Spring 4-2014

Spring 2014

Center for Research & Grants

RESEARCH MATTERS
CENTER FOR RESEARCH & GRANTS

INTRODUCING ONCORE CLINICAL TRIALS MANAGEMENT SYSTEM

OnCore Enterprise Research

OnCore Clinical Trials Management System (CTMS) is a web-based solution for the centralized management of Clinical Research, Billing Compliance, Electronic Data Capture, Integration, Biospecimen Management and Patient Registries. OnCore will provide efficiency and transparency of clinical trials research across BHSF by streamlining research operations and administrative processes, financial management processes and system integrations. OnCore will provide a platform for BHSF that facilitates the performance of Principal Investigator (PI) Initiated studies and biobanking at the highly anticipated Miami Cancer Institute (MCI).

Implementation of OnCore is planned for the end of Q3. Baptist Cardiac & Vascular Institute and South Miami Heart Center have been invited as the first entities to go-live with OnCore. Thereafter, OnCore will gradually be rolled out to other departments across BHSF. Data conversion will occur in phases. Phase 1 of the implementation will consist of having all sponsored prospective studies that meet a defined criteria entered into OnCore. Protocols consisting of research studies that require billing to the subject or third party (e.g., Insurance) and studies registered with Clinicaltrials.gov will be entered into OnCore initially. In later phases, retrospective studies will be entered into OnCore after MCI opens.

You can also visit the OnCore SharePoint site for updates on the progress of the OnCore implementation.

Continued on page 2

2014 SPRING EDITION

In this issue: **Page:**

WELCOME SHONNA D. WALKER

We are pleased to announce that on March 11, 2014 Shonna D Walker joined the Center for Research & Grants as our Research Project Specialist. She will oversee the implementation of OnCore Clinical Trials Management System (CTMS) throughout the BHSF system. Shonna has over seven years of project management experience implementing software in the healthcare industry.

ONCORE CONTINUED...

Forte Research Systems

Forte Research Systems, Inc. is the vendor that BHSF is collaborating with to implement OnCore CTMS. Forte develops clinical and research management software and provides free educational resources for the clinical research community, one of which is Onsemble.net. Onsemble.net is an online resource comprised of a diverse community of OnCore users and stakeholders. Onsemble allows the research community to collaborate, share ideas and best practices. Members of the Onsemble community include academic institutions such as Yale University, Vanderbilt University and the University of Maryland and cancer research centers that have NCI designations such as the Moffitt Cancer Center, Stanford Cancer Institute, Georgetown Lombardi Comprehensive Cancer Center and other healthcare and research systems.

Onsemble.net hosts a wealth of knowledge and opportunity for collaboration. Please be sure to request an account to become a registered user. Thereafter, you will be able to explore the vast resources onsemble.net has to offer including: a calendar of events, current collaborations, a learning portal with training documentation and webinars, shared reports, special interest groups, the ability to join various ListServs and presentations from past conferences.

Request an account for Onsemble.net here.
For more information on Forte Research Systems, Inc. please go visit http://forteresearch.com and visit http://onsemble.net/ to learn more about Onsemble.

INTRODUCING REDCAP

REDCap (Research Electronic Data Capture) is a web-based software application created by Vanderbilt University that allows users to build and manage online surveys and databases quickly and securely. It is primarily used to facilitate research and data collection, but can by used for operational and performance improvement and activities. REDCap is currently in use at over 900 institutions in 79 countries.

Using REDCap's stream-lined process for rapidly developing projects, you may create and design projects using 1) the online method from your web browser using the Online Designer; and/or 2) the offline method by constructing a 'data dictionary' template file in Microsoft Excel, which can be later uploaded into REDCap. Both surveys and databases (or a mixture of the two) can be built using these methods. Listed below are some of REDCap's most popular features:

• **Build online surveys and databases quickly and securely** - Create and design your project rapidly using secure web authentication from your browser on your desktop computer or mobile device. No extra software is required.

• **Fast and flexible** - Conception to production-level survey/database in less than one day.

• **Export data to common data analysis packages** - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.

• **Ad Hoc Reporting** - Create custom queries for generating reports to view or download.

• **Scheduling** - Utilize a built-in project calendar and scheduling module for organizing your events and appointments.

MORE ABOUT REDCAP...

• Easily manage **a contact list of survey respondents or create a simple survey link** - Build a list of email contacts, create custom email invitations, and track who responds, or you may also create a single survey link to email out or post on a website.

• **Save your data collection instruments as a PDF to print** - Generate a PDF version of your forms and surveys for printing to collect data offline.

•**Advanced features** - Auto-validation, calculated fields, file uploading, branching/skip logic, and survey stop actions.

REDCap training is currently provided through a library of video tutorials (see website below) that walk a user through each step of the process in creating their REDCap project. REDCap is designed to be intuitive and user-friendly, requiring only basic computer skills to enter data and create projects.

The Baptist Health South Florida IT department is in the process of testing and installing REDCap. All data collected in REDCap data will be securely hosted by BHSF's IT department.

