Banner Health Research Institute

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Changing the Approach—Research and Nursing

Author: Sydney Schilcher, Research Director, Banner Thunderbird Medical Center

Evidence based medicine is one of several bases of clinical practice. Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients [(1)]. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.

Judy Crook, RN, MSN
Clinical Nurse Specialist

Professional Practice at Banner Thunderbird Medical Center has had a long standing leader in Clinical Nurse Specialist Judy Crook, who challenges the normative approach and pushes to develop evidence based medicine programs in the hospital, and to collaboratively expand those programs system wide. Judy has been promoting methods that change the approach in bedside care amongst her peers and colleagues for 13 years, by following the evidence based medicine practice model: asking the tough clinical questions, finding the best evidence, critiquing the evidence, applying the evidence, and evaluating the changes. She has been involved in using evidence based medicine to develop multiple facility-based and system level programs, including critical rescue, hematoma research, and pain management in nursing.

Upcoming programs in evidence based medicine for Judy involve administrative efficiency research projects, partnering with researchers from academic centers from University of Chicago examining structural holes, partnering with researchers from Arizona State University to investigate workstation ergonomics and efficiency, and designing systematic investigations to examine RN to RN handoff, with principal goals of all projects to examine how physical and social communication structures impact and enhance individual patient care and safety. Judy Crook and Banner Thunderbird Medical Center in collaborative partnerships *(continued on page 5)*

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Publication and the Research Contract

Author: Jeremy Stoloff, Research Attorney, Banner Health Research Institute

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An investigator's ability to publish research results begins with the Research Contract.

If the Research Contract does not contain a publication section which gives the investigator publication rights, then no such rights will exist and the investigator will not be able to publish results.

The publication of research results has become an area of controversy and concern. The suppression of negative research results has always been frowned upon in the academic healthcare and university setting; however, it is now clear that the general public considers such secrecy unacceptable. In order for investigators to assure their ability to publish research results is not curbed or eliminated an investigator must consider the language of the Research Contract.

An investigator's ability to publish research results begins with the Research Contract. There are generally three methods used in a Research Contract which lead to the suppression of publication: (1) the absence of permission to publish, (2) a sponsor's ability to remove "confidential information," which includes study data, and (3) a sponsor's ability to delay the publication for months or even years.

Absence of permission to publish. Research Contracts often contain significant confidentiality protection for the research sponsor. It is common for the sponsor to assert ownership and control of all study protocol documentation, written instructions, case report forms and the study results themselves. The investigator will then agree to use all such materials and study results only for the conduct of the study and will not disclose such materials and results to any other person or organization. If the Research Contract does not contain a publication section which gives the investigator publication rights, then no such rights will exist and the investigator will not be able to publish results.

Sponsor's ability to remove "confidential information." In almost every research contract which allows for investigator publication the sponsor will retain the right to remove "confidential information" prior to the publication's submission and release. The danger here is the definition of "confidential information" in the Research Contract. If the definition is too broad, such as to include all study results, the investigator may find him/herself unable to write a meaningful article on the research. Furthermore, many journals will not be interested in research articles without the supporting data. The sponsor's ability to remove information from the article may effectively serve as a bar to publication.

Sponsor's ability to delay publication. In most Research Contracts which contain a publication section, the sponsor will outline a period of time for which they can review the article to decide if it contains information which may require patent or copyright protection. Additionally, for multi-site studies, the sponsor may insist that all sites first complete the study and the sponsor is given an opportunity to write the first publication, prior to any investigator-initiated publications. In both instances, the investigator may be required to stall their publication for months or even years. Many investigators would find this delay too burdensome and will forgo the opportunity to publish an article.

The publication of study results is an integral part of the conduct of ethical research. Additionally, investigators may discover interesting and unexpected information in the course of a research study and wish to share this information with their fellow professionals. Investigators are encouraged to review the Research Contract to see if the publication rights and restrictions are consistent with their intent.

Coordinating the Clinical Trial Pieces

 AIS, (2006) *Report on Research Compliance*, Volume 3, Number 1, page 4.

"...medical community needs to take a new approach to how they manage compliance with the clinical billing rules."

The Rush University Medical Center settlement is the first to emerge in the complex area of billing Medicare for "routine services" provided to beneficiaries enrolled in clinical trials. In Rush's press release, Dr. Cynthia Boyd, associate vice president and chief compliance officer, said, "In the course of working through this issue, we realized that the academic medical community needs to take a new approach to how they manage compliance with the clinical trials billing rules."

