BANNER RESEARCH ADMINISTRATION
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Banner Health®

2009: Times are Changing!

Author: Wendy Schroeder, RN, CCRC, National Speaker on Medicare Coverage Policy

Change is upon us. The economy has forced cost saving measures across households and businesses. In less than 30 days, our government will transition to a new presidential administration. For Banner Health (BH) Research Administration, one of the changes as we move into 2009, includes a trend toward increased investigator-initiated research as compared to industry sponsored clinical trials. This is likely due to many factors:

- robust nursing research efforts in support of magnet status;
- the volume of basic science research conducted at Sun Health Research Institute;
- newly employed physicians with research included in their scope of employment;
- research required for scholarly accreditation; and,
- a system initiative to explore more external funding for these types of research interests.

Research administration faces different "pre-subject" enrollment review challenges for investigator-initiated projects. Admittedly, the most common BH sponsored research has included retrospective chart review and prospective observational studies that are typically considered minimal risk. The trend, however, is toward more randomized designs of clinical interventions. In these designs, scientific rigor, human subject risk and safety monitoring require extra review steps when Banner is engaged in research as both the site and the sponsor. In addition to the compliance obligation to assure the proper conduct of these studies, it becomes increasingly important to document the level of human subject risk involved in the proposal. This includes scrutiny of regulatory requirements which may involve the identification of an internal safety committee for study monitoring and the sponsor (BH) liability related to these risks. In assuming these risks and liability, BH facilities are likely to expect evidence of project value, especially if the research requires resource investment in excess of funding.

In 2009, the Banner Health strategy for research will continue to take form and changes are expected. One thing remains constant, Banner Health will continue to work diligently with investigators to “ensure that research is conducted safely, ethically and efficiently”.

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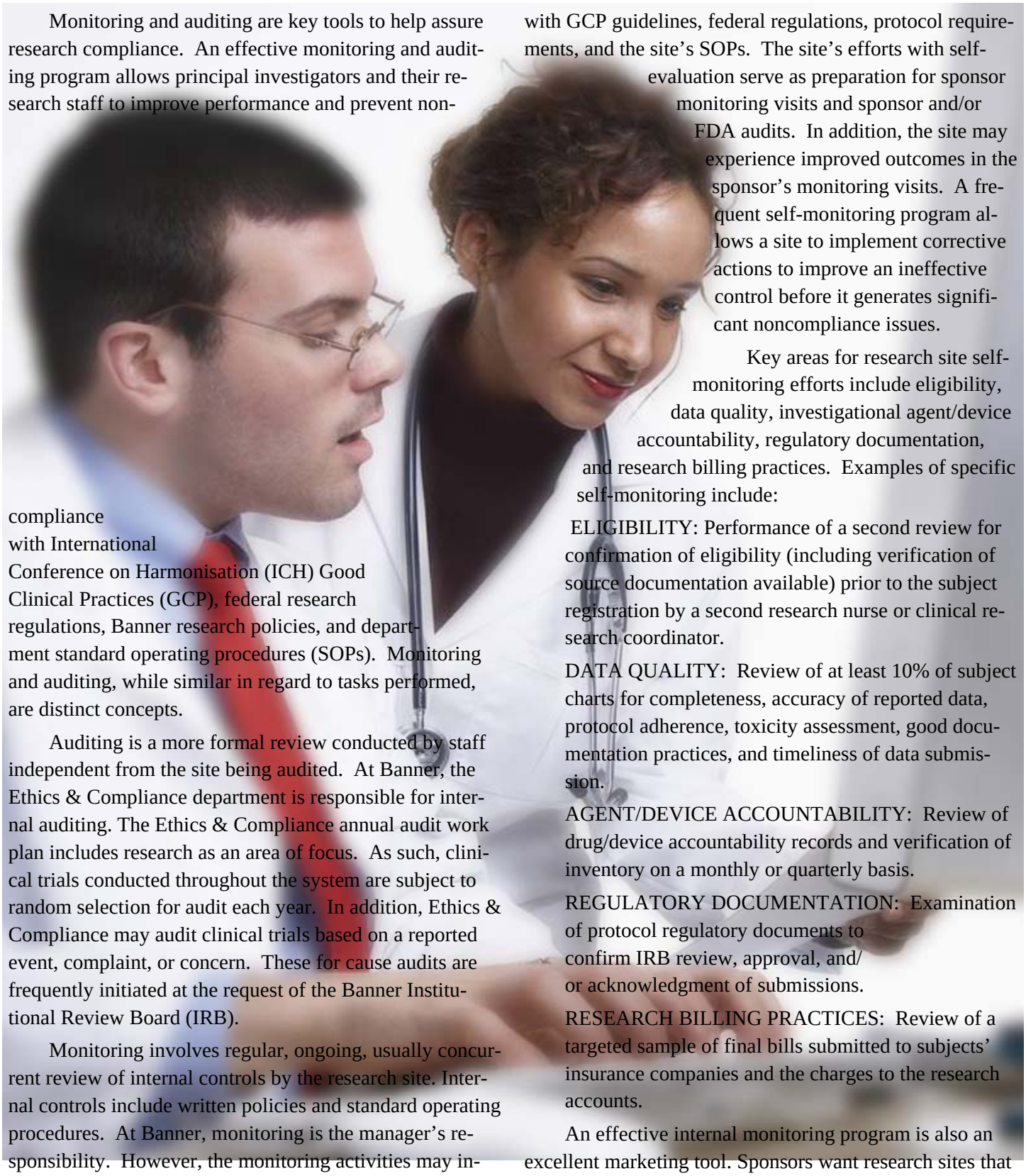
Research Compliance: Site Self-Monitoring

