October 2015

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News for the Research Community

DOCR Satisfaction Survey Results Are In!

A summary of the 2015 DOCR Satisfaction Survey results is available on the DOCR Wiki.

Congratulations to Sharon Minda who was the raffle prize winner for completing the survey.

ICD-10 Brings Changes to V70.7 Codes

On October 1st, ICD-9 codes were replaced with ICD-10 codes. Moving forward V70.7, “examination of a participant in a clinical trial,” has been replaced with the code Z00.6. What does this mean for study teams? Fortunately, all existing functionality in Maestro Care, including billing calendars and smart phrases, was automatically updated with the new Z00.6 code. However, when manually entering an ICD-10 code in an order set, please remember to use Z00.6. If you use V70.7 today, it will correspond with the diagnosis of “person on outside of bus injured in collision with pedestrian or animal in traffic accident,” which may or may not be related to your study.

Submit your ideas about how to “optimize” Maestro Care Research

The Maestro Care Research Optimization project is a collaborative effort between the Duke Office of Clinical Research (DOCR), Office of Research Informatics (ORI) and Duke Health Technology Solutions (DHTS) to make the Maestro Care Research system more useful to the
Duke research community. The project has three high-level goals: 1) provide additional support with the Maestro Care Research Concierge (MCRC) Service, 2) establish a Task Force to improve the workflows, and 3) provide the enhanced functionalities. The first two enhanced functionalities that will be offered are Silent Alerts (in-basket message once a potentially eligible subject is identified) and MyChart Questionnaires for Research. Additional information on the project can be found on the ORI Wiki page.

If you would like to request an optimization, complete the first form in this survey. A member of the optimization team will follow up with you and present your request to the Research Optimization Committee.

**Updating Maestro Care when a Patient is Deceased**

Have you ever discovered that a patient in your study is deceased but not documented as such in Maestro Care? If so, below are three options on how to communicate this information to the Health Information Management.

1. If you DON’T have a death certificate or obituary, put in an IT Support Ticket with the information and they will contact you if they have questions.
2. If you have a death certificate or obituary, you can fax it to 919-383-4154
3. If you have a death certificate or obituary, you can scan it to a GROUP EMAIL that has to include all three of the following people: anderson.springfield@dm.duke.edu, jodi.orlando@dm.duke.edu, sharon.d.stewart@dm.duke.edu.

**2015 Symposium for Research Administrators**

Mark your calendars for the 2015 Symposium for Research Administrators. This year’s theme, “Research Administration: Inside Out,” reflects the broad variety of skills and knowledge represented in today’s research administration professional. The event will take place November 10th, 8:30 am – 3:30 pm at the Durham Convention Center. Additional information is available.

**October is National Cybersecurity Awareness Month**

As part of National Cybersecurity Awareness Month, Duke University's IT Security Office and Duke Medicine's Information Security Office are inviting staff, faculty, and students to take a CyberSmart Pledge to commit to secure computing practices both at home and at work. The 10-step pledge focuses on basic behaviors such as using strong passwords and multi-factor authentication, installing anti-virus software, and reporting suspected security incidents to security@duke.edu. All Duke faculty, staff and students who take the pledge will be entered into a drawing to win an Apple Watch.

IT security staff will also be sponsoring two Learn IT@Lunch information sessions, will be available at a variety of campus events with free T-shirts and other giveaways, and will be
present at multiple departmental meetings this fall and winter. To take the pledge or learn about the October events, visit security.duke.edu.

**New IRB Website**

The IRB has updated its website – please check it out at https://irb.duhs.duke.edu/.

The Search feature at the top of every page is more robust than before so when looking for a policy or form, it is now easier to find it by searching on the name of the policy or form, or a keyword from the policy or form. Also, note that in the yellow strip of main headings across the top of the home page, you can click on any of those headings to get to those landing pages (e.g., About Us, Training and Education, etc.), and you can also hover over them and see a drop-down of menu choices. The link to the CITI website is on the Training and Education page.

There are also three role-based portals at the bottom of the home page, and these present information tailored for three groups: Researchers, IRB Members, and Research Participants. We have also added new information helpful to the research community, such as FAQs and a “Getting Started” page.

The new website displays best and has correct functionality on the newer browser versions: Internet Explorer versions 10 and 11 and Firefox versions 40 and 41.

Please let us know if you find any dead links on this website as you use it. Please share your comments and complaints with June Walker and Minna Pak in the IRB Office.

**USDHHS Proposes Major Overhaul of the Common Rule**

[note: the majority of information below was taken directly from Ropes & Gray Alert, September 2015]

We wanted to alert you about potential changes coming to the common rule. On September 8, 2015, the Department of Health and Human Services proposed significant revisions to the Federal Policy for the Protection of Human Subjects (“Common Rule”), the set of federal regulations governing the conduct of clinical research involving human subjects. HHS’s notice of proposed rulemaking (NPRM), joined by 15 other federal departments and agencies, marks the first systematic attempt to overhaul the Common Rule since its promulgation in 1991. The NPRM sets forth proposals to modify informed consent for biospecimen research, improve the understandability of consent forms, mandate single institutional review board (IRB) oversight of research, and establish data security safeguards. The changes, once implemented, will have implications for most clinical research being conducted at Duke.
The NPRM is actively seeking public input on numerous proposals and questions. A summary of the proposed changes, the full NPRM, and directions for public comment can be found [here](#). The 90-day comment period closes on December 7, 2015, with a possibility for extension. Changes likely will not go into effect until late 2016.

The DUHS IRB is leading a committee of regulatory experts and investigators to formulate a response. As part of its review, the committee will solicit comments from the general research community in October.

