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Research Matters

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Center for Research & Grants

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# RESEARCH MATTERS

## Center for Research & Grants

### Welcome...

This is the first edition of **Research Matters**, a quarterly e-newsletter brought to you by the Center for Research & Grants. For those who are not aware of the resources the Center provides to the Baptist Health South Florida community, we have included a list of our services on the last page of this newsletter. **Research Matters** is intended to be an educational tool to: A) Provide information about industry trends, standards and guidelines that could impact how we conduct research at Baptist Health South Florida (BHSF), B) Disseminate information about BHSF research initiatives and policies throughout the system, and C) Inform researchers, and those who *want to do* research, about the resources BHSF has available. Each edition will provide regular features covering Industry News Updates, Research Compliance, Grants Updates, Library Services, a quarterly Education Calendar and more. We welcome volunteer guest columnists as well as suggestions for research topics that you would like to hear about. For example, if you would like to write an editorial about the Sunshine Act and how it might impact doing research at BHSF, we would like to hear from you. Please send Debbie Eyerdam ([deborahay@baptisthealth.net](mailto:deborahay@baptisthealth.net)) or Jossy Sanchez ([josefinasa@baptisthealth.net](mailto:josefinasa@baptisthealth.net)) your questions, comments and suggestions. We look forward to working together on **Research Matters**.



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## Library Services

Looking for literature to support your research project? Any Baptist Health staff member may use library resources for the improvement of quality of care of patients. Library services support patient care, evidence based practice,

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electronically by e-mail, fax, photocopy or mail ; access to core reference and journal collection; circulation and interlibrary loan of books, and DVDS for ongoing learning; electronic access to OVID MEDLINE and other databases and

## Cont'd Library Services...

e-textbooks and e-journals (from offices and home, after library hours, using the ATHENS portal); and educating library users regarding effective searching for evidence based resources, relative to the provision of excellent health care to patients.



South Miami Hospital,  
Victor Clark Building



Baptist Hospital,  
3 South



Doctors Hospital  
3<sup>rd</sup> floor (by elevator A)



Internet/Intranet

**For more information: [library@baptisthealth.net](mailto:library@baptisthealth.net); 786-308-3344**



Allison Bivin



David Puente



Karen Holmes

## The Grants Team

Wish you had access to funding to help support your program or research project but don't know where to turn to for help? Look no further, Baptist Health has a team of dedicated professionals to help you apply for grant funding. The Grants Team is here for you and will help you every step of the way in the pre- and post-award process. Serving the Baptist Health system and its employees, our subject matter experts have the experience to assist you in developing your research or program initiative, look for appropriate federal, state, local or foundation funding, guide you through the application process, compose and edit your proposal, build your budget, create an advisory board and timeline for your project, assist you in managing the award once awarded and much more!

To learn about our wrap-around services or if you are ready to make a difference at Baptist Health and take the lead on a research or program launch, please email us at [grantsinfo@baptisthealth.net](mailto:grantsinfo@baptisthealth.net).

## EDC and EMR leading to increased remote monitoring – are we ready?

By Jacqueline Mejias, BS, LPN, CCRC, CCRP

The use of Electronic Medical Records (EMR) by sites and Electronic Data Capture (EDC) by sponsors will inevitably lead to increased remote monitoring instead of, or in addition to, the traditional on site monitoring visits. In August 2011 the FDA issued a guidance titled "Guidance for Industry Oversight of Clinical Trial Investigations- A Risk Based Approach to Monitoring" in which it details the different monitoring methods that can be used while maintaining human subject protection and quality of clinical trial data as a top priority. (Walker, 2011)

The previous FDA guidance on monitoring issued January

1988 stated "the most effective way to monitor a trial was to maintain personal contact between the monitor and the investigator throughout the clinical investigation." (FDA, 2011) The new guidance is in keeping with the technological advances and changes in communication. Email, webcasts, and online training modules are commonplace and already a large part of sites communicating with sponsors. Remote monitoring would be an extension of that communication.

