Banner Health®

POLICY and PROCEDURE

TITLE: Research Conflict of Interest - Disclosure, Review & Management			
Number: 9163		**Version: 9163.6**	
Type: Administrative		**Author: Jeremy Stoloff, JD, MS**	
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Replaces:			
Approved by: Administrative Policy Committee, Senior Management Team			

TITLE: *Research Conflict of Interest – Disclosure, Review & Management*

I. Purpose/Expected Outcome:

A. To establish standards for the disclosure, review and management of conflicts of interest in Research at Banner Health and any of its consolidated subsidiaries (Banner Health and each of its consolidated subsidiaries may be referred to as "BH").

B. To ensure that the design, conduct, review, oversight and publication of Research at BH will not be biased by Conflicts of Interest.

II. Definitions:

A. **Conflict of Interest (COI):** For the purposes of this policy there shall be a rebuttable presumption that a Reportable Significant Financial Interest is a Conflict of Interest (see Part II.L. of this Policy). Such presumption can be overcome by a determination by the Conflict of Interest Committee or the designated BH officials set forth in this Policy. Additionally, the following shall also constitute types of Conflicts of Interest:

1. Investigator COI: Any situation in which financial or other personal considerations may compromise or have the appearance of compromising an Investigator's professional judgment in conducting Research, reporting Research, publishing Research, overseeing Research, or protecting a human subject in accordance with applicable law and regulation.

2. Covered Individual COI: Any situation in which financial or other personal considerations may compromise or have the appearance of compromising a Covered Individual's professional judgment in conducting Research, reporting Research, reviewing Research, publishing Research, overseeing Research, or protecting a human subject in accordance with applicable law and regulation.

3. Institutional COI: Any financial interest of BH, or an official acting within his or her authority on behalf of BH, that might affect, or reasonably appear to affect, BH processes for conducting Research, reporting Research, reviewing Research, publishing Research, overseeing Research, or protecting a human subject in accordance with applicable law and regulation.

4. Institutional Review Board Member COI: any situation in which financial or other personal considerations may compromise or have the appearance of compromising an IRB member's professional judgment in reviewing and overseeing human subject Research in accordance with applicable law and regulation. An IRB member is presumed to have a COI if:

a. He/she is acting as an Investigator, co-investigator, sub-investigator or support staff of the Research or is responsible for the design, conduct, reporting or publication of the Research;
b. He/she has a financial or business relationship to the Investigator, sponsor or Research (an IRB member's BH-employment status shall not, by itself, constitute a COI);
c. He/she is a subordinate, by contract, employment or professional position of the Investigator, sponsor or BH department conducting the Research;
d. He/she has a financial interest in the Research; or
e. He/she has an interest that may conflict with his or her ability to objectively review the Research.

B. **Conflict of Interest Committee (COIC):** A committee, appointed by the Human Protections Administrator, consisting of three (3) voting committee members with the following qualifications: (1) a member of the BH Legal Department or BH Compliance Department with regulatory, compliance or ethics experience, (2) an employee of BH who is not part of the Research Office or affiliated with the BH facility performing the Research, and (3) an employee of BH with Research ethics experience. The Human Protections Administrator may appoint additional voting members where such appointment(s) will enhance the COIC's quality of review and/or efficiency.

C. **Conflict of Interest Official (COI Official):** The Human Protections Administrator as specified in BH's Federal Wide Assurance (FWA) or such other individual as may be appointed by the Executive Vice President/Chief Medical Officer of BH. The COI Official may assign, in writing or by electronic mail, some or all of their obligations under this policy to one or more designees.

D. **Conflicted Party:** An Investigator or other Covered Individual with a Conflict of Interest or a Covered Individual reporting/associated with an Institutional COI.

E. **Covered Individual:** Any employees (full or part time, or non-salaried), staff, students, fellows, trainees, independent contractors, their agents or an administrator who, within the scope of their position within BH or subject to BH's designated IRB, conducts, reports, oversees, or publishes Research. Covered Individual includes a related trust, organization or other enterprise in which a person or a person's Immediate Family Member, alone or together, has an interest. Covered Individual includes their Immediate Family Member. The Investigator is a Covered Individual. Additionally, an Investigator who is a physician has medical privileges (through Medical Staff Services) at the BH facility, and who is conducting Research at such BH facility is a Covered Individual. Where the COI Official believes that an Investigator should not be considered a Covered Individual the COI Official shall obtain a waiver with regard to such Investigator in accordance with Article IV.G of this policy. An IRB Member is a Covered Individual.