Many facilities have a decentralized structure, which does not lend itself to the synchronization necessary to coordinate the various parties and requirements involved in clinical trials, such as the Medicare rules, the compensation arrangements with the sponsors, and the financial discussion in the patient's informed consent.

Rush, as part of its corrective actions, has established a new office, the Research & Clinical Trials Administration Office. This office will coordinate the operational efforts and will establish a financial analysis and compliance process to determine whether a research-related procedure qualifies for Medicare billing. If it does, the office will communicate these determinations to the billing information systems. (Rush's press release is posted at www.rush.edu/webapps/MEDREL/servlet/NewsRelease?id=716.)

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Banner Health Research Institute

Our Values

We Value:

People, Subjects, Investigators, Sponsors, and Collaborative Partners… *by treating them with respect, beneficence and justice.*

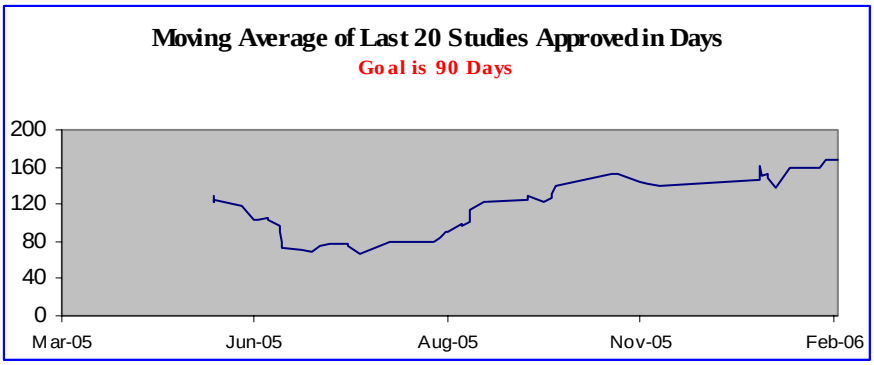
Excellence… *by assuring human subject protection and research compliance, and striving for the highest quality customer service.*

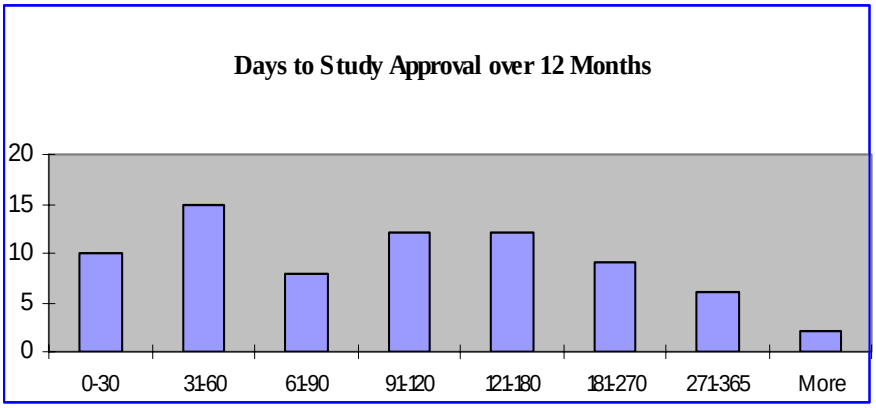
Results… *by contributing to the advancement of medical science and the improvement of patient care.*

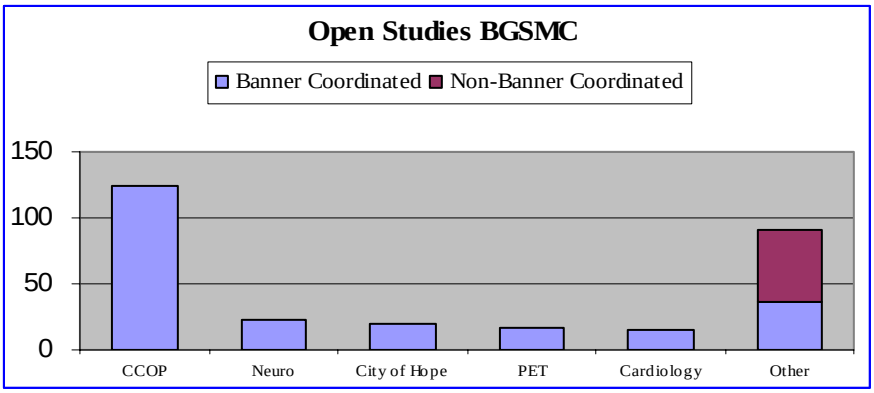
Dashboard Reports (for the period ending February 28, 2006)

