Banner Health Research Institute

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Banner Good Samaritan Medical Center: Pioneering Cardiovascular Research

Author: Pam Thompson, Research Director, Cardiovascular/CV Surgery, TGen Initiatives, Banner Good Samaritan Medical Center

The Banner Good Samaritan Medical Center (BGSMC) Cardiovascular Research Department is nationally known for its pioneering work in diagnostic technology, treatment innovations and improved outcomes through research conducted on campus. Such research initiatives evolve through collaborative partnerships between Banner Health staff and our practicing Cardiologists and Cardiovascular Surgeons.

Banner Health Research Institute

Cardiovascular Research Team at Banner Good Samaritan Medical Center

From left to right: **Pam Thompson,** RN, BSN, CCRC, Research Director; **Gabriella Diaz,** RN, Clinical Research Nurse; **Pat Pierard,** Regulatory Affairs Coordinator

Over the past ten years, research has demonstrated successful results in making a difference in our patient's lives. Such research has provided opportunities for patients to avoid open heart surgery through the use of coronary stents, which in recent years have advanced to drug eluting stents. The drug eluting stents now reduce the probability of restenosis in the vessel wall. Additionally, research conducted on site at BGSMC has advanced patient comfort by allowing Cardiac Catheterization patients the ability to be up and around within hours of a procedure with the use of closure devices. The BGSMC Cath Lab was one of the first in Arizona to conduct phase 2-4 clinical trials on such closure devices; as well as the first in the country to have access to the use of stents.

The BGSMC Cardiovascular Research Department played a pivotal role in the research that established carotid stenting as an alternative to carotid endarterectomy. Such research continues to provide patients access to evolving technology in the world of noninvasive carotid intervention. Additionally, this knowledge allows physician training to occur on campus to proliferate technical expertise throughout the communities Banner Health serves. BGSMC currently has two open and enrolling carotid stent trials.

In recent years, advancements in the Cardiovascular Surgery arena have included investigational pharmaceutical agents that ultimately allow patients to recover more quicky from Cardiac Bypass. Other projects allowed physician's access to investigational heart valves and agents that potentially minimize bleeding complications during open heart surgery. Furthermore, patients admitted with acute coronary syndrome are now given anticoagulation therapy within specific time frames. These time frames were proven successful and developed through data collection and clinical studies conducted here on campus.

(continued on page 2)

INSIDE THIS ISSUE:

Research Conflict of Interest Management

Author: Jeremy Stoloff, JD

Photo by: Gracie Chavez, Multimedia Specialist, BGSMC

Jeremy Stoloff, JD,
candidate for MS Bioethics, 2008,
Research Attorney,
Banner Health Research Institute

In order to accommodate the expectation of regulatory agencies, professional organizations and the public, Banner Health will be implementing a new policy entitled: *Research Conflict of Interest – Disclosure, Review & Management.*

It is well accepted that hospitals which engage in human subjects research must ensure that the health, safety and welfare of those subjects and the integrity of the research are never subordinated to, or compromised by, financial interests or the pursuit of personal and professional gain.[1] Most researchers, research support staff and hospitals would argue that research conflicts of interest are rare and even when present, would not affect the quality or integrity of the study, nor the study subjects' safety or welfare. However, there is significant increasing public concern about the existence of research conflicts of interest and an expectation that researchers, their staff and hospitals respond to such conflicts in ways that re-instill confidence in the research community.[2] There is now a public and regulatory agency request that such conflicts be appropriately managed so that a reasonable outside observer would not assume that the conflict *could* have impacted the research study or study subjects.

When evaluating whether a researcher, research support staff or the hospital as an organization has a research conflict of interest it is important to distinguish between situational and realized conflicts. *Situational* conflicts occur when persons find themselves in a situation in which a neutral, outside observer would assume a conflict is present which *may* impact the study or study subjects. *Realized* conflicts occur when the researcher, research support staff or hospital *actually* take action (or choose not to act) based upon their conflict. Guidance from regulatory agencies and professional organizations clearly suggest that both types of conflicts must be effectively managed.