Author: Susan Colvin, MHSA, BSN, OCN, CCRP, Compliance Analyst, Banner Health Ethics and Compliance Department



Monitoring and auditing are key tools to help assure research compliance. An effective monitoring and auditing program allows principal investigators and their research staff to improve performance and prevent non-compliance with International Conference on Harmonisation (ICH) Good Clinical Practices (GCP), federal research regulations, Banner research policies, and department standard operating procedures (SOPs). Monitoring and auditing, while similar in regard to tasks performed, are distinct concepts.

Auditing is a more formal review conducted by staff independent from the site being audited. At Banner, the Ethics & Compliance department is responsible for internal auditing. The Ethics & Compliance annual audit work plan includes research as an area of focus. As such, clinical trials conducted throughout the system are subject to random selection for audit each year. In addition, Ethics & Compliance may audit clinical trials based on a reported event, complaint, or concern. These for cause audits are frequently initiated at the request of the Banner Institutional Review Board (IRB).

Monitoring involves regular, ongoing, usually concurrent review of internal controls by the research site. Internal controls include written policies and standard operating procedures. At Banner, monitoring is the manager's responsibility. However, the monitoring activities may include other staff members at the research site.

Self-monitoring should be designed to improve the quality of the studies conducted and assure compliance with GCP guidelines, federal regulations, protocol requirements, and the site's SOPs. The site's efforts with self-evaluation serve as preparation for sponsor monitoring visits and sponsor and/or FDA audits. In addition, the site may experience improved outcomes in the sponsor's monitoring visits. A frequent self-monitoring program allows a site to implement corrective actions to improve an ineffective control before it generates significant noncompliance issues.

Key areas for research site self-monitoring efforts include eligibility, data quality, investigational agent/device accountability, regulatory documentation, and research billing practices. Examples of specific self-monitoring include:

ELIGIBILITY: Performance of a second review for confirmation of eligibility (including verification of source documentation available) prior to the subject registration by a second research nurse or clinical research coordinator.

DATA QUALITY: Review of at least 10% of subject charts for completeness, accuracy of reported data, protocol adherence, toxicity assessment, good documentation practices, and timeliness of data submission.

AGENT/DEVICE ACCOUNTABILITY: Review of drug/device accountability records and verification of inventory on a monthly or quarterly basis.

REGULATORY DOCUMENTATION: Examination of protocol regulatory documents to confirm IRB review, approval, and/or acknowledgment of submissions.

