Banner Health Research Institute

VOLUME 3, ISSUE 1 MARCH 31, 2007

Banner Desert Medical Center
Advancing Research to Improve Patient Care

Banner Desert Medical Center (BDMC), situated on an 80-acre medical campus, is the largest, most comprehensive hospital in the East valley of metro Phoenix. Several expansion projects are underway to enhance and grow several programs including various surgical specialties, oncology, pediatric and women's services.

Denise Drumm-Gurnee, Ph.D.,
Facility Research Director,
Banner Desert Medical Center

Physicians and other healthcare providers at BDMC are developing innovative programs to improve patient care and manage disease. In addition to regular medical care, some healthcare providers are involved in cutting edge research in areas such as cardiovascular disease, intensive care, nursing and pediatric oncology. The Research Department is available to support clinical investigators as they conduct biomedical research. Some of these efforts may result in safe and effective methods to treat and prevent common diseases. Bringing research to BDMC provides an opportunity for patients to access clinical research studies and the technology and related resources. New studies are processed every month through the Research Department. Presently, there are thirty-four active studies including 12 pediatric oncology research protocols. In addition to the active studies, there are ten studies that are pending final approval, six that are in draft form, and three research protocols under consideration. Facility expansions and related infrastructure are anticipated to increase the number of research protocols.

Recently, one of the research projects received distinction. Banner Desert Medical Center is one of five hospitals nationwide selected by Boston Scientific Corporation for a clinical trial of an innovative therapy to treat Atrial Fibrillation, a rapid irregular heart beat. The first procedure in the nation related to the clinical trial was performed at BDMC last month. Through the clinical trial, the safety and efficacy of the FLEX Microwave Ablation System for patients with symptomatic, paroxysmal Atrial Fibrillation will be evaluated. Paroxysmal A-Fib is characterized by shorter (less than seven days) episodes of A-Fib that terminate spontaneously. Specifically, the study will examine the FLEX 10® Probe and Guidant Microwave Generator in a minimally invasive, thoracoscopic procedure. Patients in the study will be evaluated for 12 months following the procedure. Atrial Fibrillation, or A-Fib, may result in a decrease in the heart's pumping efficiency and,

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Jeremy Stoloff, JD, candidate for MS Bioethics, 2008
Research Attorney

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HIPAA Advice

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

The "Privacy Rule" is a Federal regulation established under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain patient health information. The Privacy Rule became effective on April 14, 2003 and since that time certain individuals and organizations were required to follow it. Interestingly, many of the organizations and individuals who participate in biomedical research are not required to comply with the rule.

In general, physician and nurse researchers, interacting with patient information, will have to comply with the Privacy Rule. This places many researchers in the odd position of having to protect certain patient information but interact with individuals and organizations which do not have the same obligation. Many pharmaceutical, device and biotechnology companies are eager to offer researchers advice on how to use and transfer patient information, but researchers must view this advice with caution and skepticism since these very same entities are not themselves required to comply with the Privacy Rule and may face few direct consequences for noncompliance.

In general, those organizations or individuals who must comply with the Privacy Rule are defined as "covered entities." Covered entities fall into one of three categories: (1) health care providers who electronically transmit any health information, (2) health plans, and (3) healthcare clearinghouses. A healthcare provider is a provider of medical or health services. A health plan is an individual or group plan that provides or pays the costs of medical care. A healthcare clearinghouse includes a billing service, repricing company, community health management information system, "value-added" networks and switches that either process or facilitate the processing of health information. Entities and individuals which cannot be categorized as health care providers, health plans or healthcare clearing houses are not required to comply with the Privacy Rule.

In general, physician, nurse, and hospital employee researchers who are using and/or transferring patient information for research will be "covered" by the Privacy Rule and must follow the rule. In order to comply with the rule the researcher must choose one of nine "methods" offered in the rule to properly transfer patient health information. Two examples of the "methods" offered in the rule are: (1) obtaining written authorization from the patient granting permission to use/transfer their information, and (2) de-identifying the patient's information. It is imperative for the researcher to assure that, prior to any use or disclosure of patient information, one of the nine methods is implemented.