In order to accommodate the expectation of regulatory agencies, professional organizations and the public, Banner Health will be implementing a new policy entitled: *Research Conflict of Interest – Disclosure, Review & Management.* The new *Research Conflict of Interest – Disclosure, Review & Management* policy will be listed on the Banner Health policy and procedure database at http://policyprocedure.bhs.bannerhealth.com/default.aspx. This policy and its effective implementation will show Banner Health's commitment to addressing emerging ethical concerns in this exciting and complex field.

1. Association of American Medical Colleges, Task Force on Financial Conflicts of Interest in Clinical Research, Protecting Subjects, Preserving Trust, Promoting Progress (2001), 3.
2. Id.

BGSMC Cardiovascular Research *(continued from page 1)*

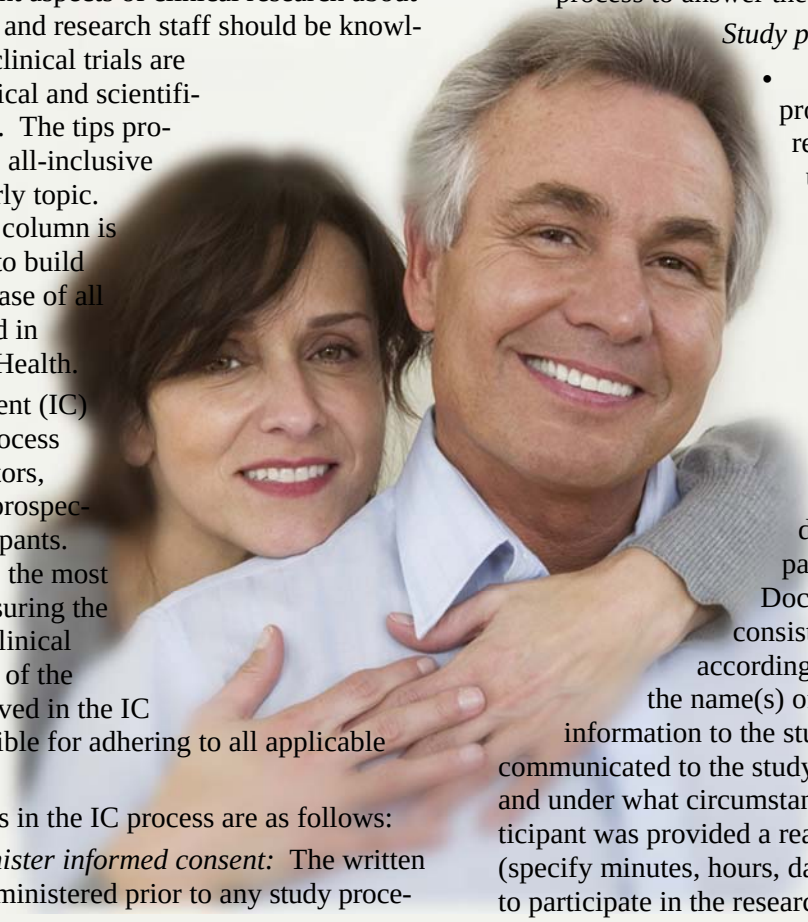
Currently, BGSMC is conducting a trial which allows patients to undergo mitral valve repair within the Cardiac Cath Lab. The goals of this study are to lessen the duration of a patient's hospital admission, decrease patient pain, and improve throughput. Should this study prove successful, some patients may no longer need to undergo open heart surgery in operating rooms.

Ongoing research involves the discovery of plaque characteristics and the relationship to genetic markers that may unlock future treatment modalities. Since 1900, cardiovascular disease has been the number one killer in the United States. BGSMC's Cardiovascular Research Department has a vision to discover and treat the disease process and ultimately contribute to a cure.

Research Compliance: What You Need to Know for Success

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

Compliance with federal, state, and local regulations is key to the responsible conduct of clinical research. This column will highlight aspects of clinical research about which investigators and research staff should be knowledgeable to assure clinical trials are conducted in an ethical and scientifically sound manner. The tips provided will not be an all-inclusive guide on the quarterly topic. The purpose of this column is to provide a forum to build on the knowledge base of all individuals involved in research at Banner Health.



Informed consent (IC) is an educational process involving investigators, research staff, and prospective research participants. Administering IC is the most critical aspect in assuring the ethical conduct of clinical research. Members of the research team involved in the IC process are responsible for adhering to all applicable regulations.

Some key areas in the IC process are as follows:

When to administer informed consent: The written IC **must** be administered prior to any study procedures.