F. **Financially Interested Company:** A commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the Research. This term includes the sponsor of the Research or the manufacturer of the investigational product. This term also includes any entity acting as the agent of a Financially Interested Company.

G. **Immediate Family Member:** The spouse and dependent children of the individual.

H. **Investigator:** A principal investigator, co-investigator, sub-investigator, researcher or an individual with a clinical supervisory function who is responsible for the conduct, reporting, or oversight of the Research. An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

I. **Institutional Review Board (IRB) Member:** A member of BH's IRB.

J. **Research:** The following shall constitute "Research" for the purposes of this policy:
1. A systematic investigation, including Research development, testing and evaluation, designed to develop or contribute to generalizable knowledge;

2. Any study of a drug, device or biologic in humans submitted in a marketing application or reclassification petition subject to FDA regulations;

3. Any Research or Research procedure involving human subjects or the use of the human samples/materials for the development and evaluation of therapies such as diagnostic test, drug therapies, or medical devices. It includes clinical studies, evaluative Research, epidemiological studies and clinical trials;

4. The conduct of Research, meaning, with respect to a Research protocol, designing Research, directing Research or serving as the Investigator, enrolling Research subjects (including obtaining subjects' informed consent) or making decisions relating to eligibility to participate in Research, analyzing or reporting Research data, or submitting manuscripts concerning the Research for publication.

K. **Research Office:** Banner Research (BR), the BH office responsible for Research ethics, compliance and transactional processing.

L. **Reportable Significant Financial Interest**:
1. A financial interest consisting of one or more of the following interests of a Covered Individual (e.g., Investigator) that reasonably appears to be affected by the Research and/or in a Financially Interested Company:
   a. With regard to any **publicly traded** Financially Interested Company, a Reportable Significant Financial Interest exists if the value of any remuneration received from the Financially Interested Company in the twelve months preceding the disclosure and the value of any equity interest in the Financially Interested Company as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
   b. With regard to any **non-publicly traded** Financially Interested Company, a Reportable Significant Financial Interest exists if the value of any remuneration received from the Financially Interested Company in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Covered Individual holds any equity interest (e.g., stock, stock option, or other ownership interest); or
   c. Intellectual property rights and interests (e.g., patents or copyrights);

2. Reportable Significant Financial Interest also includes occurrences of any reimbursed or sponsored travel by a Financially Interested Company. This does ***not*** apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a Research institute that is affiliated with an institution of higher education. This also does ***not*** apply to travel if ***both*** of the following criteria are met: (a) the travel is done in preparation for a specific FDA

regulated clinical trial where the Covered Individual is an Investigator or member of the Research team which will conduct the clinical trial; and (b) where the Covered Individual is not compensated for their attendance (i.e., consulting fee, stipend, or professional fee for time dedicated to the travel). The actual cost of reasonable transport, food and hotel accommodations are not considered "compensation" for the purpose of this Part II.L.2 (though other policies, procedures, applicable law and regulation may apply).

3. Reportable Significant Financial Interest does ***not*** include the following types of financial interests: salary paid by BH to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by BH; income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a Research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a Research institute that is affiliated with an institution of higher education. Reportable Significant Financial Interest does ***not*** include payments to BH, or via BH to the Covered Individual, that are directly related to reasonable costs incurred in the conduct of Research as specified in a BH-approved agreement. This Part II.L.3 does not include (i.e., does not except) royalties relating to the Research.

III. Policy:

A. **Requirement for identification and management of Conflicts of Interest in Research:** This policy is intended to identify and manage any Investigator, Institutional, Research personnel or IRB member financial interests that may affect the design, conduct, oversight, publishing or reporting of Research conducted at BH. The identification and management of Conflicts of Interest serves to protect BH's patients and others who participate as Research subjects.

