must review the information contained in all advertisements and the mode of their communication. Advertisements cannot be displayed or put to use until the IRB has approved the final copy of printed and electronic ads and the final version of audio/video tape recorded advertisements. As an additional layer of review, the Duke Health Office of Marketing and Communications must approve advertising style and format.

The entire "[Policy and Guidelines for Advertising \(Subject Recruitment Materials\)](#)" is available on the DUHS IRB website. Additionally, you can contact both your [IRB Board Specialist](#) as well as the [Recruitment Innovation Center](#) with questions.

Regarding advertising placement within Duke Health facilities, Duke Health strictly prohibits the use of easels/posters and flyers (such as research recruitment advertising) in DUH and Duke South clinics. There are 17 digital signs in public areas throughout DUH and in strategic locations in Duke South Clinics that can be used for advertising purposes. The entire "[Duke University Hospital Digital Signage](#)" policy is available on the Duke Medicine intranet.

Preparing for the Epic 2017 Upgrade

Maestro Care will be upgraded to the 2017 version of the Epic electronic health record during scheduled maintenance 12:01–4:00 AM on Sunday, October 22nd. Over the days leading up to the upgrade, training materials will be distributed to the RPMs and posted on the CRC Epic Dashboard and the Wiki. Please direct questions to docr.help@dm.duke.edu.

2017 Influenza Vaccination Campaign

School of Medicine faculty and staff who are required to be compliant with the School's influenza vaccination policy may receive a free vaccination. Free vaccinations will be available in several locations throughout the Duke medical campus and off-site facilities. Compliance with the policy is required by November 1st. The School of Medicine will send regular communications and updates during the campaign. For more information about the faculty and staff included in the vaccination cohort, and about tracking compliance within your unit, please visit the [SoM influenza policy page](#) or contact Sue Budinger at susan.budinger@duke.edu.

A schedule of times and locations the flu shot will be offered to Duke employees [is available here](#).

CRPWG Update—Tier Testing this Fall

As you may know, tier testing for staff in tiered research positions will be launched this fall. In preparation for this, the CRPWG held brief informational sessions on September 20th and September 21st with chief administrators, business managers, HR managers, and Research Practice Managers within each department, center, and institute. In addition, manager training sessions will occur in late September/early October.

Managers were informed that tier testing is not for everyone. We encourage collaboration between managers and tiered staff to determine the appropriate time for individual staff to participate.

Please visit the CRPWG website to see the tools available to assist with the tier assessment process. [Watch here](#) for a voice-over slide deck to walk employees through the process. If you have additional questions, we are hosting office ours on Mondays from Noon to 1PM from September 25th to December 18th in room DMP 2W92 and on November 13th in DMP 2W94. Office hours will not be held on October 9th.

Duke, NCCU Announce Clinical Research Partnership

Duke University Health System and N.C. Central University campus leaders announced a partnership to encourage joint medical research projects and provide training and certification to NCCU students in how to conduct clinical research. The agreement is intended to “produce a partnership around developing careers in research,” said Duke CTSI Director Dr. Ebony Boulware. “There are scientific strengths N.C. Central has that Duke doesn’t have. They’re complementary.” Additional details are available on the [Duke Clinical & Translational Science Institute website](#).

Duke Project Management Community of Practice Launch

The Duke Project Management Community of Practice (PMCoP), an initiative of the Duke Clinical and Translational Science Institute, is launching this fall.

Duke PMCoP connects people who have project management responsibilities across Duke University, Duke University Medical Center, and the Durham Veterans Affairs Health Care System. The mission of Duke PMCoP is to provide professional development and professional networking opportunities for project managers; education and opportunities for students, faculty, and staff; and a repository for best practices, tools, and resources in project management.

To join and receive notices of all upcoming events, [click here](#).

A launch event will be held October 4th from 4:00-5:00 PM in Hanes House Room 131. The launch will include an introduction to Duke PMCoP, a presentation by Geoffrey Ginsburg and time for networking.

Duke Mobile App Gateway Launch Event October 19th

The Duke Clinical & Translational Science Institute will host the Duke Mobile App Gateway launch event on October 19th from 8 AM to noon in the Trent Semans Great Hall.

The Mobile App Gateway is entry point for all support of digital health and mobile app research and development throughout Duke Health and Duke University.

For a description of the event and to register, visit <http://bit.ly/DukeMAGlaunch>.