Who can administer the IC:

- The IC **must** be administered by a person who is medically qualified **and** is an Institutional Review Board (IRB) approved member of the research study team.
- The qualified person administering the IC **must** be identified on the Banner Health Research Institute (BHRI) study application as being an authorized administrator of the IC.

Signatures on the IC. **All** required signatures (i.e., subject, *witness, person administering IC, investigator) **must** be obtained and the signature fields **must** be complete.

- All signatures are to be dated by the person who signs the form.
- If required, each page is initialed by the study participant or the study participant's legally authorized representative.

Investigator/ sub-investigator: The investigator or-sub-investigator **must** be available during the IC process to answer the study participant's questions.

Study participant:

- The study participant **must** be provided information on the research study, must express an understanding of the facts, and voluntarily agree to participate.
- The study participant **must** be given a reasonable amount of time to ask questions and have those questions answered to his/her satisfaction.

Documenting research activity in chart/medical record: All research activity **must** be documented in the study participant's chart/medical record. Documentation for the IC process consists of: (1) a copy of the IC form according to Banner Health policy; (2) the name(s) of those who presented the study information to the study participant; (3) what was communicated to the study participant, with whom, where, and under what circumstances; (4) whether the study participant was provided a reasonable amount of time (specify minutes, hours, days) to consider whether or not to participate in the research study; (5) the study participant's suspected level of comprehension and how comprehension was assessed (ref: Banner Health Research Institute Investigator Manual).

Revising the informed consent form:

- The IC form must be a duplicate of the IC form approved by the IRB.
- Revisions to an IC form are not valid until proposed revisions are approved by the IRB.

For complete information on requirements see the following policies and regulations:

BH Policy #3127 *Research – Informed Consent for Participation*

45 CFR 46

21 CFR 45

21 CFR 50

Declaration of Helsinki

*A witness is defined as an individual (family, friends, or other medical staff) not involved in the research and who witnessed the entire IC process.

Research Billing: Banner Hits the Road

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

Photo by: Gracie Chavez, Multimedia Specialist, BGSMC

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

I…..am often pulled aside to talk more about the "Banner way". Everyone wants to know, "How do you do it? How did you get your organization to understand the importance of an investment in research compliance? Could we come and visit your site?"

As I return from the [exl] Pharma conference on clinical trial billing held in Annapolis, MD, I further appreciate the research compliance infrastructure known to us fondly as BHRI (Banner Health Research Institute).

In the ranks of presenters, many of them speak from experience – a different kind of experience. The message and sentiment speaks of "learning the hard way", self disclosure, false claims settlements and corporate integrity agreements. As a result, a concurrent review infrastructure involving scientific merit, human subject protection and legal and finance assessments of risk and research compliance has gained increasing respect among organizations across the country.

While the concept of systematic comprehensive research oversight is ideal, creating and supporting the organizational model to move concept into practice has posed significant challenges. One of these challenges in the budget support necessary for positions and training. Another is administrative buy-in to the concept that dollars spent on establishing a research compliance infrastructure translate into a worthwhile prevention strategy. The alternative to such a prevention strategy is potentially the aftermath of a false claims or anti-kickback settlement, which includes rigid internal auditing, obligatory agency reporting and damage control following headlines news.

I have now presented the Banner review process to our local community (Gateway Research Symposium), in Hawaii (Western Section SRA meeting), in Annapolis, MD ([exl] Pharma) and will be heading to San Francisco and Boston in the next few weeks.

After each workshop or session, I field audience questions and am often pulled aside to talk more about the "Banner way". Everyone wants to know, "How do you do it? How did you get your organization to understand the importance of an investment in research compliance? What does your organizational chart look like? How many FTEs does it take to manage your volume? What is your operational budget? How do you get it all done in 90 days? Could we come and visit your site?" As I hear myself in the midst of these discussions, I suddenly realize that Banner Health research has arrived. Collectively, the members of the BHRI team have over 200 years of research experience. They are experts in their areas of oversight. They work diligently every day to "ensure that research is conducted safely, ethically and efficiently." Amongst ourselves, we speak often of Banner's support for our efforts. I speak for many of us when I thank Banner for the buy-in, for the proactive approach to an investment in research compliance oversight, for training, for the technological tools we have to do our jobs and for the privilege of working with some of the most experienced and respected research colleagues in the country.