**AWARE for All Event—Informing Community Members About Research**

Research faculty and staff are invited to attend AWARE for All, an educational event that is designed to empower patients in our community with information that they need to make informed decisions about their healthcare and opportunities to participate in research. CISCRP is collaborating with Duke to make this an exciting and helpful event for the public. Details about the event, which takes place on 10/22, are available [here](#). Our very own Mark Stacy, MD is serving as the keynote speaker. Note that ACRP members can obtain two contact hours. ACRP requires attendees seeking contact hours to [register](#) through their chapter site to activate an evaluation process, which will open up closer to the event.

**Training Opportunities**

**Upcoming DOCR Training Offerings**

DOCR training offerings are available in the [Duke LMS](https://vmw-lmsweb.duhs.duke.edu/SabaLogin). 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:  

[Duke LMS](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>
<td>1 PM – 2PM</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>- RFD Pilot</td>
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<tr>
<td>- FDA Draft Guidance Document Related to Sponsor Investigator INDs</td>
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<td><strong>Research Professionals Network:</strong></td>
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<td>Event</td>
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<tr>
<td>REDCap Playground</td>
<td>October 13</td>
<td>1 PM</td>
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<tr>
<td>- Discovering Your Team Dynamics</td>
<td>November 17</td>
<td>4 PM</td>
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<tr>
<td>MC Clinical Research 100</td>
<td>October 5, 12, 19, 26 November 2, 9, 16, 23</td>
<td>Noon – 3:30 PM</td>
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<tr>
<td>MC Clinical Research 100</td>
<td>November 30</td>
<td>12:30 PM – 3 PM</td>
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<tr>
<td>MC Clinical Research 100</td>
<td>October 7, 14</td>
<td>8:30 AM – 11:30 AM</td>
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<td>Biobanking Best Practices</td>
<td>October 20</td>
<td>10 AM - 11:30 AM</td>
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<tr>
<td>Budget Development and Negotiation Training</td>
<td>October 15</td>
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<tr>
<td>Duke Human Research Training</td>
<td>November 12</td>
<td>1 PM – 3 PM</td>
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<tr>
<td>IRB Overview</td>
<td>October 20</td>
<td>10 AM - Noon</td>
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<tr>
<td>- The Informed Consent Process</td>
<td>November 17</td>
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<td>Phlebotomy Competency for Research</td>
<td>November 12</td>
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<tr>
<td>Phlebotomy RENEWAL Competency for Research</td>
<td>November 12</td>
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<td>Research Data Security Plan</td>
<td>November 5</td>
<td>Noon – 1 PM</td>
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<td>Study Documentation Regulations and Best Practices</td>
<td>October 12</td>
<td>Noon – 2PM</td>
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<tr>
<td>Urine Pregnancy Screening for Research</td>
<td>November 4</td>
<td>9 AM – 11 AM</td>
</tr>
<tr>
<td>Workshop: Consenting a Subject to a Research Study</td>
<td>October 19</td>
<td>Noon – 3 PM</td>
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**Did You Know?**

Do you know the difference between a Maestro Care billing protocol amendment and a Maestro Care billing protocol revision?

A Maestro Care billing protocol amendment is a change due to an IRB-approved amendment or a change in the contract that affects the way charges are routed. The billing changes only apply
from the date of the approval forward. A Maestro Care billing protocol revision is a change or update that affects all charges, historical and future. An example of a revision would be after reviewing the charges, a CRC notes that the contrast for a CT scan had not been identified as a research charge and was not on the Maestro Care billing protocol. A Maestro Care billing protocol revision should be requested by the study team via Service Now to add the contrast to the Maestro Care billing protocol. This change will result in a review of historical charges to date of all subjects on the study to ensure the charge routes correctly.

Clinical Research Employee Highlights

The Psychiatry CRU would like to congratulate Nilda Itchon-Ramos and Rachel Kozink on their promotion to Research Project Manager.

The Department of Surgery welcomes new Assistant Research Practice Manager, Mary Beth Davis, MS, CCRP.

The Department of Surgery congratulates Sarah Casalinova on her promotion to CRCI in the Cardiothoracic Division.

It is with great pleasure that the School of Nursing CRU welcomes Rebecca Jones as a CRCIII, effective August 3rd. Rebecca comes with many years of neonatal research experience. Rebecca will be working with Dr. Robin Dail on her Innersense baby research study and with Dr. June Cho on her Testosterone and Cortisol Levels in Infant Health and Development.

It is with great pleasure that the School of Nursing CRU welcomed Cristy Van Sant as a CRC I, effective August 10. Cristy comes to DUSON from UNC where she has spent several years recruiting through their OB/GYN research program. Cristy works with Dr. Sophia Smith on her Pillars for Life study.

DCRU would like to congratulate Catherine Foss on her new role as Assistant Research Practice Manager.

The Center for Nursing Research and Translational Science would like to welcome Emily Riggan-Stuekle to the Research Oversight and Compliance Core as a CRC. Emily has transferred to DUSON from the Duke Division of Cellular Therapy and Hematologic Malignancies. She will be working with Sophia Smith on her Pillars for Life research study and with Devon Noonan on her Tobacco use disparities/mobile phone intervention study.

The Office of Audit, Risk and Compliance is pleased to announce that Holly Benton, J.D., has joined as Director, Privacy Compliance. Holly’s addition will bolster capacity in the Privacy Program to address the increase in volume of incidents after the HITECH amendments and enable the Privacy Program to assist with the full implementation of the Research Data Security Plans and remediation of high risk data storage practices.

Partner Resources

DUHS Compliance Office Newsletter
Catch up on news from the DUHS Compliance Quarterly Newsletter.

CTSA Updates

Take a look at the most recent Duke CTSA newsletter, featuring an article about DOCR’s Rebecca Brouwer. Like what you see? Sign up to receive the newsletter twice a month.

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.