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

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 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.

Duke University School of Medicine Announces 2017 Research Staff Appreciation Awards

The [School of Medicine Research Staff Appreciation Awards](#) recognize staff members who provide exemplary support in the conduct of research.

Nominations for these awards are now being accepted and can be submitted online at the link below. A nomination can be submitted by any School of Medicine faculty or staff member. Nominators may only nominate one candidate. The application requires endorsement from the respective chair or center/institute director of the staff member. Self-nominations will not be accepted.

To submit nominations for the 2017 SOM Research Staff Awards:

- To apply visit [MyResearchProposal](#) and click on “Create New User” (or log in if you already have an account.)
- A step-by-step user’s guide for applying via the MyResearchProposal software is available - Please review this [document](#).
- Enter Access Code ‘SOM’ then select the “2017 SOM Research Staff Awards” opportunity and follow the instructions.

If you are having trouble accessing the system, please contact Anita Brantley at myresearchproposal@duke.edu or anita.brantley@duke.edu.

Applications are due October 19, 2017, and winners will be announced in November. Three awards will be presented. Each winner will receive a certificate and \$500.00.

Save the Date: 2017 Symposium for Research Administrators November 28th

Please join the research administration community at the 2017 Symposium for Research Administrators on November 28, 2017 at the Durham Convention Center. This year’s theme, Collaboration, Community, Continuous Improvement, reflects the collaborative nature of the research and research administration communities at Duke University and our drive for success.

Individuals who would like to present a break-out session at this year’s Symposium should complete and submit a Call for Proposals form to rcc-cert@duke.edu no later than Wednesday, October 4, 2017 for consideration. All submissions will be reviewed, and we will inform individuals of the decision by no later than October 9, 2017. To request a form, contact RCC at rcc-cert@duke.edu.

Those interested in exhibiting a poster should complete and submit a Call for Posters form to rcc-cert@duke.edu no later than Wednesday, October 4, 2017 for consideration. Submissions will be reviewed, and we will inform individuals of the decision to include their poster in the Symposium by no later than October 9, 2017. To request a form, contact RCC at rcc-cert@duke.edu.

Save the Date: Basic Science Day November 29th

This year’s annual Basic Science Day will be held Wednesday, November 29th in the Trent Semans Center Great Hall. The event will feature Dr. Jennifer Doudna speaking on “CRISPR Systems: Biology and Application of Gene Editing.” For a full agenda of the day’s events and to register, visit <http://medschool.duke.edu/Basic-Science-Day>.

Test Your Cybersecurity Knowledge for Chance to Win Apple Watch

As part of National Cybersecurity Awareness Month in October, Duke's IT Security office invites Duke staff, faculty and students to [learn about cybersecurity best practices and to take a security quiz](#) for a chance at an Apple Watch Series 3.

Office of Sponsored Programs Quarterly Outreach Session

THE OSP EXCHANGE is a 1 hour quarterly session designed to exchange tips, facts, and ideas.

This month's OSP Exchange is specifically targeted to Departmental Grant Managers and their teams. Session participants will take a deep dive into SAP, discovering a wealth of master data/information, and will learn how these details can assist you in the ongoing management of your sponsored project.

Two sessions will be held different campus locations. Register using the links below.

[October 19th](#) – Erwin Square, Room 837, 11:00 AM – Noon

[November 7th](#) – Sociology and Psychology 130, Karl E. Zener Auditorium, 11:00 AM – Noon (No food or beverages allowed)

If you have any questions or need additional information email sponsoredprograms@duke.edu or call (919) 684-5442.

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 on October 10th from 11:00 AM until 1:30 PM. Highlights of the event include an address from the newly appointed Vice Dean for Clinical Research, Adrian Hernandez, MD, 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 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 10 AM-11 AM. Office hours will continue to be held in Hock 9047 from 11 AM-12 PM until October 10th.