To our customers, realize that sometimes this business of "doing it right" means a bit more attention to detail and negotiations, necessary to protect investigators and Banner. Understand that we do aim to please while maintaining a healthy respect for research regulations. Be confident that we consider it a responsibility and opportunity to assist you in compliant research conduct. Your satisfaction and appreciation is our goal as we hone and refine a concurrent research review and compliance infrastructure about which most organizations only dream.

Medical Education: New Territory in Research

Author: Jennifer L. Lower, Research Director, Medical Education, M. Div.

Trauma Services, the Surgical Residency Program, and the Simulation Education and Training Center are entering new territory in research. In collaboration with Arizona State University, a project involving cognitive complexities has been proposed. This proposal, funded by the James S. McDonnell Foundation's award to Arizona State University, is titled, "Cognitive Complexity and Error in Critical Care." The research team will bring together an interdisciplinary team of cognitive psychologists, critical care clinicians, simulation experts, biomedical informaticians and complex systems scientists to develop a holistic research effort dedicated to modeling of complexity and errors in medical environments.

Travis Bilanzich, DO *(left)* and **James Spangler, DO *(right)*** are participating in an exercise in the SimET Center.

There are two objectives for this project:

1. Design, development and initial evaluation of technology that can aid in capturing clinical interactions and decision making process. This research to be conducted in Simulation Education and Training (SimET) Center, will develop a radio frequency identification based monitoring and tagging system coupled with audio recorders to capture verbal interactions between doctors, nurses and patients. This is primarily technology development and requires only few evaluation trials with selected doctors for evaluating the technology, its security and privacy and enabling a proof-of-concept of its working.
2. Complexity modeling of errors. The team's approach to error emphasizes the thought process that underlies collaborative decision making. It is based on the theoretical framework of distributed cognition, which views collaborative work as the product of a cognitive system consisting of human agents, machine agents and representations that exist in the minds of humans, or on physical media.

Team members include Dr. John Ferrara (Trauma Services and Surgical Residency), Dr. Mark Smith (System Director, Simulation Training), Dr. Vimla Patel (Arizona State University), and Dr. Kanav Kahol (Arizona State University), to name only a few. According to one of the team members, "Trauma Services is very excited about the opportunity to participate in the cognitive complexities study. This endeavor represents our initial effort to enter the realm of clinical research, the results of which we expect will enhance the level of care we deliver to our trauma patients as we reach towards Designation as a Level I Trauma Center through the American College of Surgeons committee on Trauma." Cognitive complexities research will encompass trauma, ICU and the SimET Center at Banner Good Samaritan Medical Center.

Banner Health Research Institute

Our Values

We Value:

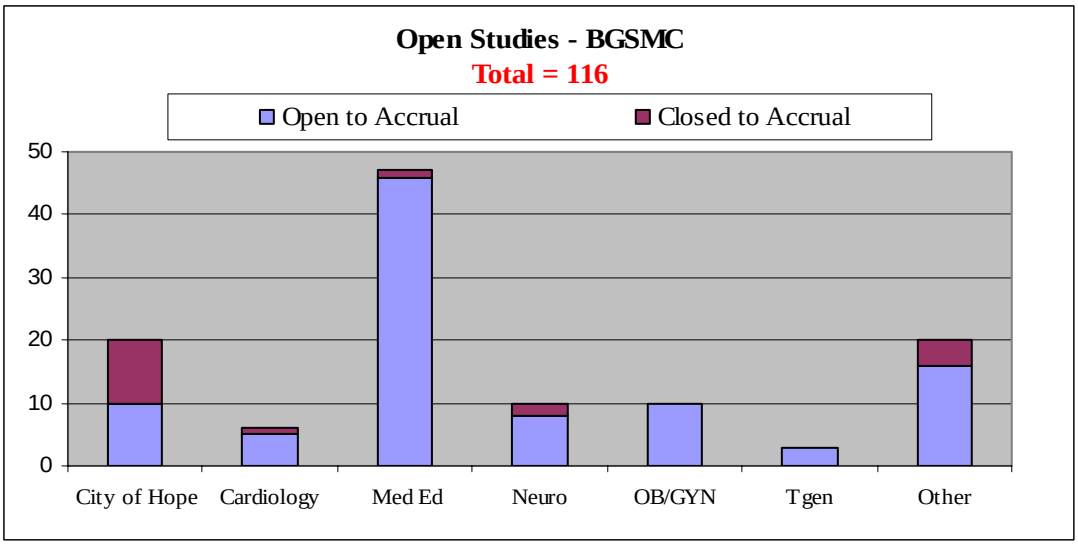
People, Subjects, Investigators, Sponsors, and Collaborative Partners… *by treating them with respect, beneficence and justice.*