B. **Scope of Policy:** This policy applies to all Research conducted at BH regulated by 21 CFR 50 & 56, 45 CFR 46 and 45 CFR 160 & 164. This policy applies to all Research as defined by Part II.J of this policy. This policy applies to all members of BH's IRB. This policy also applies to BH as an organization and Covered Individuals acting within the scope of their employment and/or responsibilities within BH. An individual Research project may be subject to additional conditions or restrictions imposed by other state and federal law, regulation, or a regulatory, sponsoring or funding agency or entity. Research funded under Public Health Service grants, cooperative agreements and contracts are subject to additional conditions and restrictions beyond the scope of this policy (see 42 CFR 50 (Subpart F), 45 CFR 94 and the BH Policy: *Research Conflict of Interest Relating to PHS Grants, Cooperative Agreements & Contracts*). Where an Investigator is subject to the BH Policy: *Research Conflict of Interest Relating to PHS Grants, Cooperative Agreements & Contracts* (the "PHS COI Policy") and this policy with regard to a particular COI, the COI Official designated under the PHS COI Policy will apply the PHS COI Policy. The COI Official designated by this policy may choose to: (a) also apply the provisions of this policy, but only to the extent the two policies do not conflict; or (b) not apply the provisions of this policy where the COI Official designated by this policy determines that the goals of this policy are achieved with regard to the particular COI by implementation of the PHS COI Policy. This policy does not apply to COI's involving non-BH IRBs, external contracted IRBs, or their respective members.

C. **Basic Policy:** Covered Individuals shall exercise good faith, honesty, loyalty and fidelity in all Research at BH. Covered Individuals will refrain from and avoid Conflicts of Interest of any type or the

appearance of Conflicts of Interest of any type. Each Covered Individual shall disclose any COI immediately upon learning of the circumstances that constitute, or give the appearance of constituting, a COI, whether such COI is a Covered Individual COI, an Investigator COI, an Institution COI or an IRB Member COI.

D. **Review, Approval and Management of Conflicts of Interest**:

1. Review, Approval and Management. The COIC will review all ***COI Disclosure Forms*** which indicate the presence of a COI and decide whether the Conflicted Party should be permitted to conduct, review, oversee, publish, report or otherwise participate in the Research and in what capacity. The COIC should prohibit any Conflicted Party from conducting, reviewing, overseeing, publishing or otherwise participating in the Research unless the provisions of the COI management plan will eliminate circumstances that would cause an independent observer to reasonably question whether the Conflicted Party's professional actions or decisions in the Research are determined by considerations of personal gain, financial or otherwise.

2. COI Management Plan. If the COIC permits the COI, the COIC shall create a COI management plan and such plan shall be enforced by the COI Official. In developing a COI management plan, the COIC will consider options that will eliminate or manage the COI. The COIC will consider the COI's potential impact on the design, conduct, review, oversight, reporting, publication and integrity of the Research. The COIC will consider the COI's potential impact on the Research subject, including such Research subject's health, safety or welfare. The COI management plan should eliminate circumstances that would cause an independent observer to reasonably question whether the Conflicted Party's professional actions or decisions in the Research are determined by considerations of personal gain, financial or otherwise. The COIC will consider the nature of the Research, the magnitude of the COI, the degree to which it is related to the Research, the extent to which the COI could be directly and substantially affected by the Research, and the degree of risk to the Research subjects.

3. Remedial Options for COI Management Plan. The COIC may adopt one or more of the following options for its COI management plan as appropriate for the circumstances creating the COI, or may adopt an option not listed here as appropriate in its best judgment:
   a. Monitoring of Research by independent reviewers, such as a data and safety monitoring committee or similar monitoring body;
   b. Modification of the Research, Research protocol or safeguards in the Research to prevent the introduction of bias, such as "blinding" the Investigator and Research team, randomly selecting Research subjects or independent corroboration of Research results;
   c. Requiring an independent person or organization to administer the informed consent process and present the informed consent form (ICF) to the Research subjects;
   d. Monitoring of the informed consent and enrollment process;
   e. Disclosure of the COI to the Research subjects; noting, however, that where a COI may directly affect the health, safety or welfare of the Research subjects, disclosure cannot be the sole method of managing a COI;
   f. Disclosure of the COI to the public;
   g. Requiring the Conflicted Party to divest the interest creating the COI as a condition for approving the Research;
   h. Requiring an independent/non-interested party to hold or administer the interest creating the COI;
   i. Requiring the Conflicted Party to sever the relationships that created the COI (such as resignation from a board of directors);

j. Disapproval of Research or termination of the Research if underway, or the portion of the Research that could be affected by the COI;
k. Modification of the role of particular Research staff or Covered Individuals;
l. Disclosure of the COI to those publishing the results of the Research;
m. Review of the COI management plan or the COIC's decision by an independent person or organization.