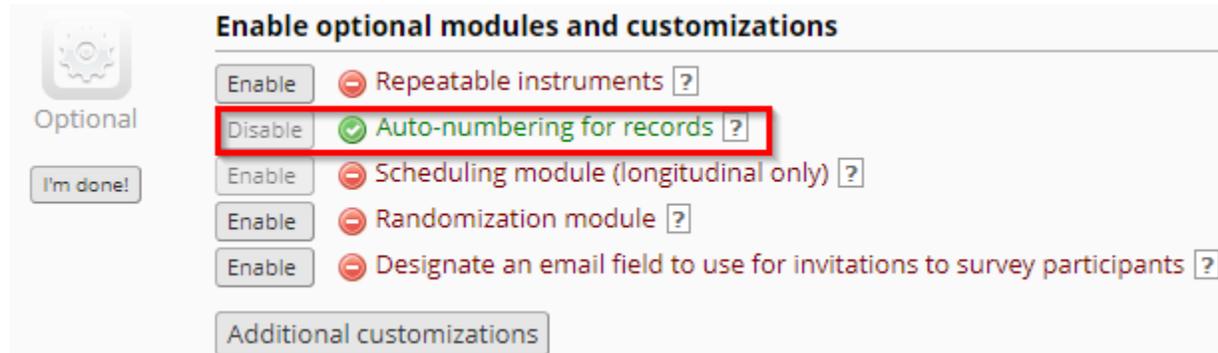
Don't forget office hours are also held the first Thursday of the month, 10:00-11:00 AM in DMP 2W93.

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

Did You Know?

REDCap: Disabling the Auto Numbering Feature

Users can disable the auto-numbering feature in REDCap on the Project Setup tab. This option will give users the ability to name new records manually. The unique record name can be include numbers and letters.

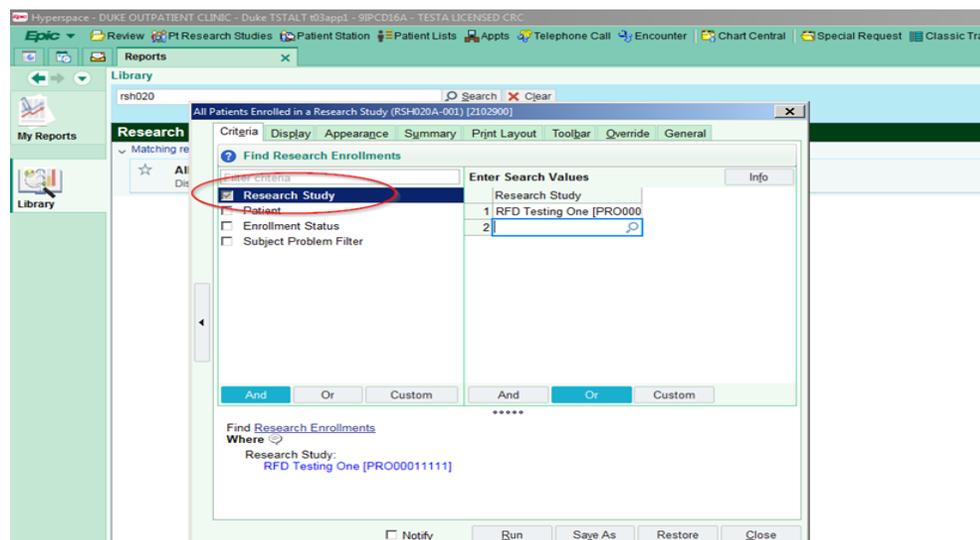


Maestro Care: Adding WebEx Productivity Tool to Outlook Email

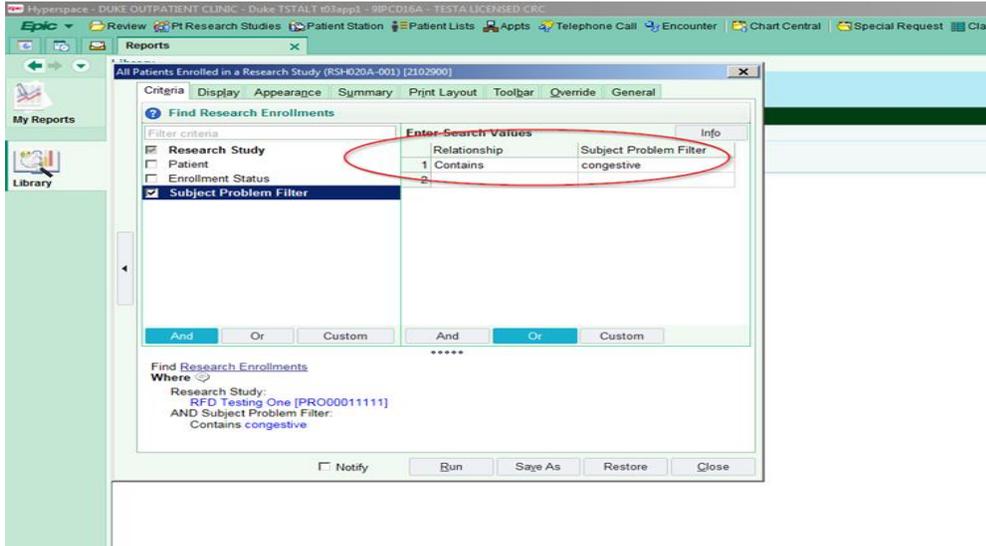
When submitting help requests for Maestro Care, it is useful to have the WebEx Productivity Tool as an application in Outlook Email. This feature allows technical support to better troubleshoot and solve any Maestro Care issues you are experiencing. With this tool in place, your technical support team can securely access your desktop screens to help troubleshoot and resolve any problems as you see them. To add the WebEx Productivity tool [submit a Service Now ticket](#).