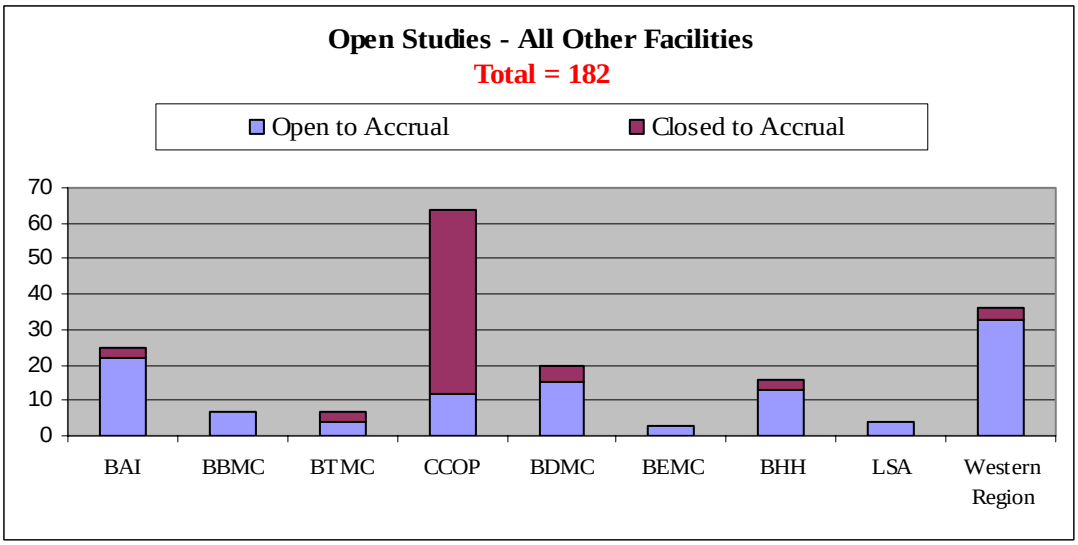
Excellence… *by assuring human subject protection and research compliance and striving for the highest quality customer service.*

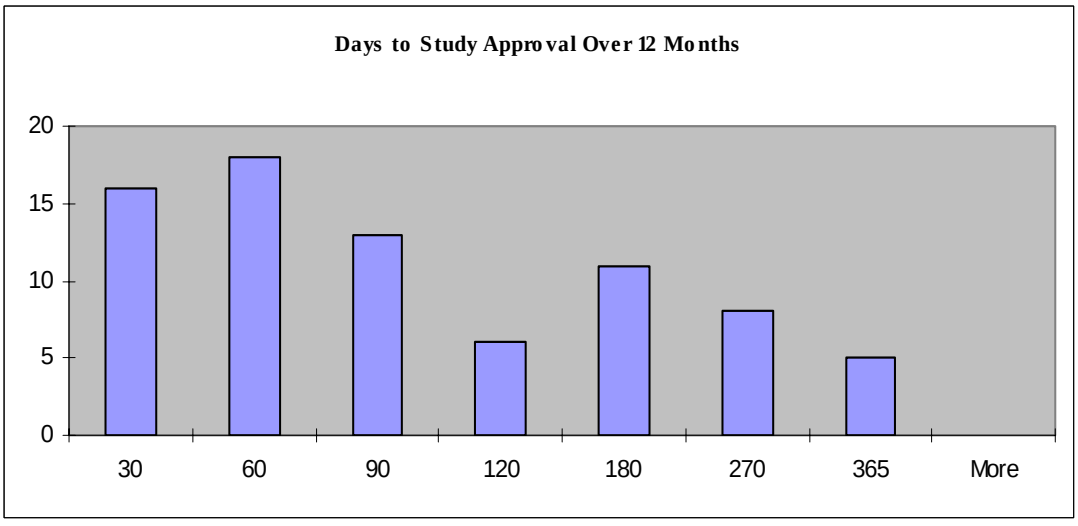
Results… *by contributing to the advancement of medical science and the improvement of patient care.*