RESEARCH BILLING PRACTICES: Review of a targeted sample of final bills submitted to subjects' insurance companies and the charges to the research accounts.

An effective internal monitoring program is also an excellent marketing tool. Sponsors want research sites that adhere to GCP guidelines, produce a quality product, and conduct well-run clinical trials producing clean, reliable data.

Research Compliance Training for Banner Health Researchers

Author: Wendy Schroeder, RN, CCRC, National Speaker on Medicare Coverage Policy

There is a robust research interest within Banner Health. From evidence based practice projects, to research required for scholarly pursuits and accreditation… from basic science to translational research …from diagnostics to interventions…from behavioral observations to off-label use of drugs…from devices and investigational treatments to technology applications, and the list goes on. Over a period of time, the research director (RD) on each campus has been identified as the "point of entry" for research activity and continues to be the ultimate authority for research compliance and accountability. With volumes of research compliance regulations, it would be impossible for the RD to individually train the large numbers of research team members and each new investigator. Instead, Research Administration has developed a training program to explain just a few of the key compliance regulations and orient researchers to the Banner Health process for research conduct and approvals. The minimum expectation for research training is the mandatory successful completion of Banner Learning Center Modules. RA has been assigning these modules to all key study personnel on research studies since March 2007. They include:

Banner Research Administration Module 1: Good Clinical Practice

Banner Research Administration Module 2: Research Administration

Banner Research Administration Module 3: The Institutional Review Board

Banner Research Administration Module 4: Investigator Responsibilities

Banner Research Administration Module 5: Electronic Submission - iRIS

In January 2008, Research Administration began accepting alternative human subject protection certification such as the National Institutes of Health (NIH) training certification and the Collaborative Institutional Training Initiative (CITI) web based training program for the ethical conduct of research. To maintain research privileges, all active research team members must comply with the BH requirement to complete research training and renew it every 2 years.

In addition to these mandatory requirements, RA engaged in the philosophy that "it takes a village" to train researchers. A formal 2-day program (ITAV) has been developed to equip our customers with research information critical to compliance as well as process. The program includes presentations on topics including protection of human subjects, financial disclosure, Institutional Review Boards, investigational new drugs and devices, informed consent requirements, privacy regulations for research, adverse event reporting and data integrity. With this background information on research rules and regulations, the RA expert presentations that follow explain the BH process approach to assuring research regulatory compliance. The agenda also includes an afternoon of database training with hands on instruction. Program evaluations and attendee feedback have been extremely positive. Consider some of the comments, "I learned so much that I had never heard of"…"I'm…proud to be part of an organization with this exceptional research administration department…the information I received will help guide me in the future, make me more efficient and allow me to be part of a high quality, ethical and protocol oriented research that will respect the legal, financial, safety, organizational and regulatory issues surrounding research. Thanks!" Collectively, there is over 200 years of research experience shared by BH professionals committed to ensure that research is conducted ethically, safely and efficiently and willing to share their expertise. ITAV is held bi-monthly on the first and second business days of the month and anyone is welcome to attend. Advance notice is requested to assure adequate planning and materials. The next scheduled event will be March 2 and 3, 2009 in the RA conference room. Perhaps we will see you there!

Study Performance after Enrollment

Author: Jeremy Stoloff, JD, MS Bioethics, Associate General Councel, Research Administration

Investigators and research support staff dedicate time, effort and expertise to each proposed research study assuring the study has ethical, financial and transactional integrity. Investigators and research support staff are an integral component of this "pre-subject-enrollment" work. Upon completion of this phase, the research study may proceed and study subjects, also called volunteers, are enrolled into and become participants in the research study.

The second phase of the research study is the "post-enrollment" work. This phase of the research study has the bulk of study performance (or work to be accomplished). Post-enrollment work is under increasing scrutiny by sponsoring organizations (such as pharmaceutical, device and vaccine companies) and professional research organizations.