It has been my experience that currently sponsors utilize a combination of on site and remote monitoring depending on complexity of clinical trial, data analysis deadlines, staff knowledge and experience. The first visit is usually done in person and if the monitor feels the site knows what they are doing then subsequent visits may be done remotely. Changes in staff, protocol amendments, or lack of

enrollment may require on site visits.

The staff site will need to keep in mind the potential cost of remote monitoring. The initial study agreement needs to clearly define what will be expected of monitors, coordinators and the Principal Investigator (PI) to make sure budget reflects the hours allocated for monitoring or a mechanism for invoicing. It is not uncommon for a coordinator to dedicate extensive hours completing EDC forms and then be asked for additional information via phone, email or data queries within EDC system as preparation for a monitoring visit - remote or on site.

The guidance documents issued by the FDA are the current thinking on the topic and provide suggestions or recommendations but not legally enforceable responsibilities or

requirements.

It is clear that “no single approach to monitoring is appropriate or necessary for every clinical trial.” (FDA, 2011) It is important to keep in mind that changes in technology will have an impact on clinical trials overall not just with monitoring. At the site level, being open to interactions whether it is via email, online chat, phone or in person will allow for a successful trial.

### **Bibliography**

FDA, U. D. (2011, August). Retrieved from FDA.GOV : <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

Walker, E. P. (2011, September 02). *FDA says Industry Should Monitor Trials Remotely*. Retrieved from Med Page Today : <http://www.medpagetoday.com/PublicHealthPolicy/ClinicalTrials/28344>

## **Is Social Networking a Medical Breakthrough or a Media Disaster?**

By Ivette De Pool, B.A.

Having jumped from 50 million users in 2007 to 800 million in 2011, Facebook™ is now the largest social networking site in the world, according to company figures. With a quick click of the mouse and its vast array of services, users are able to connect within seconds. Facebook™ has the ability to keep users on its site for hours every day by providing features such as music streaming, advertising, delivery of the latest news and more. The evidence is clear, in less than a decade, this spaghetti digital connection has ballooned into a giant corporate social web, encouraging users to find new ways to communicate and share information.

Medical professionals are not exempt from using this technology for the betterment or detriment of their careers. Doctors, nurses and researchers alike often consider social media as a way to exhibit their knowledge and educate those who are interested. Therefore, social networking can be beneficial for patients. Networking allows patients to share personal experiences and learn about treatment options based on similar illnesses and experiences. Also, networking can empower patients to take control of their health care decisions. An informed patient, leads to a rise in patient/provider relations, which in turn leads to healthier individuals overall. “Fifty-seven percent of Americans surf the web for health-related information”, reports The Pew Research Center in Washington, D.C.

Moreover, pharmaceutical companies are also learning fairly quickly that networking has become a sure fire way to recruit participants for clinical trials. Recruitment is one of the biggest obstacles that pharmaceutical companies face when initiating a study. The issue is that they are never able to reach certain demographics. Social networking is able to open the door to specific groups and allow participant quotas to be met in a timely manner. Scott Connor, VP of Marketing for Acu-

rian, a clinical trial patient recruitment and retention provider explains, “The Facebook™ ad network can display a clinical trial message to those Facebook™ users that you only want to target, say, women aged 40-54 for your female incontinent study and then you can narrow it further to only those women who live within 25 miles of your active clinical trial site.”

The downside that stems from networking sites is that of privacy. How much of it do we have, or not? Keep in mind that once something is posted online, it never goes away. Ryan Greysen, M.D., M. A, Clinical Scholar of the Robert Wood Johnson Foundation reiterates that, “physicians may not consider the potential impact of their online content on their patients and the public. A momentary lapse in judgment by an individual physician to create unprofessional content online can reflect poorly on the entire profession.” HIPAA Privacy Rule protects the patient’s health information, which is, “all individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper or oral.” 45C.F.R 160.103.



Networking sites are designed for just that, to network. When using or posting something on a social networking site, take a moment and think. Would this be considered a HIPAA violation? Take precaution and be responsible for the use of social media because it can be a blessing if used properly, and a detriment if not. Remember, if you would not say it in an elevator, you certainly should not post it online.

