What’s New?

**Newsletter Name Update**
As you can see, we have changed the name of the newsletter from HRPP Newsletter to the Clinical Research Update. We will continue to have the same informative updates, but hope the name change more broadly reflects the content of the newsletter. If you know of anyone who would like to be added to our listserv, please encourage them to send an e-mail to docr.help@dm.duke.edu requesting that their address be a part of the distribution.

**Updated Consent Process Information**
With the recent deployment of the research component of Maestro Care and revised standards from The Joint Commission (TJC, formerly JCAHO) and the Centers for Medicare & Medicaid Services (CMS), the School of Medicine must enact a new requirement for the entry of time of consent on the signature page of research consent forms for each party signing the consent. Starting in July 2013, you began seeing a new line for time added to the signature page of the IRB’s consent templates. This entry must be completed by the subject and the study team member who is conducting the consent process at the time of his/her signature. This requirement applies only to the signature page, not to each page of the consent document. We have been advised since issuance of the first notification that TJC requires an entry of time on each signature of the consent form, not just for the study team member conducting the consent.

This new requirement became effective in July 2013, but does NOT affect consent forms that have already been approved and/or executed. IRB personnel will work with study teams for all new studies, renewals, and amendments that require revision of the consent form for other reasons, that are currently under review in the IRB to ensure that this new requirement is met before IRB approval is issued. If you are preparing a new submission, or an amendment that revises your consent forms, please incorporate this new time element into your revised documents before completing your submission. **Please do not submit an amendment solely to add this revision to your consent documents.** This will create unnecessary work for both the study team and the IRB.

The IRB plans to bring all watermarked consent templates for active studies into compliance with this new requirement either at their next renewal or at the time of submission of an
amendment that requires revision of the consent form for other reasons. In one year’s time, all active studies should be in compliance with this new requirement.

**REDCap Survey First Tuesdays**
The Duke Office of Clinical Research (DOCR) is happy to announce REDCap Survey Tuesdays. The first Tuesday of each month a DOCR RMT member will be available to provide guidance with any REDCap survey issues you may be having in an informal roundtable format. This will be a chance to ask general or specific questions concerning existing or potential project including demonstrations, if requested. The meeting will take place at DOCR (Hock Plaza, 9th Floor, Room 9047) from 11:00am-12:00pm. We look forward seeing you there. For additional information contact REDCap support at dtmiredcap@dm.duke.edu.

**Education Opportunities**

**BLS Blitz Available in November**
The American Heart Association is holding a Basic Life Support (BLS) Blitz November 18th-21st in Hock Plaza. Providers with cards that will expire soon can plan to attend the BLS Blitz training. Registration instructions and additional information about the event are available on the Duke website.

**ResearchMatch CTSA Tool Shop Webinar**
The next CTSA monthly Tool Shop webinar will be held on Friday, November 8th at 11:00am when Kathy Edson will present ResearchMatch 2.0. Kathy will discuss the ways that ResearchMatch can be used to recruit participants for research studies and reach out to individuals affected by specific medical conditions. ResearchMatch is an online tool that can help recruit participants for your study, and Duke has already had a number of researchers register and begin recruitment efforts through the program. For more information, you can visit the ResearchMatch webpage. Registration for the webinar is available online.

**Research Wednesdays**
DOCR and the Medical Center Library & Archives will be hosting the next Research Wednesdays session on November 13th when Dr. Rob Califf will present Future of Clinical Research at Duke, and on December 11th Mina Silberberg will present Community Engaged Research. Both sessions will be held from 12:00pm-1:00pm in Duke North 2001, and more information is available on the DOCR website. Please note that the November 27th Research Wednesdays session has been cancelled.

**Upcoming DOCR Trainings**
The following DOCR trainings will be held in the month of December for research staff at Duke, and registration instructions are available on the DOCR website:

1. Research Data Integrity/Data Security will be held on December 3rd and December 19th.
2. Human Subjects Research at Duke will be held on December 3\textsuperscript{rd} and December 19\textsuperscript{th}.
3. IRB Overview will be held on December 17\textsuperscript{th}.
4. Informed Consent will be held on December 10\textsuperscript{th}.
5. Study Documentation: Regulations and Best Practices will be held on December 12\textsuperscript{th}.
6. Investigator Responsibilities will be held on December 4\textsuperscript{th}.
7. Workshop: ClinicalTrials.gov Results Entry will be held on December 18\textsuperscript{th}.
8. Urine Pregnancy Screening for Research will be held on December 4\textsuperscript{th}.
9. Biobanking Research Specimens will be held on December 5\textsuperscript{th}.
10. Industry Funded Clinical Research- Process for Contracts will be held on December 9\textsuperscript{th}.

Don’t Forget!