Sponsoring organizations and professional research organizations voice their critique of study site underperformance of the protocol after study subject enrollment. This underperformance is evidenced by a lack of study data produced by the study site, unmet study performance thresholds (such as study subject visits, interviews and follow-up), poor quality and inaccurate study data, and frequent violations of the study protocol (either reported by the study site or discovered through the sponsoring organization's audits). Not only does the sponsoring organization lose its investment in the pre-enrollment phase of the research study, it also suffers a loss of opportunity: the sponsoring organization could have chosen a different and well-performing study site. Further exacerbating the problems for the sponsoring organization are the time, resources, and money spent identifying and auditing underperforming study sites.

Given this focus on the post-enrollment phase of the research study, and the sponsoring organization's interest in obtaining comprehensive study data which reflects the accomplishment of all of the work required by the protocol; investigators and support staff should assure that they have the resources and capacity to oversee and guide each research study to completion. By fully performing each research study we honor our obligation and promise to the sponsoring organization to effectively implement the study. Additionally, full performance of the research study assures that the time, energy and skill of the investigator and research support staff devoted to the earlier phase of the study was meaningful and worthwhile. Perhaps most important, full study performance shows the greatest respect for our study subject volunteers who altruistically donate their time and diligence in the hope of creating final study data that will help others in the future.

Institutional Review Board (IRB) Fee Schedule

Effective January 1, 2009, Banner Health's Institutional Review Board (IRB) Fees will be changing. These changes are necessary to offset the increased costs associated with operating Banner Health's IRB which include educational materials/programs, rent expense, supply expense, administrative support and overall inflation. The current fees, along with the January 1, 2009 fees, are as follows:

Banner Health IRB Fee Schedule	*Effective January 1, 2007-December 31, 2008*	***Effective January 1, 2009***
Initial full board review of new study for one site	$2,500	**$2,750**
Expedited review of new study for one site	$1,250	**$1,350**
Exempt review of new study	$500	**$650**
Amendments to protocol (after initial approval) with revision to the consent	$500	**$550**
Amendments to protocol (after initial approval) without revision to the consent	$250	**$350**
Continuation Review (subject to prorating)	$1,200	**$1,450**
Final Review	$500	**$650**
No Fee items:		
Initial full board review of study packet for each additional Banner site	No fee	**No fee**
Expedited review of study packet for each additional Banner site	No fee	**No fee**
Adverse event notification	No fee	**No fee**

**The Fee Schedule is reviewed periodically and is subject to change*

Please note that the last increase in Banner Health IRB Fees was January 1, 2007.

Please contact Research Administration Finance at 602-747-9701 if you have any questions regarding Banner Health's IRB Fee Schedule.

Banner Health Institutional Biosafety Committee

Author: Barbara Lambeth, RN, CCRC, Research Director; Banner Heart Hospital, Banner Baywood Medical Center, Banner Gateway Medical Center

An Institutional Biosafety Committee (IBC) is a review body appointed by an institution to review and approve all research involving the transfer of recombinant DNA or RNA derived from recombinant DNA, into human research participants. Institutional Biosafety Committees (IBCs) were established under the NIH Guidelines for Research Involving Recombinant DNA Molecules to provide local review and oversight of nearly all forms of research utilizing recombinant DNA.

Institutional authority and responsibility place accountability for the safe conduct of the research at the local level. More specifically, each institution conducting or sponsoring recombinant DNA research that is covered by the NIH Guidelines is responsible for:

- Establishing an IBC;
- Ensuring that the IBC has adequate expertise and training (using *ad hoc* consultants as necessary);
- Providing appropriate training for the IBC chair and members, Biological Safety Officer, principal investigators, and laboratory staff;
- Filing an annual report with the NIH Office of Biotechnology Activities

The Banner Health IBC was established by the Baywood campus research office with the assistance of Western IRB [WIRB] to review and approve the two gene therapy studies in which this campus is participating. The WIRB is responsible to make sure that our IBC meets the requirements set forth in the NIH Guidelines and that it provides reviews of Banner Health recombinant DNA research including:

- Protocols, revisions and/or amendments
- Continuing review
- Long-term follow-up
- Serious adverse events
- Research-related accidents and/or illness
- Assessments of the facility and staff
- Biological safety practices
- Biological safety containment levels