## What the Final Rule on FCOI in Research Means to BHSF investigators and Research Staff

By Ofer Amit, MSEM, CHRC, Research Compliance Administrator

The Department of Health and Human Services (HHS) has announced a Final Rule that lays out Public Health Service (PHS) requirements relating to Individual Financial Conflict of Interest (FCOI) in research. Although the existing rule and the Final Rule are similar, the Final Rule includes new provisions and changes to existing requirements. Among the changes, are a revised definition of the term Significant Financial Interest (SFI), the addition of training requirements, expansion of the scope of required disclosures, and the inclusion of specific reporting and public disclosure requirements. Compliance with the Rule is required by August 24, 2012.

Research institutions, sponsors, and governing bodies are aware of the ethical concerns that financial interests of investigators and key research personnel can bring to bear. Most are cognizant of the effect conflicting financial interests for researchers (whether real or perceived) could have on the value, integrity and reputation of their research programs. To this end, the Food and Drug Administration (FDA) lays out its own criteria for the disclosure of financial interests of Clinical Investigators conducting a Covered Clinical Study. The Common Rule prohibits participation of Institutional Review Board (IRB) members in initial or continuing review of projects in which they have conflicting interests. Similarly, the Final Rule, entitled “Promoting Objectivity in Research”, sets up the expectation that, following its implementation, “...the design, conduct, and reporting of research...will be free from bias resulting from Investigator financial conflicts of interest.”

PHS is an office within the Department of Health and Human Services (HHS) that houses a number of HHS offices and agencies including, for example, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). One of the key elements of the Final Rule, which applies to all PHS funding recipients, is the redefinition of the threshold for Significant Financial Interest (SFI). The Final Rule distinguishes between financial interests in publicly traded entities and those in non-publicly traded entities. It considers an amount in excess of \$5,000 received from a publicly traded entity, when aggregated over the 12 month period preceding a disclosure, for any remuneration for services and equity interests, an SFI. Consider a scenario in which an investigator is holding shares of Boston Scientific - a public company that makes less-invasive medical devices – and is speaking at a variety of com-

pany events. Over the 12 months prior to a disclosure, he or she received from Boston Scientific \$3,000 in honoraria and \$3,000 in dividends due to his or her holdings. In this case, the aggregate amount of his or her remunerations from Boston Scientific exceeds \$5,000 thus constituting an SFI.

The Final Rule is more stringent regarding equity interest (e.g., stock, stock option, or other ownership interest) in a non-publicly traded entity and deems any holding of such interest SFI. For example, if an investigator is among a limited number of investors holding shares in a startup company, this holding, regardless of size, is considered SFI. Although not dubbed SFI, the Final Rule also requires disclosure of any reimbursed or sponsored travel.

Additionally, the Final Rule mandates that Investigators complete training on SFI. The Final Rule is not specific on the training's content, delivery method or documentation. It places however the responsibility for obtaining such training with the investigator and requires completion prior to engaging in research related to a PHS-funded award and at least every four years.

Further, the Final Rule expands the investigator's disclosure requirements. In doing so defines the term “investigator's institutional responsibilities” as “Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest.” The Final Rule thus means that everything and anything the investigator does as part of his or her relationship with the institution could, and probably should, be considered for disclosure purposes.

The requirements for reporting and public disclosure are expanded as well. Prior to expenditure of PHS research funds, the institution must report to the funding agency any SFI of study's Investigator(s) it found conflicting. Prior to spending PHS research funds and at any point thereafter, the institution must allow public access to study investigators' SFI disclosures that 1) constitute FCOI, 2) are related to the specific study, and 3) pertain to interests held by the Investigator at the time of disclosure.

Continue ...