4. COIC Action. The COIC shall make formal decisions and create a COI management plan by consensus of the members of the COIC.

5. Retention of Experts. The COIC may retain experts to provide advice and guidance with regard to its review of the COI. Additionally, the COIC may request an expert memorandum from any Covered Individual or any other expert in order to obtain advice and guidance for its review of the COI. The COIC may accept or reject such expert advice and guidance, in its sole discretion.

6. COIC Member COI. In the event the COIC member has a COI, the COIC member shall recuse himself from the COIC review of the COI. In the event of such recusal the COI Official shall designate a replacement COIC member in accordance with the COIC membership requirements stated above.

E. **IRB Review of the COI:**

1. Disclosure to the IRB. Where there is IRB oversight over the Research, the COI Official will forward the completed ***COI Disclosure Form*** and ***COI Management Plan*** to the IRB for its consideration prior to the IRB's final approval of the Research and prior to initiation of the Research. Where IRB approval has already occurred, the foregoing documents will be submitted to the IRB and the IRB may reevaluate its approval. The Investigator shall assure that Research is not initiated prior to the IRB's consideration of the ***COI Disclosure Form*** and ***COI Management Plan***.

2. IRB Discretion. If the IRB disagrees with the ***COI Management Plan*** the IRB may decline to approve the Research (e.g., the IRB may decline to approve the Research if the IRB finds the ***COI Management Plan*** to be insufficient to adequately protect the Research subjects, fails to maintain the integrity of the Research, or fails to meet any approval criteria of the IRB). Changes to the ***COI Management Plan*** may be suggested by the IRB to the COIC, though such suggestions will not be prescriptive upon the COIC. The IRB remains free to make all determinations and decisions as specified by law or regulation (e.g., 21 CFR 50 & 56, 45 CFR 46). The COIC remains free to set a ***COI Management Plan*** under the auspices of BH (e.g., 21 CFR 56.112 and 45 CFR 46.112).

3. Informed Consent. The IRB should evaluate the COI materials presented and should consider implementing the most effective means of informing Research subjects of the COI. The IRB should review the COI materials presuming that any COI should be disclosed to the Research subject in the ***Informed Consent Form*** (ICF) and/or in a medium most conducive to the Research subject's understanding of the COI.

IV. Procedure/Interventions:

A. Covered Individual Conflict of Interest (e.g., Investigator COI)

1. Disclosure

a. The Conflicted Party will submit a ***COI Disclosure Form*** to the electronic mail address set forth in this policy, where the Conflicted Party will describe the COI.

b. The ***COI Disclosure Form*** (and accompanying material, if any) will be directed to the COI Official.

2. COI Official & COIC Review Procedure
   a. The COI Official will evaluate whether the ***COI Disclosure Form*** indicates a COI; if so, the COI Official will transfer the form and other relevant materials to the COIC.
   b. Prior to the initiation of the Research, the COIC will implement Section III.D. of this policy, including but not limited to, review the designated ***COI Disclosure Form*** (and accompanying material, if any) and determine if, in its judgment, a COI is present, and if so prescribe a COI management plan to the COI Official. The COIC may, in its discretion, contact a Covered Individual or any other individual, to facilitate its consideration of the COI and creation of the COI management plan.

3. Appeal of COIC's Decision & COI Management Plan
   a. The Investigator, Covered Individual and the Covered Individual representing an Institutional COI may appeal the COIC's decision and COI Management Plan. Within thirty (30) days of the COIC's decision an appellant should submit written notice of a request to appeal, justification for the appeal, and supporting documentation to the COI Official. The request for appeal will be evaluated by a committee composed of the following members: the BH General Counsel, BH Vice President of Ethics & Compliance/Chief Compliance Officer, and an individual, selected by the two prior members, with expertise in Research ethics ("COI Appeal Committee"). If an appeal is granted the COI Appeal Committee will review the appellant's written submission and/or have the appellant present to the committee in person or by a medium selected by the committee (e.g., telephone or video-conference). The COI Appeal Committee may also have the COIC, COI Official and any Covered Individual present or provide information to the committee. The following shall be considered a final determination of the COI Appeal Committee: the COI Appeal Committee's written final decision after consideration of the appeal; or, the COI Appeal Committee's denial of appeal.