Though it would be ideal if all of the organizations and individuals working within biomedical research had to follow the Privacy Rule, under one uniform standard, this is not the case. In general, pharmaceutical, device, biotechnology companies, and contract research organizations ("CROs") are not covered entities and therefore do not have to follow the Privacy Rule. Instead of following advice from organizations and individuals who are beyond the jurisdiction of the rule, researchers should refer to the language of the Privacy Rule, guidance documents offered by HHS, NIH, the Office for Civil Rights, and the policies and procedures of the hospital in which they are affiliated or have privileges.

The Banner Concurrent Review as a Research Compliance Strategy

Author: Wendy Schroeder, Coverage Analyst, Banner Health Research Institute

It is rare to find an infrastructure that supports research compliance as a part of clinical trials management and operations and even more difficult to find the application of such an infrastructure to a multi-facility and multi-state healthcare system. While Universities and Academic Medical Centers (AMC) have often been perceived as research centers of excellence, there seems to be little consistency in their organizational construct and even less consideration for a concurrent research review process that minimizes compliance risk by assuring consistency in documentation. While human subject protection and Institutional Review Board (IRB) policy and procedures have been recognized as integral to a research infrastructure for quite some time, it is only recently that research billing compliance and Stark and Anti-kickback laws have prompted thoughts of new models for research conduct and oversight.

It is well known that research activity and data collection for the purposes of contributing to generalizable knowledge requires review by the IRB for human subject protection and usually involves an in-depth assessment of the protocol, data collection tools and consent documents as an element of research compliance and accountability. It is also typical research process to establish a legal arrangement with a sponsor and include a mutually agreed upon budget for reimbursement. In most settings however, IRB review and study approval is an isolated practice with little or no consideration for the final versions of negotiated and executed budget and legal documents. The validity of the IRB review conducted in such a vacuum comes into question when their review could not have assessed any assurances that subject confidentiality has been secured by an appropriate legal agreement or that study payments are appropriate for the study expenses and not coercive to enrollment. There is further increased compliance risk associated with this type of disconnected review when legal agreements are inadequate to support any litigation and final documents contain inconsistencies that could raise questions about research payments and billing and full disclosure to subjects. Banner has successfully implemented an effective concurrent review process to assure that research conduct is expertly reviewed for:

- Scientific merit and human subject protection
- Contractual arrangements that minimize legal risk
- Research services billable to a third party payor, and
- Funding appropriate and adequate to cover study cost

Upon completion of these reviews, all documents related to the research study are in harmony with one another. For example, subject compensation for study related injury and subject responsibility for costs associated with the research project is uniformly addressed in the consent document and the clinical trial agreement; subject compensation or stipends acknowledged in the consent document are included in a cost analysis and covered by the budget; study budget exhibits are consistent with billing regulations, reflect sponsor payment for all items and services required solely to accommodate the protocol and provide the reference to assure appropriate billing; and a legal agreement assures human subject confidentiality and protects the investigator and institution from serious litigating consequences. (References omitted. Contact Wendy Schroeder at wendy.schroeder@bannerhealth.com.)

Visit our website at www.bannerhealth.com/research

A Research Collaborative Agreement between Banner Health and the University of Colorado, Denver Health Science Center has been executed.

Western Region Research Activity

Author: Michelle Faber, IRB Coordinator, Banner Health Research Institute; North Colorado Medical Center

One of the goals for 2007 for the Western Region is collaboration with other research professionals to access studies for Banner facilities in the rural communities. To date, a Research Collaborative Agreement between Banner and the University of Colorado, Denver Health Science Center has been executed. In addition, Banner Health Research Institute (BHRI) is finalizing a Research Collaborative Agreement with the University of Northern Colorado.

Ann Coombs, Facility Research Director for the Western Region, and Marc Ringel, MD, a physician with Brush Family Medicine, are collaborating with Jack Westfall, MD, MPH and Kent Voorhees, MD, of the University of Colorado Health Sciences Center. The Banner facilities involved with the research are Brush Family Medicine Sterling Family Care Clinic, these facilities are located in northeast Colorado.

Ann Coombs and Dr. Ringel feel that pursuing research in the rural communities provides the opportunity for both physicians and the citizens of the rural communities in which they practice to be actively involved in studies that can make a real impact on the way patients are cared for on the front lines.