REDCap will be available for use in the near future. Stay tuned for more updates.

To learn more about REDCap and all of its features or to access the training videos, please visit www.project-redcap.org.

WHEN TO USE ONCORE AND REDCAP

	ONCORE	REDCAP
BILLING	✓	
DATA CAPTURE	✓	✓
INVOICES	✓	

BROWN BAG LUNCH & LEARN

May 2: Research HIPAA, Don Parris, PhD

12:00pm – 1:00pm BHM Classroom 5

May 28: How to Utilize the BHSF Library for your next Literature Search, Carrie Figuerido

12:00pm – 1:00pm BHM Classroom 5

REGISTRATION FOR RESEARCH TRIALS ON WWW.CLINICALTRIALS.GOV

ClinicalTrials.gov

This article offers guidance and support to researchers who must register and report clinical research trials to ClinicalTrials.gov, a database of clinical research trials conducted in the United States and around the world.

WHAT IS CLINICALTRIALS.GOV?

ClinicalTrials.gov is a registry of federally and privately supported research studies conducted in the United States and worldwide. Each entry is provided by the sponsor and includes a brief summary of the protocol together with the purpose, recruitment status, and criteria for patient participation. Trial locations and specific contact information are provided to assist enrollment. Some entries provide summary study results, including number of participants starting and completing the trial, baseline characteristics, outcome measures, and adverse events information. ClinicalTrials.gov is a free service of the U.S. National Institutes of Health (NIH), developed by the National Library of Medicine.

WHY REGISTER?

> **Required by law.** Section 801 of the Food and Drug Administration (FDA) Amendments Act mandates the registration with ClinicalTrials.gov of certain clinical trials of drugs (including biological products) and medical devices subject to FDA regulations for any disease or condition. Trials that must be registered under the **FDA Amendments Act of 2007 (FDAAA)** are called "Applicable Clinical Trials."

Under the statute, these trials generally include:

Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.

ClinicalTrials.gov accepts registration of all clinical trials (1) approved by the institutional review board (IRB) and (2) conforming to the regulations of the appropriate national health authorities. Both
Interventional and observational studies are accepted. Trials can be registered at any time, but many policies require registration prior to the enrollment of the first participant.

> **Required for journal publication.** The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition for publication of research results generated by a clinical trial. http://www.icmje.org

Investigators should go to http://prsinfo.ClinicalTrials.gov for detailed information on creating an account and also contact Jacqueline Mejias, Protocol Registration System Administrator or Dawn Prospect, Research Compliance Administrator, for assistance in registering their trial. NIH encourages registration of ALL trials whether required under the law or not, and the International Committee of Medical Journal Editors (ICMJE) advises that those who are uncertain whether their trial meets the ICMJE definition of eligible trials should consider registering if they wish to seek publication in an ICMJE journal.

Since responsibility for registering trials lies with the lead sponsor of the clinical study, most industry sponsored trials will be registered by the sponsor, which can be a pharmaceutical company or Clinical Research Organization (CRO). Investigator initiated studies need to be registered by the investigator prior to study enrollment.

NURSING HEALTH SCIENCE RESEARCH SPOTLIGHT

We are currently conducting a Neuroscience Nursing Foundation grant funded collaborative study in the critical care units at West Kendall Baptist Hospital and South Miami Hospital. This randomized controlled study is looking at the effect of nighttime use of earplugs on delirium onset and sleep perception in older critical care patients.

Early onset delirium among older patients in the intensive care unit (ICU) is a post-admission complication. This study hypothesizes that a reduction in sound during the night through the use of earplugs may be beneficial in the prevention of critical care delirium and improvement in quality of sleep in the older patient. We are utilizing a randomized controlled study design to recruit patients during the first 24 hours of their admission, who are 65 years or older, alert, awake, and orientated at time of enrollment. The experimental group is receiving standard of practice with earplugs for eight hours at night and the control group will receive only standard of practice. Data is then collected for the first three ICU days including: (1) chart review for patient specific data and Confusion Assessment Method (CAM) screening; and (2) daily sleep perception survey. This study will: (a) investigate the effect of earplugs at night in preventing delirium in older patients, (b) explore predisposing factors that may lead to hospital-acquired delirium in older patients, and (c) compare patient outcomes (ICU length of stay and medications ordered for delirium) between the experimental (earplugs at night and standard of practice) and control (standard of practice) group.

Examining and comparing the use of earplugs at night on the development of ICU delirium and the quality of sleep will make a significant impact on intensive care and neuroscience nursing care for the older patient population. The results of this study will add to the body of knowledge that explores the relation between night sleep quality and early onset of ICU delirium in older patients as well as improving the nursing care we are providing.

This study is supported through the mentorship of Tanya Cohn, MSN, MEd., RN and Shakira Henderson, MS, MPH, RNC-NIC, BCLC, Nurse Scientists from Nursing and Health Sciences Research, assisted by Clinical Research Coordinator Jacquie Mejias