The core committee membership has experience and expertise in biological safety issues and recombinant DNA research. The local membership required to complete the committee comprises a representative from our site, and an unaffiliated community member. The unaffiliated community member represent the concerns and attitudes of our community and, in our case, serves as the IBC member who has expertise to inspect our physical site for biological safety issues. Our site inspector is an Infection Control RN from another hospital system in the Phoenix area. Our local site representative is Susan Hill, RN, Director of the Banner Baywood Medical Center Wound and Ostomy Center. Most of the IBCs have 6-9 committee members; depending on the type of research being performed. The IBC meetings for our site take place via telephone conference with members calling in from all over the United States.

If you have any questions or would like more information regarding recombinant DNA research and the Banner Health IBC, do not hesitate to contact me at 480-854-5178.

2008 is an Active Year for Medical Education Research

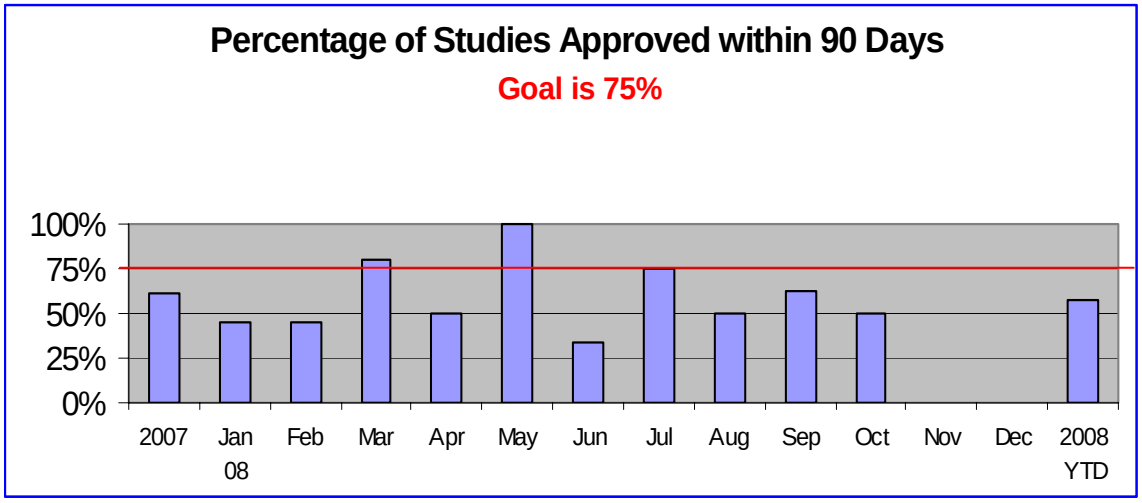
Author: Jennifer L. Lower, M. Div., Research Director, Medical Education, Banner Good Samaritan Medical Center, Research Administration

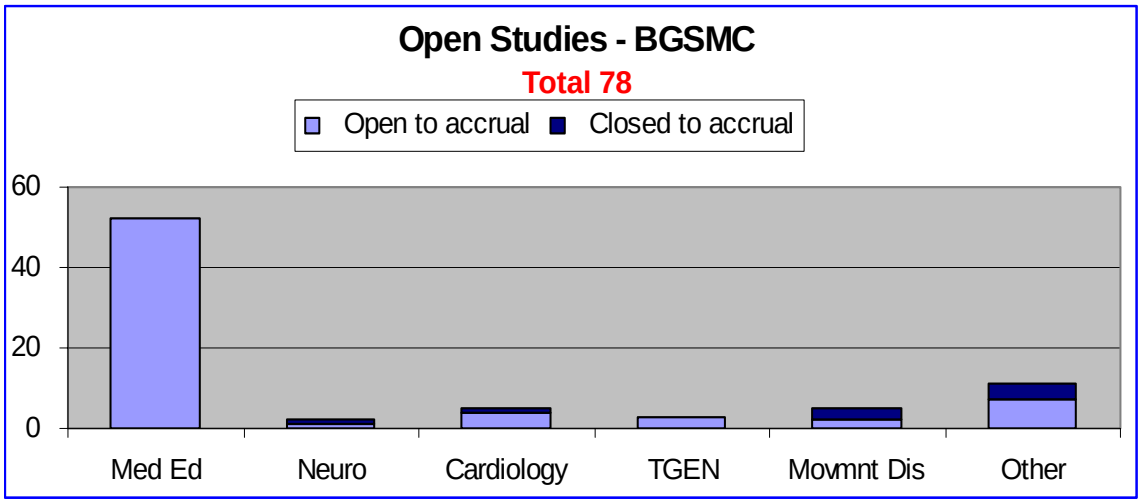
Graduate Medical Education (GME) research has opened fifteen new studies in 2008, as well as two clinical trials in Trauma and OB/Gyn. An additional eighteen studies are in some stage of initiation for IRB review, including clinical trials for Toxicology and Trauma. Studies for GME have ranged from new projects involving Arizona State University and the Simulation Education Training Center to retrospective chart reviews. The following is a summary of projects approved thus far in 2008:

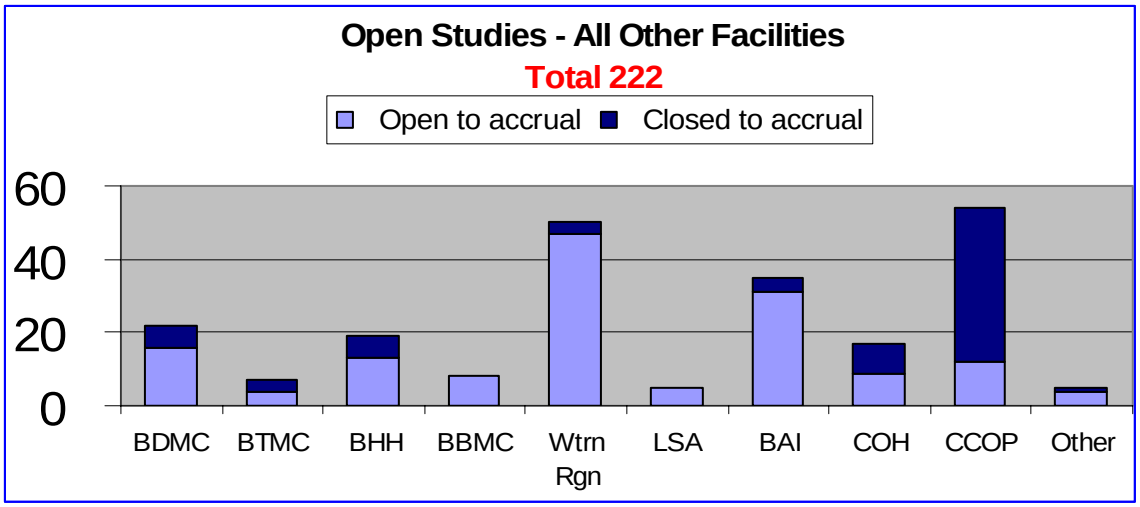
BHRI #	Study Title	Principal Investigator	Resident or Fellow
01-08-0005	Why Do Patients Call Their Doctors?	Steve Brown, M.D.	Suzanne Burkett, M.D.
01-08-0008	Air Transport in Trauma II	Terry Loftus, M.D.	Kevin Masur, M.D.
01-08-0009	Qualitative Review of Lithium Toxicity	Daniel Brooks, MD	Spencer Greene, M.D.
01-08-0017	Use of Hepatically Metabolized Psychiatric Medications in Patients with LFT abnormalities: A Physician Survey	Daniel Brooks, M.D.	
01-08-0021	BINGO! Fun with drug advertising and other teaching tools for evaluating pharmaceutical marketing	Steve Brown, M.D.	
01-08-0041	Retrospective Review of Patients Undergoing Computed Tomography Coronary Angiography for Evaluation of Chest Pain	Akil Loli, M.D.	Jason Klein, M.D. Nahel Farraj, D.O.
01-08-0043	Complications Associated with Cesarean Hysterectomy: A Time Series Cohort Study	Rod Edwards, M.D.	Brian MacArthur, M.D.
01-08-0046	Response Time for Emergency Cesarean Section Delivery for Fetal Indications: Evaluation of the "30 Minute Rule"	John Elliott, M.D.	Kelly Goad, D.O.
01-08-0049	Optimal Route of Delivery in Pregnancy Complicated by Maternal Aortic Stenosis Optimal Routes – AS	Garrett Lam, M.D.	Ravi Gunatilake, M.D.
01-08-0058	Clinical and Microbiologic Evaluation of Patients Infected with Daptomycin-Resistant MRSA	Edwin Yu, M.D.	
01-08-0061	Vaginal Birth after Cesarean and Repeat Cesarean: Patient's Understanding of Potential Risks	Michael Urig, M.D.	Nicole Seacotte, M.D.
01-08-0065	Link between Transfusion of Older Allogenic Red Blood Cells and Complications after Cardiac Surgery	Richard Gerkin, M.D.	Amir Etimad, M.D.
01-08-0066	Who's My Doctor II?	Cheryl O'Malley, M.D	
01-08-0071	A Chart Review on the Outcomes of Multiple Births including Quadruplets, Quintuplets and Sextuplets	John Elliott, M.D.	Candice Park, M.D.
01-08-0020	Cognitive Complexity and Error in Critical Care	John Ferrara, M.D./ Mark Smith, M.D.	
01-08-0033	Identification of Proteomic Markers of Intra-Amniotic Infection (IAI) in Patients with Preterm Rupture of Amniotic Membranes (PPROM)	Rod Edwards, M.D.	