Maestro Care: Adding Problems to the RSH020 Report

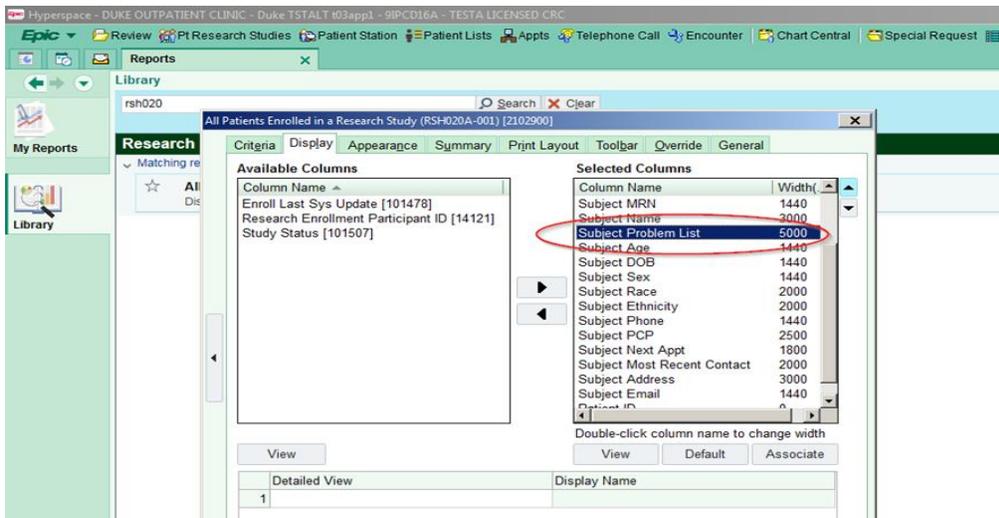
1. Verify that the Research Study is appropriately filled in



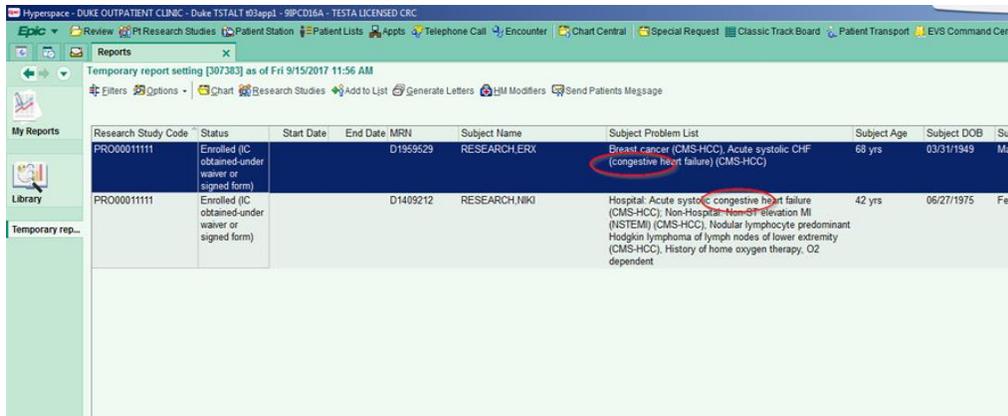
2. Fill in all pertinent fields including Enrollment Status
3. Select Subject Problem Filter
4. Set Subject Problem Filter (Relationship = "Contains"; Subject Problem Filter = "specified problem")