Both the Western Region Panel One (at McKee Medical Center) and the North Colorado Medical Center (NCMC) panel of the Banner Health IRB have gotten off to a strong start this year in reviewing multiple studies. We anticipate an increase in review of studies in the Western Region by both panels in 2007.

In addition, Michelle Faber, IRB Coordinator, member of the NCMC Nursing Research Council, is working with the sub-committee to plan for the 3rd Annual International Research Conference, *Building a Toolkit for Implementing Evidence-Based Practice*. The conference will be held May 4th at the University of Northern Colorado. This conference is a combined effort between NCMC Professional Nursing Organization, McKee Medical Center Nursing Research Council and UNC's School of Nursing. Heidi Terry, RN, MSN, Systems Operations Manager for BHRI, will speak about ethics and research. For more information, please visit the following website: www.unco.edu/nhs/nursing/conference. Hope to see you at the conference!

3rd Annual International Research Conference

Building a Toolkit for Implementing Evidence-Based Practice

University of Northern Colorado

May 4th, 2007

Keynote Speaker: Roxie Foster, PhD, FAAN

Nursing Credits

CEU's will be awarded for attendance at this conference. Banner Health is an approved provider of continuing education by the Colorado Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation. Provider ID#BHC-0303, Expiration date: 05/31/09.

Who should attend

Health Care Providers: nurses, physicians, residents, students, etc. who strive to use evidence-based practice to improve quality in health care.

Poster Presentation Guideline

Information is available online at www.unco.edu/nhs/nursing/conference

Electronic submission:
Wayne.Potter@bannerhealth.com

Deadline: by April 1, 2007

Changes in Medical Education Research

Author: Jennifer L. Lower, M.Div

From left to right:

Lisa Diaz, CCRA, Study Coordinator;

Richard D.Gerkin, MD, MS, Medical Education Dr. Scientific Services;

Jennifer L. Lower, M.Div, Functional Research Director, Medical Education

Heraclitus is credited with saying, "There is nothing permanent except change." This is certainly the case for Medical Education Research in the past several months. Jennifer Lower moved from her role as Regulatory Affairs Coordinator to Functional Research Director, taking over responsibilities temporarily handled by Dr. Richard Gerkin. Dr. Gerkin continues in his role as Medical Director for Scientific Services, Banner Health Research Institute.

Medical Education Research is pleased to introduce Lisa Diaz. Lisa Diaz is a Certified Clinical Research Associate (CCRA) and has stepped into the position of Study Coordinator. Lisa comes to Banner Health Research Institute from the University of Arizona Cancer Center's Colon Cancer Prevention Project.

Lisa is available to assist the residents in many aspects of research development, from the IRB submission to final data analysis. Jennifer has oversight for all research submissions in Medical Education Research, including budget management and research compliance. Dr. Gerkin continues to assist residents in the preparation of their research projects, particularly statistical calculations and analysis. The Medical Education Research team looks forward to assisting the residents and their supervising physicians with their research needs.

Medical Education Research team can be reached at:

Lisa—(602)239-3037

Jennifer— (602) 747-9731

Dr. Gerkin— (602)747-9713

STUDY TITLE	Investigator	Department
Coccidioidal Prophylaxis	Little/Kolli	Hepatology
Methamphetamine Abuse in Trauma	Loftus/Swearingen	Surgery
Awaiting approval:		
Patient perspectives on MHT	Roy/Mallin	Internal Medicine
Hospitalist Questionnaire	Smith/Iacovelli	OB/GYN
Coccidioidal Meningitis	Gutierrez/Johnson	Preliminary Medicine

Academic Excellence Day

will take place at Banner Good Samaritan Medical Center on
Wednesday, May 2, 2007 in the auditorium and Sandstone Conference Rooms.