Dashboard Reports (data through March 31, 2008)

Data provided by Banner Health Research Institute Finance





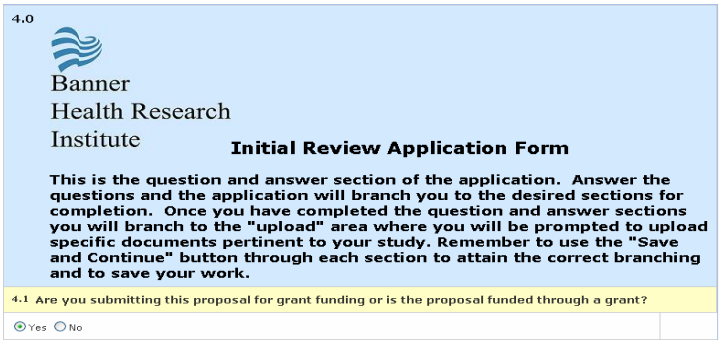


Integrated Research Information System (iRIS): Tips & Tricks

Author: Peggy Yena, BS MT (ASCP) SH, CLS (NCA), Systems Consultant, Banner Health Research Institute

New Grants Sections

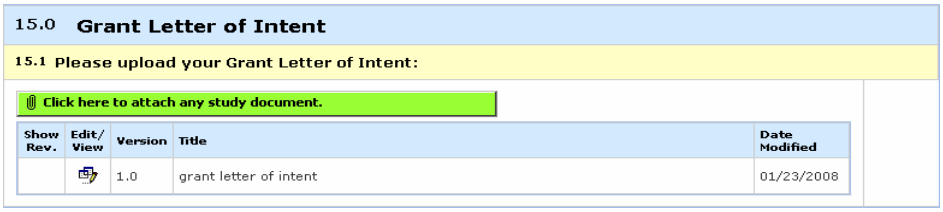
Did you know that we have added new Grants Sections to the application to accommodate studies funded by grants? At the beginning of the question section of the Application (4th Section), there is a new question "Are you submitting this proposal for grant funding or is the proposal funded through a grant?" If the question is answered "Yes", then the application will branch you to the new Grants Sections.

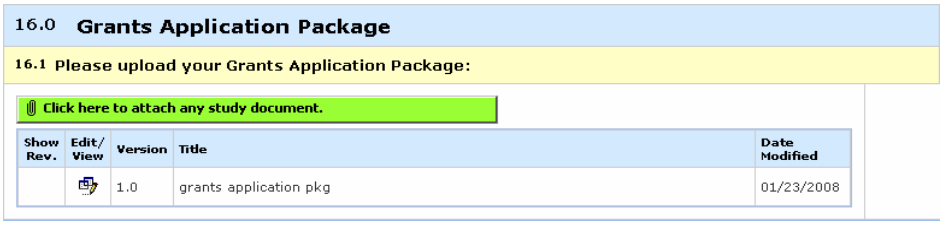


The new Grants Sections added to the "question" portion of the application include the following:

- Grant Letter of Intent Section
- Grant Pre-Award Section
- Grant Award Outcome Section
- Grant Post-Award Outcome Section

Additionally, there are two new upload sections called "Grant Letter of Intent" and "Grants Application Package". Once you complete the question sections of the application, the system will automatically branch you to these upload sections.





New Document Categories

There are new document categories to accommodate the new Grants upload sections. The document category is what you select in the category drop down box when you are uploading a document.

The Following are the new document categories:

- Grant Letter of Intent
- Grants Application Package
- Notice of Grant Award

Children's Oncology Group (COG) research team members at Banner Children's Hospital at Banner Desert Medical Center

Front Row L to R: Mali Cotton, RN; Lisa Dicks, PharmD; Jane Perlstein, RN; Val Schwehr, RN

Back row L to R: Steve Abella, MD; Maureen Cahill, RN, MSN; Hardeo Panchoosingh, MD/COG PI; James Williams, MD; Laurie Smith, RN, MSN

Banner Health Research Institute

Banner Health Research Institute
926 E. McDowell Road, Ste 122
Phoenix, Arizona 85006