What’s New?

FDA Mandated Changes in Consent Language
The U.S. Food and Drug Administration (FDA) has added new requirements for informed consent language, which applies to subjects consented to clinical trials on March 7, 2012 or later. By federal regulation, this new consent language must be incorporated verbatim and cannot be altered in any way to new studies created on or after March 1, 2012. No existing studies from before that time period need to be revised. More information about the required consent language is available by clicking here.

Research Data Security Plan (RDSP) Allows Revision
Study teams can now use the eIRB system to submit revisions to previously approved Research Data Security (RDSP) plans. Revisions follow the same review and approval process as the initial RDSP. An updated User Guide with step-by-step instructions is in the User Guides section of the eIRB Home page.

New Federal Regulations
As of August 24, 2012, new federal regulations relating to conflict of interest will be in place for individuals who receive Public Health Service funding for research (e.g. NIH, CDC, FDA). Any individual who receives and/or is paid on a PHS-funded research grant is now required to disclose all reimbursed or sponsored travel (i.e., that which is paid on behalf of the individual) taken on or after August 24, 2012 if the travel meets certain criteria. A Sponsored Travel FAQ is available online with further details about the new regulations.

Biobanking Question Added to eIRB Submission Form
As of September 30, a new question has been added to page 10.1 (Subject Procedures and Costs) of the new protocol submission form in eIRB to help identify protocols in which there is a biobanking component. This is a first step towards the implementation of a biobanking education program at Duke. The use of human biological specimens and associated data is a critical component of translational research. As with all human subjects research, there is an obligation on the part of the institution and the principal investigator to ensure that the interests of the participants are protected and that their specimens and data are stored safely and responsibly and used to their full potential, while adhering to the participants’ wishes. An objective of the Duke Biobank is to develop a resource to provide oversight of biobanking research on campus and provide guidance and education to Duke researchers. The question is the following: “Does this study involve the collection, use, tracking, banking (storage), or
distribution of human biological specimens? Yes/No” The question is required for new protocols submitted by the study team after October 1st. Study teams will be able to answer the question, or change the answer, when submitting amendments to previously approved studies.

**Contract Services Available through the DOCR**
The Duke Office of Clinical Research (DOCR) employs a group of highly skilled individuals who are trained in aspects of data and research study management and are available for hire on a short-term contract basis to provide cost effective research solutions particularly for investigator-initiated research at Duke. Benefits to using DOCR contract staff include paying only for the skills and time that you need, reduction in time spent hiring and managing research staff, as well as immediate access to experienced, service-oriented, research trained staff with broad skill sets. DOCR data managers and analyst programmers can clean data, build database solutions with audit trail components (e.g., REDCap, MS Access), mine data from the EHR through DEDUCE, design online surveys, and provide long-term data management partnering with study teams and statisticians. DOCR research coordinators can support IRB submissions, provide participant recruitment, consenting, and enrollment, conduct manual chart abstractions and research mailings, enter results, and provide long-term project management. Investigators wishing to explore use of DOCR contract services can contact Shelly Epps at 668-2349 or at shelly.epps@duke.edu for a free consultation and estimate for services.

**DOCR Satisfaction Survey Results**
During the month of August, DOCR solicited responses to our customer satisfaction survey. THANK YOU for all your responses. We received 276 responses and will use these data and your comments to improve our services over the next year. Please continue to send your feedback to DOCR.help@dm.duke.edu throughout the year. We welcome your partnership in fostering a strong research community! Please see tables below for a summary of the results.

<table>
<thead>
<tr>
<th>DOCR CONTRACT WORK</th>
<th>Cost (salary + fringe) of using DOCR (former RMT) staff</th>
<th>Ease of getting an estimate for DOCR (former RMT) support</th>
<th>Benefit to your research</th>
<th>Data integrity, compliance and security</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very dissatisfied</td>
<td>5.60%</td>
<td>5.40%</td>
<td>2.30%</td>
<td>2.60%</td>
</tr>
<tr>
<td>Somewhat dissatisfied</td>
<td>2.80%</td>
<td>0.00%</td>
<td>4.70%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Somewhat satisfied</td>
<td>8.30%</td>
<td>13.50%</td>
<td>23.30%</td>
<td>13.20%</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>83.30%</td>
<td>81.10%</td>
<td>69.80%</td>
<td>84.20%</td>
</tr>
</tbody>
</table>
## Education Opportunities

### Fall Clinical Science Day
The Fall Clinical Science Day is a celebration of clinical research at Duke University School of Medicine, and it will be held on Friday, October 19th from 11am-2:30pm. This event will feature keynote speaker James Gavin, III, M.D., Ph.D., and presentations from Duke faculty members about clinical research taking place at the School of Medicine. For more information or to register for the event, [click here](#).

### Billing Education Series
The DOCR, DUHS Compliance Office and the Patient Revenue Management Organization (PRMO) have partnered to create a four-course educational series required for all study team members who work on billing risk studies and who do billing charge reviews, billing grids, and enter subjects into eResearch. [Registration is open](#), and the schedule is shown below. Anyone not available to attend the in-person training will have the opportunity to view the course online after the event. Due to limited room capacity, the course is open on a first come, first serve basis.
- IDE Training on Tuesday, October 30th, 10:00 am – 11:30 am, presented by Chuckie Chinault and Julie McCauley
- V70.7/Grant Billing Reports Training on Tuesday November 6th, 10:00 am – 11:30 am, presented by Jan Collins and Julie McCauley
- CPOE Application Training on Monday, November 12th, 10:00 am – 11:30 am, presented by Julie McCauley
- Pre-authorizations and Grant Scheduling Training on Wednesday, December 5th, 10:00 am – 11:30 am, presented by Jane Pike and Eliana Owens

**DUSON Genomics Courses**
The Duke University School of Nursing will hold three forums on “Genomics & Personalized Medicine” in October and November. The forums will address issues surrounding the application of genomic information collected from patients at Duke among other topics. More information about the forums and a link to registration can be found by clicking here.