Banner Health Research Institute

Our Values

We Value:

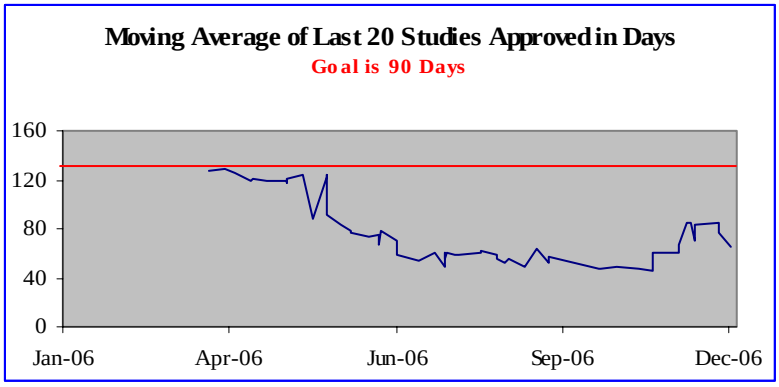
People, Subjects, Investigators, Sponsors, and Collaborative Partners… *by treating them with respect, beneficence and justice.*

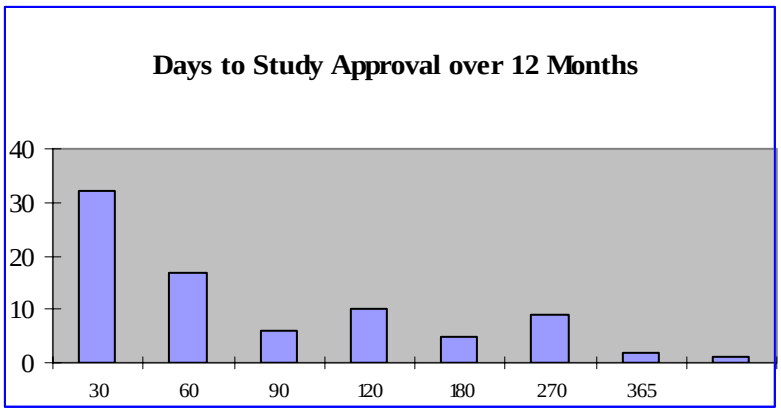
Excellence… *by assuring human subject protection and research compliance, and striving for the highest quality customer service.*

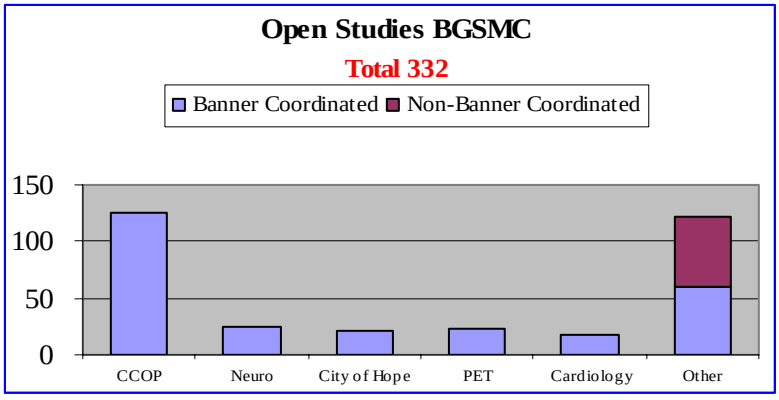
Results… *by contributing to the advancement of medical science and the improvement of patient care.*

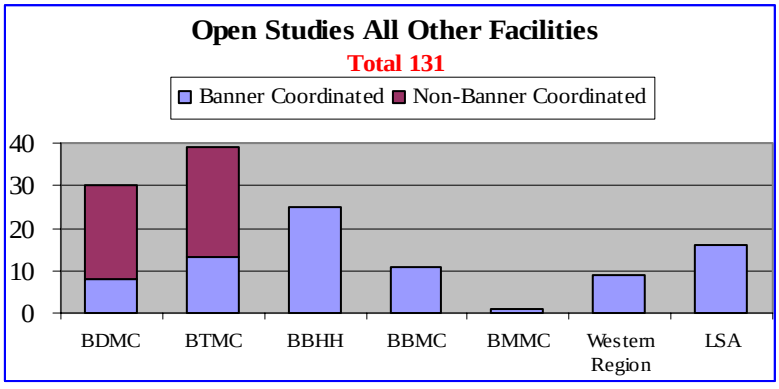
Dashboard Reports (data through December 31, 2006)

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









Research Billing: Ask the Coverage Analyst

Author: Wendy Schroeder, RN, CCRC

Wendy Schroeder, RN, CCRC
Coverage Analyst, Banner Health Research Institute

Q: What are "routine costs"?

