September 2015

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Regulations, Policies, and Procedures

New Way to Track DOCR Approval of Your Study!

DOCR and ORI have teamed up to create a new tool for you to see where your protocols stand in the DOCR Approval process. The web-based tracker provides an easy “at a glance” view of document receipt status, study initiation meeting scheduling, and Maestro Care build requirements. Updated nightly, it also shows the status of fund code receipt, ClinicalTrials.gov requirement satisfaction, and key personnel DHRT completion, as applicable. This increased visibility can be utilized along with the study initiation information on the DOCR web page to improve the efficiency of DOCR study sign-off. Please feel free to send any questions or feedback on the Study Initiation Tracker to DOCR-Startup@dm.duke.edu.
DOCR Teams add Targeted Email Addresses

In an effort to continue to improve the customer experience, DOCR teams have added targeted email addresses in order to more directly route customer queries. In addition to DOCR.help@dm.duke.edu which can continue to be used for general DOCR questions, customers can use:

- **DOCR-Startup@dm.duke.edu**, Study Startup
- **DOCR-rmt@dm.duke.edu**, Research Management Team
- **DOCR-Website@dm.duke.edu**, Website issues
- **DOCR-StudyPlanning@dm.duke.edu**, Studies without Maestro Care setup and Research Match
- **DOCR-Training@dm.duke.edu**, Training and communications
- **DOCR-Grants@dm.duke.edu**, Grant development
- **DOCR-CTGOV@dm.duke.edu**, Study closeout and CT.gov
- **DOCR-Contracts@dm.duke.edu**, Contracts
- **docr.help@dm.duke.edu**, General help questions
- **docr.rpn@dm.duke.edu**, Research Professionals Network
- **redcap-docr@dm.duke.edu**, REDCap team

DOCR Provides Free Consultation for Studies with Mobile Components

Are you planning a study involving mobile technology, such as smartphone apps or texting? If so, there is a new DOCR service to help you navigate the details and prepare your protocol. In coordination with the Information Security Office (ISO), DOCR staff can work with study teams as they develop the research summary, consent form, and RDSP. In addition, DOCR staff are automatically notified of these studies as they are submitted to the eIRB, and can work with study teams at that time. If you are interested in setting up a planning meeting or have questions about this service, please email docr-studyplanning@duke.edu.

Multi-factor Authentication when Traveling

There are several choices for using multi-factor authentication while traveling. Detailed instructions can be found here under the “Traveling Abroad” section and it is encouraged that users test these before the start of travel. Instructions include scenarios for if you have a smartphone/tablet (with or without Internet/cellular service), if you only have a basic cell phone, and choices for if you have no cell phone or tablet. Support for MFA is offered by OIT.
Learn More About the Duke CTSA

Mark your calendars for two upcoming opportunities to learn more about the Duke Clinical and Translational Science Award (CTSA). On September 21 at 1 p.m., Duke staff members are invited to join the Duke CTSA Virtual Block Party and hear a WebEx presentation about the soon-to-be-launched MyResearchNavigator program. On Oct. 29 at noon, Dr. Ebony Boulware will host the 2nd CTSA Virtual Town Hall, which will feature DOCR’s Research Management Team program. Contact Marsha.Green@duke.edu for more information about either event.

SSN Usage for Research

The Office of Audit, Risk and Compliance (OARC) would like to thank everyone for their work in getting the SSN exception requests submitted. To date, OARC has reviewed over 300 exception requests. There is now a research specific FAQ to the instructions on the eGRC. Please check it out when preparing new requests.

Remember—Only Access What You Need When in the Medical Record

When working on clinical trials and other studies, many research staff need to use the clinical electronic health record (Maestro Care). All staff with access to Maestro Care have a security template that permits specific functionality in the application. Along with this ability to view and record clinically-relevant research activity comes the responsibility to follow the Duke Medicine policy on its use. By policy, an individual should only access patient information needed to do his/her job. For example, if you need information from a CT scan on a particular day, no other CT scans are to be viewed. If others are viewed and not needed, that would be considered more that minimum necessary use of the information and a violation of the policy. Some information in Maestro Care, such as Care Everywhere, is not to be used by research personnel. While the tab for Care Everywhere is visible, research staff are not currently approved to view it or use it. If this changes in the future, it will be communicated to the research community.

Dr. Geeta Swamy Named Lead Chair for DUHS IRB

Effective September 1st, Dr. Geeta Swamy from OB/GYN will serve as a Lead Chair for the DUHS IRB. Dr. Swamy will lead IRB chairs and work with the Vice Dean for Clinical Research, Dr. Mark Stacy, and the Executive Director of the DUHS IRB, Jody Power, to redefine the roles of IRB chairs and members. She will also explore ways to improve workflows and interactions with IRB staff and our research communities. We welcome her experience and relationships with colleagues in a variety of therapeutic areas.