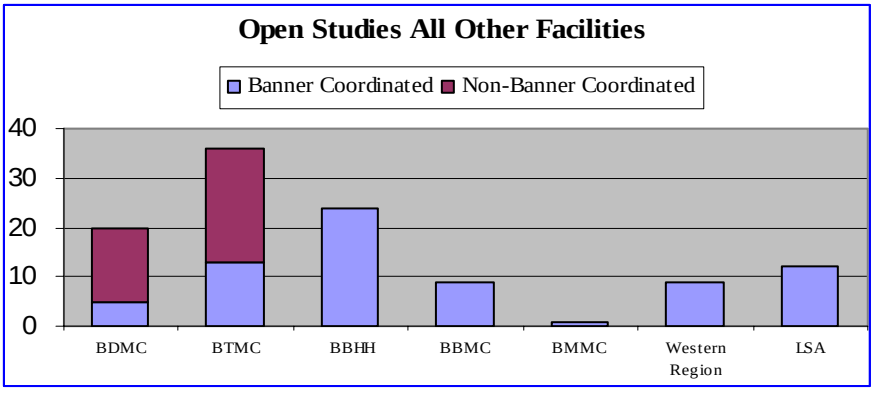
Data provided by Eric McVicker, Sr. Financial Analyst for Banner Health Research Institute

Current Month | Prior Month | YTD Avg









GateWay Community College — Clinical Research Coordinator Program

Author: Heidi E. Terry, System Manager, Clinical Operations, Banner Health Research Institute

Heidi Terry, MN, RN, CCRP
System Manager, Clinical Operations

Along with the rapid growth of clinical research opportunities, the demand for highly educated healthcare personnel to manage and implement human subject clinical trials is far reaching. Research team members, especially clinical research coordinators (CRC) can make or break a clinical trial. Food and Drug Administration (FDA) and Sponsor audits reveal that the need for highly trained CRC's will increase dramatically as the biomedical research industry goes global and becomes more specialized and regulated. One way of bridging the gap in expertise and knowledge comes in the form of the 16 credit certificate program at GateWay Community College (GWCC). The GWCC CRC series of classes is one of only two community college programs in the United States. The GWCC CRC Program has been adopted by Mayo Clinic in Rochester, New York as their curricula of choice for the education of their CRC's. The program offers both a 16 credit, four course certificate of completion, as well as a new Associate of Applied Science for Clinical Research Degree option. All courses are offered weekly as an evening hybrid (using the Black-Board internet platform to supplement classroom) or total distance education via the Internet. Program highlights include the responsible conduct of research, ethics, regulations, and the daily operations, tasks, functions, and responsibilities of research personnel. Upon graduation, students can manage human subject clinical trials, including the development of budgets, contracts and marketing plans. Students are able to assess study design logistics, control all trial data, and perform self audits for good clinical research practices. The GWCC CRC Program prepares students to sit for national certification exams offered by either the Society of Clinical Research Associates (SoCRA) or the Association of Clinical Research Professionals (ACRP). For more information, log onto www.gatewaycc.edu or contact Linda Mottle, Program Director, at 602-286-8488.

Coordinating the Clinical Trials Pieces *(continued from page 3)*:

To monitor the clinical trial area for compliance with the Medicare rules, three points must be kept in mind, says Rush's attorney, Ryan Meade, of Meade & Roach, LLP, Chicago: (1)compensation arrangements in the sponsor-ship contract; (2) the protocol's schedule of events to determine what items and services qualify as routine costs (e.g., the first and last MRIs may be billable to Medicare, but the second and third are paid by the trial sponsor); and (3) the financial disclosure language of the informed consent. "If any one of the pieces is not coordinated with the other, there is a risk the provider could be out of compliance...and receiving overpayments when it bills for Medicare services." Meade made these comments in a December interview with *A Report on Medicare Compliance.*

Research and Nursing *(continued from page 1)*:

with academia and system colleagues will continue to change the approach to individual patient care, providing new knowledge for others to utilize.

1. David Sackett, et al. "Evidence Based Medicine: What It Is and What It Isn't," *BMJ* 312, no.7023 (1996).

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Cardiology Research Team at
Banner Good Samaritan Medical Center
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*Front***: Pat Pierard,** Regulatory Affairs Coordinator

Banner
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Our Mission: ***We exist to ensure research is conducted ethically, safely and efficiently.***

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