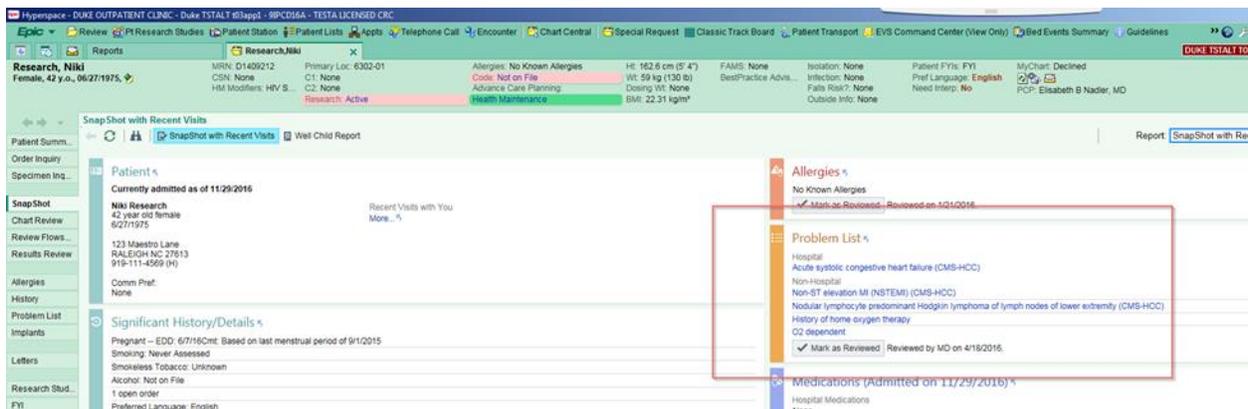
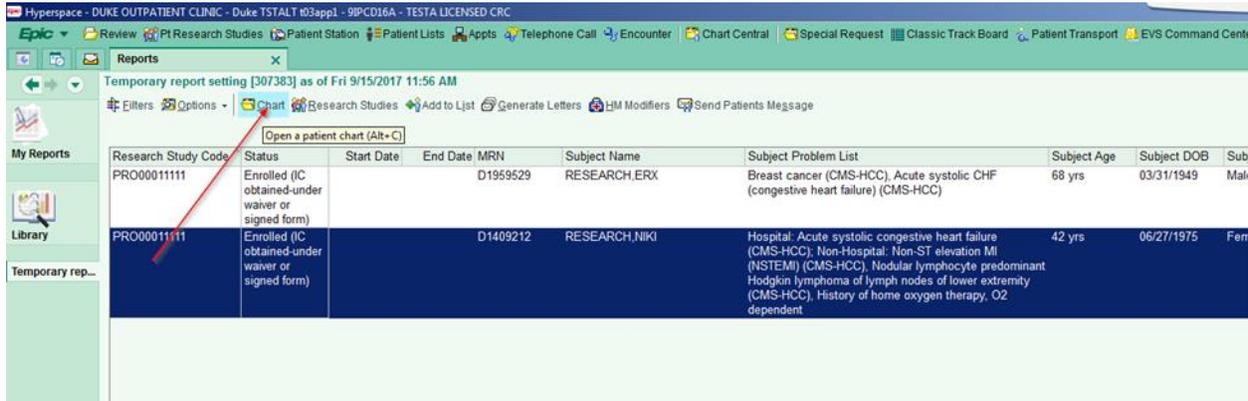
5. Select Display Tab
6. Add Subject Problem List to Selected Columns



7. Return to Criteria tab and click 'run'



- To validate subject problem list display column, click Chart from report results and compare the problem list displayed in the report with patient snap shot.



To learn more about this feature, submit an MCRC Concierge request through [Service Now](#).

