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Center for Research & Grants

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The 2014 BHSF Research Summit “Utilizing the Power of Big Data to Transform Healthcare and Research”, sponsored by the Center for Research and Grants, will take place on **Friday, November 7th at the Dadeland Marriott.** The Summit will begin with breakfast and registration at 7:30 AM, followed by the official welcome and introductions at 8:30 AM. The following lectures will be presented:

**Analytics and Big Data: Accelerating Healthcare Discovery**
John Frenzel, MD, Chief Medical Information Officer, MD Anderson Cancer Center

**Data Driven Analytics for Personalized Healthcare**
Dr. Jianying Hu, Ph.D, Manager, Healthcare Analytics Research, IBM

**Using Free Large Datasets for Research to Change How We Practice Medicine**
Leonardo Tamariz, MD, MPH, Assistant Professor of Medicine, University of Miami

**Current Issues and Topics Panel Discussion moderated by Dr. Tran**

You may register for the event online at [www.baptisthealth.net/cme](http://www.baptisthealth.net/cme). Click on “Symposiums.” You may also visit the Summit website at [researchsummit.baptisthealth.net](http://researchsummit.baptisthealth.net). For registration inquiries contact the CME office at 786-596-2398. If you have any questions regarding the 2014 Research Summit, please contact CRGRResearch@baptisthealth.net

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**UPDATE: ONCORE CLINICAL TRIALS MANAGEMENT SYSTEM**

OnCore Clinical Trials Management System (CTMS) will go-live on October 20, 2014. Users can access the live production site by copying this web link (https://ddmsoncore1p/login) into their browser. In the interim, users can access https://ddmsoncore1d/login for access to OnCore. This environment can be used as a playground for users to become more proficient in OnCore prior to go-live.

End user training is scheduled to occur on Tuesday 10/7/14 and Wednesday 10/8/14 at BHM IT Training room (2nd floor). Here users will receive hands on training by a Forte senior trainer and product support specialist.

**User Resources**

There are various resources users can leverage to educate themselves and stay abreast on the latest communication regarding OnCore. While in the implementation stage, Forte Research Systems released a new version of OnCore. Baptist Health decided to leverage the new fixes, features and functionality that version 13.5 has to offer. Baptist Health OnCore SharePoint site will obtain the most current information and resources pertaining to the OnCore CTMS implementation (http://mysites.baptisthealth.net/personal/shonnaw/oncore/). A user tip sheet has been published. Users are highly encouraged to review this document to obtain tips for easy navigation in OnCore and basic rules. Also, on the SharePoint site you can find information on who to contact if you need further assistance in OnCore. OnCore application support is structured on a tier. Super users will be the end users’ first point of contact for support. Super users are subject matter experts who will help drive the creation of detailed processes and other end user documentation with the OnCore project team. Super users attended a two day in-depth training on OnCore functionality. CRG staff members Alerik Barrios, Amy K. Starosciak, Deborah H. Eyerdam, Deborah T. Suarez, Edshelee Torres, Jacqueline Mejias, Jeanee S. McJilton, Josefina Sanchez, Lara L. Roberson and Michelle Gallas are super users. Luella Reyes from SMHC is also an OnCore super user. If a super user is not able to resolve an inquiry or issue, then (s)he will escalate that concern to the OnCore project manager. All inquiries or issues that cannot be resolved internally will be escalated to a Forte product support specialist.

Onsemble is the name of a community of OnCore CTMS users facilitated by Forte Research Systems (vendor). This group represents diverse institutions and organizations such as cancer centers, medical facilities, hospitals and academic centers. Baptist Health employees must request a user account online in order to access the site. From this website you can access the learning portal, a calendar of events, blogs, listservs, profiles of Onsemble members, resources from past conferences, collaborations, product focus groups and SOPs. The learning portal hosts extensive resources such as documentation, training manuals, webinars, workflows and on-demand videos. Access Onsemble here Onsemble or at http://onensemble.net. The learning portal can be accessed here: OnCore Learning Portal or at http://docs.onsemble.net/.

The Onsemble community also offers listservs users can join. ListServs allow subscribers to send email messages in a way similar to the way distribution lists work in programs like Outlook, but they also provide a suite of centralized functions and enhanced features. The available listservs are for OnCore Coordinators, Regulatory personnel and Clinical Trials Office Administrators. Also, there are collaborations within Onsemble which include: Biospecimen Management, OnCore Financials, Enterprise Collaboration, Coverage Analysis Special Interest Group, Protocol Submission Collaboration, OnCore Application Programming Interface (API) Collaboration, Standard Operating Procedure (SOP) Collaboration, Onsemble Metrics Collaboration “Metrics & Beyond” and Onsemble Program Committee.
The 2014 Human Subject Research Community Conference was held on September 11th and 12th hosted by the Human Subjects Research Office at University of Miami. The conference served as a learning and networking opportunity for professionals involved in every facet of human research protection program.

Conference objectives: Promote best practices in human subjects research protection; Discuss how to increase process efficiencies, transparency accountability, Collaboration within our own Human Research Protection Program.

There are three Ethical Principles in Research “Respect for Persons, Beneficence, and Justice” as described in the Belmont Report (1966). Remembering the Nuremberg Code, and the Declaration of Helsinki, were subjects rights were not respected and were entered into a study with no appropriate informed consent and were exposed to many risk. This created awareness with Public Health Trust to which a policy was enforced to protect the rights and welfare of human subjects and the “Institutional Review Board (IRB)” committee was started and the public health trust policy created a rule that prior institutional review to protect the rights and welfare of human subjects, to assure appropriate method of informed consent, determine risk and benefits must be given. IRB has authority to approve and disapprove any research that is not in compliance with the regulations (45 CFR 46.116; 21 CFR 50.25). Informed Consent is Voluntary and subjects have every right to be informed!