## Announcements

### 2<sup>nd</sup> Annual BHSF Research Pre-Conference:

April 5, 2012  
 BHM Auditorium  
 Registration & Dinner:  
 4-5pm  
 Workshop: 5:00 – 8:00pm

**“Publishing in Scientific Journals”**, a three hour workshop present by Thomas A. Lang, the former manager of medical editing services for Cleveland Clinic Foundation and author of *How to Write, Publish, & Present in the Health Sciences: A Guide For Clinicians & Laboratory Researchers*

### 7<sup>th</sup> Annual BHSF Research Conference

April 6, 2012  
 Kovens Conference Center  
 (FIU North Campus)  
 7:30am – 3:30pm

**“A Step Forward: Moving Research to the Bedside”** by Keynote speaker, Bradi Granger, RN, BSN, MSN, PhD

### First of a New Series “Investigator’s Exchange”

May 23, 2012  
 BHM Auditorium  
 7:30 – 8:30am

**“Under-treatment of Osteoporosis and What Can Be Done about It”** presented by Gary M. Kiebzak, PhD, Clinical Research Administrator. This is the first of a series in which BHSF researchers will share their research findings with clinicians for the purpose of improving patient care and implementing best practices. We invite BHSF Investigators from all disciplines to present and use this as a preparatory forum for speaking engagements.



## EDUCATIONAL EVENTS

| Date & Time                             | Event   | Location                                   |
|---|---|--|
| Thursday, 3/8/12<br>6:00 pm - 7:00 pm   | Protocol Design: The Good , the Bad and the Ugly                              | BHM Auditorium                             |
| Friday, 3/9/12<br>11:00 am - 12:30 pm   | STATISTICS: The Basics  | HH - Pineapple Room                        |
| Monday, 3/12/12<br>12:00 pm - 1:30 pm   | Certification: Navigating the Application Process & Exam                      | BHM - Classroom 5                          |
| Wednesday, 3/14/12<br>8:00 am - 9:00 am | WKBH Nursing & Allied Health Research Rounds                                  | WKBH - Classroom 4 & 5                     |
| Friday, 3/16/12<br>8:00 am - 9:00 am    | BHM Nursing & Allied Health Research Rounds                                   | BHM - Classroom 2                          |
| Thursday, 4/19/12<br>12:00 pm - 1:30 pm | Learning to Communicate in Multidisciplinary Teams                            | BHM - Classroom 5                          |
| Friday, 4/27/12<br>7:30 am - 9:00 am    | Research Compliance: The Top 10 Things you Need to Know but are Afraid to Ask | BHM - Classroom 5                          |
| Tuesday, 5/15/12<br>12:00 pm - 1:30 pm  | NTF vs. Correction Action Plan  | Town & Country Corp Bldg - Conference Rm 2 |

## Cont'd . . . . Final Rule on FCOI in Research

This article discusses only select provisions in 42 CFR 50, Subpart F, Promoting Objectivity in Research and in 45 CFR 94, Responsible Prospective Contractors. The Center for Research and Grants (CR&G), in collaboration with additional BHSF resources, is currently updating BHSF policies in light of the Final Rule. As a BHSF Investigator or research team member, you can do the following:

- Inventory all financial relationships you have in connection with your responsibilities at BHSF. Include financial relationships that your family members have since, for Final Rule purposes, their financial interests may be considered yours.
- Inquire about training on SFI. BHSF provides training on its policy on FCOI in research. The training on SFI referenced in this piece is required separately and in

addition to BHSF’s training on its policy.

- Make yourself available to training on BHSF policy on FCOI in research when it is offered.
- When requested to make an SFI disclosure to BHSF, do so promptly and fully.
- Work closely with BHSF personnel responsible for receiving and vetting SFI disclosures. They can provide guidance on this topic and help you throughout the process.
- If you need additional guidance, contact your research lead or Research Compliance [ResearchCompliance@baptisthealth.net](mailto:ResearchCompliance@baptisthealth.net) 786-594-6709.

**Baptist Health South Florida**  
**Center for Research & Grants Fact Sheet**  
 Susan Golembeski, PhD; RN, CHRC - Assistant Vice President

**Research Administration:** Jean McJilton (786) 594-6704 or [ResearchAdmin@baptisthealth.net](mailto:ResearchAdmin@baptisthealth.net)

Research Administration assists with budget preparation and pricing, contract negotiation, Medicare Coverage Analysis, Humanitarian Use Devices (HUD/HDE) and any other research administrative issue.