**Research Wednesdays**
Click here to see new learning events offered by the DOCR.

**Don’t Forget!**

**Medical Device Studies**
Medical device studies utilizing category B devices under an IDE require Centers for Medicare & Medicaid Services (CMS) approval before enrolling study subjects. PRMO facilitates this process and requires information from study teams be submitted to them on the “Notice Concerning use of and Billing for Investigational Devices” form located on the DOCR website. This form has been updated to include additional information required by CMS including the following: 1) provider name(s); 2) Medicare provider ID#s; and 3) CPT codes for which the device will be billed for the study. Early form submission to PRMO eliminates delays allowing PRMO to gather and prepare the required documentation, as well as submit the required paperwork to CMS as soon as IRB approval is received. DOCR will work with PRMO to ensure CMS approval and charge code assignment is in place before final DOCR study approval. For additional information or for questions, please contact Nancy Hassell at 684-9425 or email docr.help@dm.duke.edu.

**Reminder Regarding Ten-Digit Dialing**
Please remember to add the area code (919) in front of local telephone numbers appearing in study advertisements, consent forms, and all other study-related documents that include local telephone numbers to ensure that participants have the most updated information.
Sending a Social Security Number to a Sponsor or Data Coordinating Center
Like a name or other direct identifier, sending the social security number (SSN) to a sponsor or data coordinating center requires a scientific need stated in the protocol and a modification to the Informed Consent to state that it is being sent. Sending the SSN can put the subject at risk for identity theft (especially when combined with a name and date of birth), so additional protections are required. The Research Data Security Plan (RDSP) needs to describe how you will protect the subject while they are at Duke, and a SSN Usage Request must be filed with the Duke Medicine Information Security Office.

Did You Know?

Updates to Information Security
In recent years, Duke has seen an increasing number of attacks on its computer systems, and the Chief Information Officers have studied these concerns to look for ways to resolve the issues. As a result, the IT security offices for Duke have created policies on scanning devices within the network for vulnerabilities and asking members of the Duke community to notify their IT administrator about any compromises to the security of their computers among other measures that will help ensure the security of Duke data. More information about these policies is available on the University IT Security Office website and in the Duke University Vulnerability Management Policy.

Coverage Pre-authorization Information
Payer “coverage pre-authorization” and clinical research is an extremely complex subject. Payers can be categorized as commercial (e.g. Aetna, BCBS, Cigna, Humana, United Healthcare) or Federal Payers (e.g. Medicare, Medicaid, Tricare, Veterans Administration etc). All payers have general guidelines regarding covered benefits for research or research related healthcare, and coverage is often the exception rather than the rule. CMS/Medicare historically has had a more liberal coverage position regarding clinical research whereas commercial payers tend to be far more restrictive. FDA approval of new technology related procedures, devices and drugs does not mean that commercial and federal payers automatically consider services eligible for payment. For commercial payers specifically, if planned services are for off label use, or are involved in an ongoing study (at Duke or elsewhere), and safety and efficacy data is pending, many payers consider service(s) unproven (not an established standard of care), and therefore are considered experimental and investigational. However, depending on the planned service, the provider and/or patient has the option to approach the payer and request coverage on a case by case basis.
Applying the V70.7 Diagnosis Code
The V70.7 diagnosis code describes the “examination of a participant or control in a clinical research study”. The V70.7 code is applied to items and services that are the subject of the study including routine services. Medicare requires the V70.7 diagnosis code to attest that the routine services related to the study are covered items and services billable to Medicare as part of a qualifying trial. Billable routine services may include the infusion services for an experimental drug or the monitoring and safety tests required by the study. The V70.7 diagnosis code is applied to items and services on studies that have billing risk and require a billing grid. When applying the V70.7, research staff should review the grid for those items and services marked “I” and highlighted in yellow for insurance. The V70.7 diagnosis code should be applied to study-related items and services for all insurance payers. The PRMO Clinical Trials Billing Team will review all inpatient study related services for all payers. The PRMO also reviews inpatient charges for all subjects on Medicaid since Medicaid does not cover the routine costs directly related to a clinical trial. For outpatient charges, the study teams have the responsibility to review the weekly Clinical Trials Charge Review and Validation Report, and determine which items and services billed to insurances are related to the study and apply the V70.7 diagnosis code accordingly.

CRU Corner

Oncology CRU
Members of the Oncology CRU recently published an abstract that was presented to the Oncology Nursing Society titled “An Academic Oncology Research Team's Approach to Utilizing Oncology Nursing Skills for Success in Multi-Center Studies”. Congratulations to Christy Arrowood, Wanda Honeycutt, Anthony Amara, and Kellen Meadows who all contributed to this accomplishment!

Congratulations to Peggy Alton, RN who has been promoted to Clinical Research Coordinator III, leading the Oncology CRU BMT/ Heme Malignancy Therapy Clinical Team.

Congratulations to Beth Mancuso who has been promoted to CTA II within the Oncology CRU BMT/ Heme Malignancy Therapy team.

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