Written documentation of informed consent process should include all required elements. (45 CFR 46.116; 21 CFR 50.25) study involves research; purpose of the study; duration of participation; procedures to be followed; procedures which are experimental; foreseeable risk and discomforts; reasonably expected benefits; alternative procedures, confidentiality of identifying records, (and possibility of FDA inspection of records). For research involving greater than the minimal risk: compensation/treatment, if any, for research related injury. Informed consent should include who to contact for questions and answers about the research, research-related injury, subjects’ rights, voluntary participation, refusal without loss of benefits, subjects may withdraw at any time.

What to consider with-in compliance when monitoring Investigator- Initiated IND/IDE Trials?

What is Monitoring? The act of overseeing the progress of a clinical trial, and ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures and good clinical practice (GCP) and the applicable regulatory requirements (E6 ICH- GCP 1.38). A monitor will verify that the rights and well being of the human subjects is protected that the trial data are accurate, complete and verifiable from source documents. A monitor will check that the trial is in compliance with the currently approved protocol version. The data collected will be used in analysis to move forward to other phases of a study.

Protecting Research Participants is a shared responsibility by the research staff, investigator, coordinators, irb, and compliance staff. Together we can strengthen and promote best practice in human subjects research protection if we follow the regulations….

**2014 HUMAN SUBJECT RESEARCH COMMUNITY CONFERENCE**

DID YOU KNOW?

- The Miami Cancer Institute:
  - Is a $430 million dollar cancer facility opening in July 2016
  - The first proton therapy center in South Florida
  - Is a 395,000-square-foot cancer institute that will include a 305,000-square-foot clinical cancer center and a 90,000-square-foot research facility
Professionals of all kinds use journal clubs to keep up with current topics and research in their fields, but the busy, round-the-clock schedules of hospital employees make getting together for discussion group meetings a challenge. The Library’s solution is to offer virtual journal clubs, a place to meet and share ideas, 24 hours a day at your own computer.

Like traditional in-person journal clubs, the members of these virtual journal clubs choose a recent research article on a topic that relates to their work – intensive care, emergency, bioethics – read it at their convenience, and have a critical discussion, sharing their thoughts and experiences on the topic, and then take what they’ve learned from each other back to their practice. With the library’s journal clubs, members get an email when there is a new discussion that has a link to a pdf copy of the article, and a link to an online discussion board where they can share their thoughts. Members also get emails with each others comments.

While the first recorded journal club in North America was started at McGill University Medical School in 1875 by Sir William Osler, the first virtual journal club at Baptist Health South Florida was started by Devica Samsundar, Director of Library & Information Services, and Fatima Garcia, RN from the West Kendall Baptist Hospital Intensive Care Unit, in June of 2012, with a discussion on shared governance and evidence based practice. Baptist Health’s experiences with its journal clubs has been presented at poster sessions at the Pan American Nursing Research Colloquium and The American Nurses Association Annual Nursing Quality Conference by Ms Garcia and Tanya Cohn, Nurse Scientist at West Kendal Baptist Hospital, and in an article in the Journal of the Medical Library Association by Ms Samsundar and John Reynolds, Medical Librarian at the Medical Library.

Over the past three years, more than thirty different groups have taken advantage of the journal club service, over a dozen have had held discussion in the past few months, with several new groups starting this fall. The journal clubs have been used to support Magnet goals, such as dissemination of research, and nurses as teachers, and Avatar goals such as improving communication and educational opportunities. Various discussions have been used to start or supplement research projects, get feedback and ideas for nursing advancement and performance improvement projects, and earning nursing continuing education credit in a pilot project at Homestead Hospital, as well as simply contributing to the sharing of knowledge among professionals. Some recent examples include promoting skin-to-skin contact for newborns on International Kangaroo Care Awareness Day by the SMH NICU, adding to a research and pilot project on televisitation for ICU patients by the WKBH ICU, and new evidence on the use of therapeutic hypothermia by the Critical Care Best Practices Forum.

THE LIFE CYCLE OF A RESEARCH STUDY (PART 6 OF 6)

STUDY RESULTS: DATA ANALYSIS TO PUBLICATION

Objectives:
Learn how to improve your chance of successful publication by ensuring rigorous data analysis, appropriate interpretation of quantitative results, and manuscript preparation consistent with peer-reviewed journal standards.

Speakers:
Emir Veledar, PhD
Biostatistician

Date/Time/Location;
October 9, 2014
12:00 pm - 1:00 pm
BHM Classroom 5

Register:
On BHU or CME
Patients who seek treatment at a BHSF facility have a right to keep their health information private. As members of the BHSF workforce, Clinical Research Coordinators (CRCs) are entrusted with this information in order to carry out duties related to their assigned clinical studies. To ensure CRCs understand their roles and responsibilities in maintaining the privacy and confidentiality of the patient data entrusted to them, the following BHSF HIPAA Privacy Education must be completed:

- Watching the BHSF HIPAA Privacy Educational videos located on the BHSF Internet - HIPAA Privacy Page; and
- Reading, completing and signing the “Safeguards for CRCs with Access to BHSF Protected Health Information” form shown below.