Training Opportunities

Upcoming DOCR Training Offerings
DOCR training offerings are available in the Duke LMS. You have 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://vmw-lmsweb.duhs.duke.edu/SabaLogin

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:

<table>
<thead>
<tr>
<th>Title</th>
<th>Dates</th>
<th>Time</th>
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<tbody>
<tr>
<td><strong>Research Wednesdays:</strong></td>
<td></td>
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<tr>
<td>- Reading the Protocol from a Financial Perspective</td>
<td>September 9</td>
<td>1 PM – 2PM</td>
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<tr>
<td>- Clinical Research Job Classifications</td>
<td>September 23</td>
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<tr>
<td>- National Cybersecurity Awareness</td>
<td>October 14</td>
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<tr>
<td>- CTSA Update</td>
<td>October 28</td>
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<tr>
<td><strong>Research Professionals Network:</strong></td>
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<tr>
<td>- Having Difficult Conversations with Teammates, Employees, and Managers</td>
<td>September 22</td>
<td>4 PM</td>
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<tr>
<td>- REDCap Playground</td>
<td>October 13</td>
<td>1 PM</td>
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<tr>
<td><strong>MC Clinical Research 100</strong></td>
<td>September 7, 14, 21, 28</td>
<td>Noon – 3:30 PM</td>
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<td></td>
<td>October 5, 12, 19, 26</td>
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<tr>
<td><strong>MC Clinical Research 100</strong></td>
<td>September 9</td>
<td>8:30 AM – 11:30 AM</td>
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<tr>
<td><strong>MC Clinical Research Super User Applications Workshop</strong></td>
<td>September 10</td>
<td>2 PM – 4 PM</td>
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<tr>
<td><strong>Biobanking Best Practices</strong></td>
<td>October 13</td>
<td>10 AM</td>
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<tr>
<td><strong>Budget Development and Negotiation Training</strong></td>
<td>October 15</td>
<td>9 AM</td>
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<tr>
<td><strong>Workshop: ClinicalTrials.gov Results Reporting</strong></td>
<td>September 24</td>
<td>1 PM – 3:30 PM</td>
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<tr>
<td><strong>IRB Overview</strong></td>
<td>September 22</td>
<td>10 AM - Noon</td>
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<td></td>
<td>October 20</td>
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<tr>
<td><strong>Industry Funded Clinical Research—Process for Contracts</strong></td>
<td>September 29</td>
<td>9 AM – 11 AM</td>
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<tr>
<td><strong>The Informed Consent Process</strong></td>
<td>October 21</td>
<td>9 AM – 11 AM</td>
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### Did You Know?

If a Principal Investigator declares a conflict of interest on a Duke Proposal Approval Form (DPAF), the Research Integrity Office (RIO) must review and release the DPAF before institutional approval can be given by the Office of Research Administration (ORA) or the Duke Office of Clinical Research (DOCR)? It is helpful for RIO to see these as soon as possible. In an effort to help ensure no proposal is delayed for a conflict of interest review, once the proposal is ready for pending central approval status, the DPAF can be emailed to dukecoi@duke.edu and RIO will begin the review.

### CRU Corner

Alexis Sharp joined the Heart Center CRU Cath lab cluster on July 1st from the Biospecimen Repository & Processing Core shared resource within the Oncology CRU. She is a CRC III that will oversee the coronary, stem cell, vascular, and hypertension studies.

Megan Eure joined the Heart Center CRU Cath lab cluster on July 1st from Orthopedic Spine Surgery within the Orthopedic CRU. She is a CRC I that will work on the structural TAVR studies.

Anat Triestman is new to Duke and joined the Cath lab cluster on July 13th. She recently completed her Clinical Trials Research Associate Degree. She is a Clinical Trials Assistant I who will be working on multiple Cath lab studies.

The Heart Center CRU Cath lab cluster congratulates Caroline Bishop and Rashmi Chandra who were promoted to CRC IIs on August 1st!

The Heart Center CRU Cath Lab cluster welcomes Sara Michael, CRC I. She came from the Cardiac Diagnostic Unit (CDU). She will work on multiple coronary studies within the Cath lab.
The Heart Center CRU Cardiac Diagnostic Unit (CDU) welcomes Jennifer Tomfohr, CRC I. Jennifer previously worked as an ultrasound sonographer and started with the CDU on July 13th.

The Heart Center CRU Primary and Acute Cardiology (PAC) cluster welcomes Molly McKinney who began working as a CRC I June 1st.

The Heart Center CRU congratulates Latasha Oxendine who was promoted to a CRC III lead on July 1st. She will lead the Lumberton cluster.

Congratulations to Christine Poulsen who has been promoted to Regulatory Coordinator II effective July 2015. Christine will support Adult Bone Marrow Transplant research and specific Heme Malignancies studies.

The Psychiatry CRU would like to congratulate Jennifer Wilson on her promotion to CRC I.

Welcome Sheryl Cummings, RN MS as CRC RN III for Breast Oncology.

Welcome Nyssa Schwager, RN MS as CRC RN III for GYN Oncology.

Oncology CRU welcomes Meghan Channell, ARPM for Regulatory and Project Management.

Congratulations Ranju Singh, RN, on your promotion to CRC RN III for the Cancer Center Research Lab.

It is with great pleasure that the SON CRU welcomes Rebecca Jones as a CRC III, effective August 3rd. Rebecca comes with years of neonatal research experience. Rebecca will be working with Dr. Robin Dail on her Innersense Baby research study.

It is with great pleasure that the SON CRU welcomes Cristy VanSant as a Clinical Research Coordinator I, effective August 10th. Cristy comes from UNC and has several years of recruitment and research coordination study experience. Cristy will be working with Dr. Sophia Smith on her Pillars for Life study.

Rose Ritts, PhD, Executive Director of the Office of Licensing and Ventures, has been named the Executive Vice President of Innovation at Thomas Jefferson University and Jefferson Health System in Philadelphia, PA. Her new appointment begins November 1. A full announcement can be found here.

Congratulations to the Preston Robert Tisch Brain Tumor Center BioRepository on recently becoming CAP accredited.

**Partner Resources**

**DUHS Compliance Office Newsletter**

Catch up on news from the [DUHS Compliance Quarterly Newsletter](#).

**CTSA Updates**

Catch up on the news about the Clinical and Translational Science Award (CTSA) in the [latest 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.