What’s New?

NIH Public Access Policy
On November 16, 2012, NIH released a notice that changes the consequences of non-compliance with the NIH Public Access Policy. Awards will not be processed for non-competing continuation grants until award recipients have demonstrated compliance with the NIH Public Access policy requiring grantees to report certain publications using a Commons-linked My NCBI account. This change will take effect in the Spring of 2013 (see NIH NOT-OD-12-142).

This topic will be the focus of a Research Wednesday presentation on December 19, 2012 from 12:00-1:00 in Markee M224. Emily Mazure from the Medical Center Library will be presenting on the policy, explaining methods for submitting manuscripts, and outlining how to use My NCBI to manage professional bibliographies to demonstrate compliance with the Policy.

CITI Module Requirements
DOCR has worked with the IRB to update the required modules for CITI training starting on January 7, 2013. A number of modules have been removed, and new modules have been added to the required Duke Medicine course. The updated course will contain eight modules, including four new modules on Vulnerable Populations (Prisoners, Pregnant Women, and Fetuses), HIPAA, and Conflict of Interest. The additional Research with Children module will only be required for those individuals working with minors. All new employees will be required to take the updated Duke Medicine course containing eight modules, and existing employees who have already taken their modules in the past will be required to take the four new modules the next time their Duke Medicine course is due for renewal. To check on the status of your CITI modules, you can login to your account at www.citiprogram.org.

New Privacy Article
The DUHS Compliance Office has posted a new privacy article to their website titled Authorization for Use and Disclosure of Protected Health Information (PHI). This article provides helpful tips on how to release PHI properly, as well as how to use the DUHS authorization form in order to disclose PHI. The article can be found by clicking here.

New FDA Draft Guidance
The US Food and Drug Administration (FDA) has posted a draft guidance document on its website concerning IRB Responsibilities. The document provides guidance on the responsibility
of the IRB to review qualifications of investigators and research sites, and the need to
determine the necessity of an IND/IDE in a clinical trial. To read the full draft document on the
FDA website, click here.

Education Opportunities

ACRP Certification
The Association of Clinical Research Professionals (ACRP) has opened applications for CCRA,
CCRC, and CPI certification exams in February and March 2013. The ACRP certifications reflect
an individual's knowledge in the field of clinical research and help professionals provide better
risk management for subjects on clinical trials. More information about the certification
opportunities can be found on the ACRP website.

ACRP Global Conference & Exhibition
The Association of Clinical Research Professionals (ACRP) has opened early bird registration for
its 2013 Global Conference that will be held April 13-16th in Orlando, Florida. The conference
will offer educational and networking opportunities, and you can save $200 by participating in
the early bird registration opportunity by December 31st. Click here for more information about
the conference.

Research Wednesdays
DOCR and the Medical Center Library will be hosting two Research Wednesday sessions in the
month of December. Nadine Barrett, Ph.D. will present on the topic of Diversity in Clinical
Research on December 12th, and Emily Mazure will present on the topic of Complying with the
NIH Public Access Policy on December 19th. Click here for more information about these events.

Don’t Forget!

Billing Grid Updates
If your study has undergone an amendment (either a protocol amendment or a contractual
amendment), do not forget that the billing grid may need to be updated as well. As part of your
ongoing study management when submitting amendments to the protocol for IRB review, you
also need to determine if any changes will affect subject billing. Once the amendment has been
approved, you can request an unlocked copy of the current billing grid from DOCR, make
changes to the grid, and resubmit the updated grid for DOCR to review. DOCR will then review
the updated grid with current protocols and consent forms and obtain grid approvals from the
study team. Please contact DOCR at docr.help@dm.duke.edu to request a copy of a grid that
needs to be updated.
Confidential Disclosure Agreements Reminder
Most companies require Duke to sign a confidential disclosure agreement, or CDA, before they will provide the necessary information for an investigator to evaluate his or her interest in participating in a particular study. Such information may include the protocol, investigator's brochure, study timelines, etc. These documents typically protect only the company's information, so Duke personnel should not provide the company any information that is confidential to Duke. Additionally, all CDAs should be between the company and Duke, not the individual investigator. Investigators should not sign the CDA on behalf of Duke. The CDA should be forwarded to the Office of Corporate Research Collaborations (OCRC), along with the company contact information, for review and signature as soon as received. For additional information regarding CDAs for clinical research projects, contact Marti Salguero in OCRC at salgu001@mc.duke.edu.

Did You Know?

Consenting Subjects across Cultures
CultureVision is a website that provides resources to study teams that are consenting subjects from another culture to participate in clinical trials. The website provides helpful information for individuals who are working with diverse cultural backgrounds in the field of clinical research. More information is available on the CultureVision website.

NIH Rules for Reporting Travel
For all Duke faculty and staff who receive payments from a Public Health Service grant (NIH, CDC, AHRQ, Dept. of Defense, etc.), new travel reporting requirements exist. If you, your spouse (or spousal equivalent), or dependent children have sponsored travel paid by someone other than Duke, you probably need to report it to Duke. The government exempts universities, medical centers, governments, and research institutes as sponsors, so travel paid by those entities does not need to be reported. In addition, anything paid through Duke does not need to be reported. But the federal government does require reporting of travel sponsored by foundations, professional societies, non-profits, and for-profit companies. Sponsored travel may be reported at the following website: https://adgapps.duhs.duke.edu/phs_travel. Questions may be directed to the Research Integrity Office at (919) 684-3121.

Updated Human Research Standards Compilation
The International Compilation of Human Research Standards is a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in 104 countries and from several international organizations. The Compilation is designed for use by IRBs, researchers, sponsors, and others. Many of the listings embed hyperlinks to the source document. Click here to view the 2013 edition.
CRU Corner

**Oncology CRU**
Congratulations to Tonya DeLargy for a successful CCRP certification!

Emily A. Privette, Clinical Research Associate II with the DCI monitoring team has successfully achieved her CCRP certification. Congratulations!

The GU Oncology research team would like to welcome Michael Goodin, Study Coordinator, back from his military service. We are tremendously appreciative of the sacrifices Mike and his family made while he served our country overseas. Mike is an integral person in our team, and we are grateful that he returned safely from active duty.

**Dermatology CRU**
Dermatology/Pathology CRU would like to welcome Jennifer Kruszewski to our group. She will be working as a Clinical Trials Assistant in the Dermatology group. We are very excited to have her join us and look forward to working with her.

**DCRU CRU**
Catherine Himo Gang, RD, Clinical Research Coordinator has successfully received her CCRC certification. Congratulations!

**Heart Center CRU**
The Heart Center Clinical Research Unit would like to welcome Stephanie Decker, RN and Tracy Norris. Stephanie is the Primary and Acute Cardiology Lead CRC III, and Tracy is a CTA I with the Heart Failure Cluster. Welcome Stephanie and Tracy!

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