**Clinical Trials Operations:** Michelle Kirgan (786) 594-6701 or [Mkirgan@baptisthealth.net](mailto:Mkirgan@baptisthealth.net)

Clinical Trials Operations provides employed physicians with clinical research assistance and coordinator support which includes but is not limited to protocol development, Institutional Review Board (IRB) submission, and regulatory guidance. Clinical Trials Operations also provides research support to Florida International University Medical Students.

**Nursing & Allied Health Research**

For more information on how to get started on a research project or learn more about research, evidence-based practice, the Institutional Review Board process, and statistics, please contact your Research Specialist.

|  |                    |  |
|--|--------------------|--|
| <b>Baptist Hospital</b>                  | Eve Butler         | <a href="mailto:Eveb@baptisthealth.net">Eveb@baptisthealth.net</a>         |
| <b>Baptist Children’s Hospital</b>       | Andrea Prentiss    | <a href="mailto:Andreap@baptisthealth.net">Andreap@baptisthealth.net</a>   |
| <b>Doctors Hospital</b>                  | Carolyn Lindgren   | <a href="mailto:Carolynl@baptisthealth.net">Carolynl@baptisthealth.net</a> |
| <b>Homestead &amp; Mariners Hospital</b> | Maria Ojeda        | <a href="mailto:Mariao@baptisthealth.net">Mariao@baptisthealth.net</a>     |
| <b>South Miami Hospital</b>              | Shakira Henderson  | <a href="mailto:Shakirah@baptisthealth.net">Shakirah@baptisthealth.net</a> |
| <b>West Kendall Baptist Hospital</b>     | Tanya Judkins-Cohn | <a href="mailto:Tanyaco@baptisthealth.net">Tanyaco@baptisthealth.net</a>   |

**Research Fellowship Program:** Tiffany Llera-Lora (786) 594-6714 or [Tiffanyll@baptisthealth.net](mailto:Tiffanyll@baptisthealth.net)

The (EBP) Fellowship Program guides our healthcare professionals to identify clinical problems and seek the best evidence to support changes in practice that can be facilitated by nursing and allied health. This program is designed to assist these individuals in improving the quality of patient care they deliver through the learning and utilization of evidence-based principles at the bedside.

**Library Services:** (786) 662.8219 or [Library@baptisthealth.net](mailto:Library@baptisthealth.net)

Any Baptist Health staff member may use library resources for the improvement of quality of care of patients. Library services support patient care, continuing education, research, publications and health care management.

**Grants Division:** (786) 594-6701 or [Grantsinfo@baptisthealth.net](mailto:Grantsinfo@baptisthealth.net)

The Grants Division supports all aspects of the pre-award and post-award processes. In the Pre-Award Process we will help you to navigate through the development of an application for government and research funding. The Post-Award process focuses on contractual compliance of your government and research award.

**Research Compliance:** Ofer Amit (786) 594-6709 or [Ofera@baptisthealth.net](mailto:Ofera@baptisthealth.net)

Research Compliance provides Baptist Health investigators and research teams with guidance, training, and oversight necessary to comply with international, federal and state regulations and Baptist Health policies that govern research.

**TCC Moffitt:** Lisa C. Trebbi (786) 594-6705 or [Lisat@baptisthealth.net](mailto:Lisat@baptisthealth.net)

Baptist Health has partnered with Tampa-based H. Lee Moffitt Cancer Center & Research Institute in a research study, called Total Cancer Care™ that may lead to individualized treatments for specific types of cancer. Baptist Health joins the ranks of a select number of American healthcare institutions that have been chosen to participate in this landmark study. Baptist Hospital, South Miami Hospital, and Doctors Hospital are the hospitals participating at this time.

**Outcomes Research:** Don Parris (786)594-6715 or [Donp@baptisthealth.net](mailto:Donp@baptisthealth.net)

Investigators interested in conducting outcomes research can receive assistance in the areas of study design, research methodology, protocol development, manuscript writing, data management and statistical analysis.

For more information visit us at <http://intranet.bhssf.org/en/nursing/crg/Pages/default.aspx>