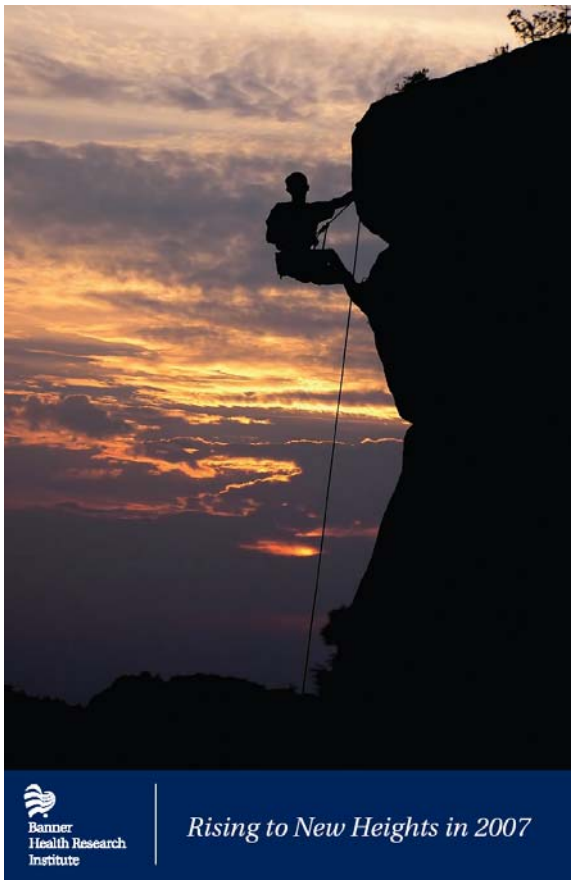
This definition as noted in the NCD has been mentioned and includes the costs associated with patient care that would otherwise be provided to treat the subject absent the clinical trial and care required to administer, monitor the effects of or treat complications related to the test article. Whether these routine costs are reasonable and medically necessary is by far the more difficult question to answer when analyzing items and services required by a clinical trial protocol to make a billing determination. A due diligence analysis using a step by step approach should be used to document each activity as medically necessary. A common algorithmic misperception is used to shortcut this process: "routine care" = "investigator standard of care" = "billable". CMS publishes a number of coverage decisions for specific patient care services that establish criteria for medical necessity. And, contrary to common belief, not all standard of care services are "created billable". Submitting a claim for services that do not meet CMS published criteria could be considered a false claim subject to significant penalties. Claiming ignorance in knowing that the claim was false is not a good defense. Instead, a research organization should perform and document a coverage analysis to determine which services should be paid by the sponsor, negotiate for adequate reimbursement and assure that these services are removed from any submitted claims. As a practical guideline, the process steps in logical order are to first create a line item list of tasks and patient care services required to meet the protocol requirements. Then decide and designate all line items already paid by the sponsor as "not billable". Determine the medical necessity of the remaining services and identify all remaining "non-billable" line items. And, finally, negotiate sponsor payment for all costs associated with services that cannot be billed to Medicare.

BDMC Research *(continued from page 1)*:

BDMC Facility Research Director, Denise Drumm-Gurnee, Ph.D. discussing a research project with Principal Investigator Dudley Hudspeth, M.D. and Jim LeBrun from Desert Cardiothoracic Surgeons.

therefore, an increase in the risk of stroke. Banner Desert is collaborating with the principal investigator for the Arizona trial, Dudley Hudspeth, M.D., of Desert Cardiothoracic Surgeons in Mesa, Arizona. Approximately 2.4 million patients suffer from atrial fibrillation in the U.S. today, and its prevalence is expected to double over the next 40 years. Drug therapy for the condition often is ineffective or causes severe side effects, making innovative therapies to suppress A-Fib increasingly valuable.

The Research Department at BDMC is available to collaborate with local investigators as well as industry and academic partners.



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