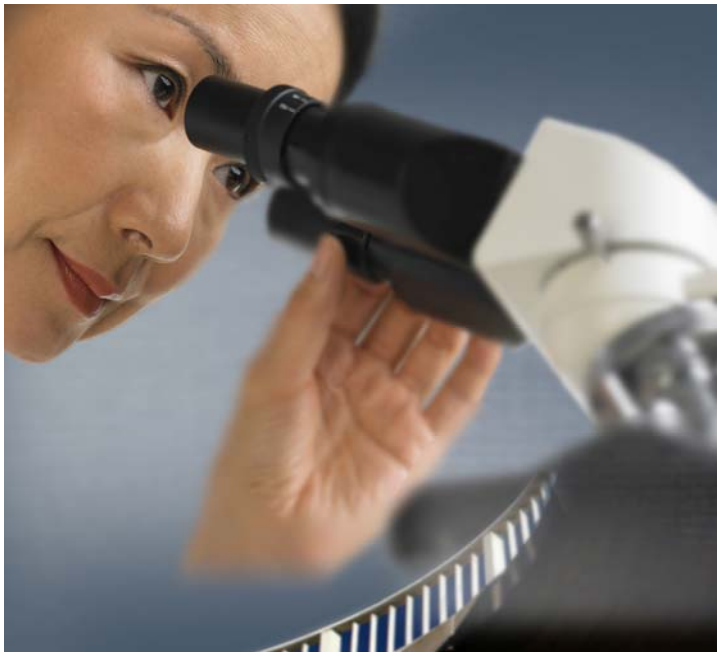
Dashboard Reports (data through October 31, 2008)

Data provided by Research Administration, Finance









For registration information and agenda, visit our website at
www.bannerhealth.com/research

OHRP RESEARCH COMMUNITY FORUM

"Human Subject Protections:
BRIDGE TO THE FUTURE"

Sponsored by Banner Health and Office for Human Research Protections

Friday, January 30, 2009

Renaissance Glendale Hotel and Spa

Glendale, Arizona

This event will be a full day of speakers and sessions dedicated as a bridge to the future of research. From innovations in clinical trials to the nuts and bolts of the Institutional Review Board (IRB) review; from ethics in research to advancements in technology, this Research Community Forum promises to offer something of interest for everyone involved in research. Whether a seasoned principal investigator, a novice IRB member, a public health official, a privacy official, a patient advocate, legal counsel or anyone in between, this forum will be of interest.

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