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: <ul style="list-style-type: none"> - Information Security Office - Epic Upgrade - NIH Updates - Implementation of Changes in the Revised Common Rule, Session 1 (3rd Wednesday in November) 	<p>October 11</p> <p>October 25</p> <p>November 8</p> <p>November 15</p>	<p>1:10 PM – 2 PM</p>
Research Professionals Network: <ul style="list-style-type: none"> - Clinical Research Appreciation for Faculty and Staff - Creating Innovative Solutions to Recruitment and Retention Challenges 	<p>October 10</p> <p>November 16</p>	<p>11 AM– 1:30 PM</p> <p>1 PM – 2 PM</p>
MC Clinical Research 100	<p>October 17, 24, 31</p> <p>November 7, 14, 21, 28</p>	<p>9 AM - Noon</p>
MC Clinical Research Oncology (Beacon)	<p>October 12, 24</p> <p>November 15</p>	<p>1 PM – 4 PM</p>
MC Clinical Research Oncology (Beacon) Refresher: Deep Dive	<p>October 5</p> <p>November 2</p>	<p>1 PM – 4 PM</p>
MC Clinical Research Personalization	<p>October 17</p> <p>November 21</p>	<p>1 PM – 4 PM</p>
MC Clinical Research Personalization	<p>October 25</p> <p>November 13</p>	<p>9 AM - Noon</p>

Budget Development and Negotiation Training	November 7	10 AM - Noon
IRB Overview	October 24 November 14	10 AM - Noon
Industry Funded Clinical Research Process for Contracts	November 16	9 AM – 11 AM
Phlebotomy Competency for Research	October 12 November 9	9 AM – 11 AM
Phlebotomy RENEWAL Competency for Research	October 12 November 9	11 AM – 11:30 AM
REDCap: Learning to Manage Surveys	October 20 November 17	11 AM - Noon
Recruiting Regulations and Best Practices	October 5	1 PM – 3 PM
Research Database Design Principles	October 6 November 3	11 AM - Noon
Screening and Consenting Subjects	October 30	1 PM – 3 PM
Study Documentation Regulations and Best Practices	October 17 November 9	10 AM - Noon
Urine Pregnancy Screening for Research	October 17 November 14	1 PM – 2 PM
Workshop: Start Building in REDCap	October 13 November 10	10 AM - Noon

Clinical Research Employee Highlights

- The Office of Research Contracts welcomes Ashley Young, J.D. to the Site Based Research Agreements team. Prior to coming to Duke, she practiced civil law in Raleigh and Durham since 1998, with a strong concentration in the medical field.
- The Heart Center CRU welcomes Kuntal Shah, CRC, MPH. Kuntal has a background in epidemiology and has joined the central team.
- The Heart Center CRU welcomes Mary Beth Summers, CRS Sr. Mary Beth is a recent NCSU grad with a degree in Chemical and Biomolecular Engineering.

- Congratulations to Sue Doyle in the Department of Medicine who received CCRC certification through ACRP.
- The Oncology CRU would like to congratulate Dennis Carmody and Nick Jeffries for passing the SoCRA exam and receiving their CCRP credentials.
- Stephen Gazda has joined the Radiology CRU Team as a CRC. Welcome to Radiology. We are happy to have you!
- Radiology would like to thank CRC Jennifer Korzekwinski for her effort in preparing for our recent FDA audit. Our success of having no findings is largely due to Jennifer's dedication, expertise and stamina. Great job Jennifer!
- Children's CRU welcomes Nicole Baisden CRC to our Division of Critical Care Medicine and Tiara Stanley CRC to our Duke Healthy Lifestyle Program in the Division of Primary Care.
- The Duke Cancer Institute would like to welcome Lynn Volk who joined their team as a Regulatory Coordinator.
- Children's CRU congratulates Cathy Williams, RN, ARPM for earning a Supervisory Excellence Certificate! Cathy has been hard at work taking professional development classes through Duke Learning & Organization Development in pursuit of this certificate. The certificate requires the successful completion of six classes designed to enhance supervisory skills.
- Please extend a warm welcome to Carol Ann Wiggs RN who joined the Melanoma research team on Sept 18th. Carol Ann is a former 2014-2017 Duke employee who worked in the Dermatology Mohs Surgery Department. She then had a brief employment at PPD as a nurse consultant. She is a 2011 NC State graduate with a BS in Biological Sciences and she received her RN in 2014. Welcome Carol Ann!
- Congratulations to Colleen Piechocki RN who was promoted in July to Clinical Research Nurse Sr. for the Sarcoma research team. Colleen has been instrumental in developing the Sarcoma research program with Dr. Richard Riedel over the past 3 years.
- Welcome to Ashley Scoggan RN who joined the Sarcoma research team on July 18th. Ashley transferred from the Oncology Treatment Center and will be working with Colleen Piechocki RN. Welcome Ashley!
- DCI Wake County welcomes Marlyne Silver, CRS, Sr to the team.

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.