When TSH is Not Billable to Insurances for Trial Safety Monitoring

TSH and other thyroid tests such as T3 Free and T4 Free are frequently performed to monitor for thyroid disorders as a side effect of treatment of experimental or investigational drugs. However, insurances do not cover tests performed for patients at “risk” for certain disease(s); instead, this is called screening. Screening is testing for a disease on asymptomatic patients so that early detection and treatment can be given to those who test positive. Some screening tests are paid for under a preventive services plan, but not under medical plans. To be covered under a medical plan, patients must have signs, symptoms or a personal history of a disease, condition or injury to qualify for payment of diagnostic tests. Medicare NCD policies state that they do not pay for tests and services solely because they are part of a hospital or clinical trial protocol. The “medical necessity” for ordering tests and services must be documented and substantiated based on the clinical assessment and plan of each individual patient or subject. Frequency of testing is restricted by the Medicare NCD laboratory policy for thyroid testing to twice per year for patients with diagnosed thyroid disease that is stable. The medical necessity for more frequent testing must be clearly documented and based on clinical indications. Screening tests performed on asymptomatic patients must therefore be charged to the clinical trial. Additional information about TSH is available on the DOCR website.

Providing Notice of Privacy Practices to Subjects

If your study recruits subject who are not patients, then the study team is responsible for providing these subjects a Notice of Privacy Practices (NPP) at the time of first study contact and getting the acknowledgement of receipt. Both forms are available on the DOCR website. The NPP changed on September 20, 2013, so be sure to use the most recent copy of the form. If you have current study subjects that received the old form, you will need to provide the new one to them at their next study visit. Subjects who have completed their participation do not need the revised NPP. Please update any copies of the NPP on your website to the revised version effective September 23, 2013.

Reminder about Temporary Monitor Requests
As of October 14, 2013 any temporary monitor request to access electronic medical records must be sent to the Health Information Management (HIM) office using the new online system. Users can access the new e-form system at the following link: https://redcap.dttmi.duke.edu/redcap/surveys/?s=pyuZcW. Study teams must complete ALL fields in the monitor access request database and submit to (HIM) at least 10 business days in advance of a monitor visit. The submitter will be notified by email of incomplete forms, and a new submission will be required. In the event of an FDA audit or similar type of visit, the request should be made as soon as possible and sent as high priority. More information is available on the DOCR website.

**Reminder from the IRB about Consent Forms**

When conducting research involving minors, sterilization should not be included as a method of contraception in the informed consent form. Please alter the standard language in the consent form to eliminate this option, and contact your IRB specialist if you have any questions about this update.

**Frequently Asked Questions**

**What Do I Need to Do If I Am Storing Social Security Numbers (SSNs) Temporarily (e.g., only long enough to ensure the subject is compensated)?**

If you are storing SSNs temporarily, you do not need to fill out a waiver with ISO; however, you still need to answer the SSN question as "Yes" on your RDSP since you are obtaining them, but only keeping the information long enough to make sure the subjects are compensated. The waiver is required for instances where you will keep the SSNs for long periods of time or are traveling with the information from one outside location to another.

**Does DCI Have a Definition of “Cancer-Related” Protocols?**

The Duke Cancer Institute (DCI) has a definition of a “cancer-related” protocol that specifies the scope of DCI oversight in such projects. All protocols that meet this definition must be reviewed by the Cancer Protocol Committee. Accordingly, the Cancer Protocol Committee must be selected as a specialty review committee in section 15 of the study’s eIRB submission. More information about cancer-related protocols is available on the DCI website, and questions can be sent to Irwin Liu for more details (irwin.liu@duke.edu).

**What is the Duke Biobank?**

Based in the Duke Translational Medicine Institute (DTMI), the Duke Biobank is a consortium organization made up of many of the larger biobanks at Duke. The Duke Biobank includes two institutionally-supported biobanking shared resources that offer biospecimen collection, processing and banking services: The Biospecimen Repository and Processing Core (BRPC) and the DNA Bank. The Duke Biobank is focused on strengthening and harmonizing existing biobanks, drawing from published biobanking best practices. Helena Ellis, the Director of the
Duke Biobank, is available for one-on-one consultations to review your biobanking operations and identify areas for improvement. The Duke Biobank’s informatics initiatives include The Index of Biospecimens, a simple, searchable, web-based catalog of collections at Duke that may be available for sharing, and LabVantage, a robust specimen inventory management system. More information is available on the Duke Biobank website, or you can send questions to Helena Ellis (helena.ellis@duke.edu).

**CRU Corner**

**Oncology CRU**
Congratulations to Catherine Taggart, CRC II, Cindy Downing, ARPM, Midge Silberman, RN, and Jenny Exelbier, BS, who all achieved their CCRP certifications!

**Anesthesiology CRU**
Congratulations to Peter Waweru, Roger Hall and Erlinda Yeh for earning their CCRP certifications!

To be added or removed from the newsletter distribution list, please contact the DOCR at docr.help@dm.duke.edu.