4. Continuing Disclosure Obligation
   a. If the information in the original ***COI Disclosure Form*** changes at any time during the Research, the Conflicted Party will provide any amendments, deletions or additions to the original ***COI Disclosure Form*** to the COIC as soon as possible by submitting a new or revised ***COI Disclosure Form*** to the electronic mail address set forth in this policy.
   b. In response to any amendments, deletions, or additions to the ***COI Disclosure Form***, the COIC will follow the COIC review procedures set forth above.

5. Sanctions for Noncompliance
   a. If a Conflicted Party does not disclose a COI, fails to complete the ***COI Disclosure Form*** in an accurate and truthful manner, or fails to update the ***COI Disclosure Form*** as required by this policy, the COIC may take appropriate actions, including but not limited to:
      i. Afford the Conflicted Party an opportunity to explain the alleged failure to disclose the COI;
      ii. Afford the Conflicted Party an opportunity to correct the alleged failure to disclose the COI;
      iii. Recommend disciplinary and corrective action to the COI Official, including but not limited to:
         (i) Limitations to the Conflicted Party's conduct of Research at BH or limitations to the Conflicted Party's duties related to Research at BH;

(ii) Referral to the medical executive committee for initiation of actions related to medical staff privileges, if applicable;
(iii) Referral to BH's human resources department for initiation of employment action, if applicable.

b. The COI Official will review the COIC's recommendation, make a final decision of the sanction and enforce such sanction.
c. Notwithstanding the foregoing or anything contained in this policy, the BH General Counsel and/or BH Vice President of Ethics and Compliance/Chief Compliance Officer may alter the implementation of this Part 5 (e.g., alter or overrule the COI Official's final decision).

B. Institutional Conflict of Interest
1. Disclosure
a. A Covered Individual who has recognized an Institutional COI will submit a ***COI Disclosure Form*** to the electronic mail address set forth in this policy, where the Conflicted Party will specify the presence of any COI.
b. The ***COI Disclosure Form*** (and accompanying material, if any) will be directed to the COI Official. The COI Official shall implement the procedures of Part IV.A.2.a of this policy.

2. COIC Review Procedure, Continuing Disclosure Obligations, and Sanctions for Noncompliance
a. The procedures of Part IV.A.2-4 of this policy shall be implemented.

C. IRB Member Conflict of Interest
1. Disclosure
a. Before each meeting of the IRB, the IRB members will be polled to determine whether they have a COI relating to the protocols being reviewed during that meeting. If information on an existing ***COI Disclosure Form*** has changed, the IRB member will fill out a new ***COI Disclosure Form***.

2. Procedure
a. IRB members with a COI may not participate in the IRB review of the Research except to provide information requested by the IRB as an outside interviewee. Additionally, an IRB member with a COI is prohibited from participating in any deliberation or voting on the Research and may not be present during any such deliberation or voting.
b. The IRB member's name must be recorded for each applicable vote indicating the member was not voting and was not present for the vote. The IRB member cannot count toward quorum.
c. The IRB Chair and/or IRB coordinator will assure that the foregoing procedure is enforced. Where the IRB Chair and/or IRB coordinator have a COI a BH delegate will be assigned to assure the foregoing procedure is complied with.

D. Arizona Medical Board & Arizona Board of Osteopathic Examiners in Medicine & Surgery
1. For Research in the State of Arizona, where an Investigator is a physician subject to the Arizona Medical Board and/or the Arizona Board of Osteopathic Examiners in Medicine & Surgery, the following shall apply ("patient" and "study subject" shall be synonymous for the purposes of this Article):
a. Where Investigator is subject to the Arizona Medical Board and where the Investigator has a direct financial interest in a separate diagnostic or treatment agency or in nonroutine goods or services that the patient is being prescribed Investigator shall disclose such facts to the patient on a form that is prescribed by the Board and that is dated and signed by the patient or guardian acknowledging that the patient or guardian has read the form and understands such facts. Investigator shall also describe on the form if the prescribed treatment, goods or services are

available on a competitive basis (A.R.S. 32-1401(27)(ff); see: http://www.azleg.gov/FormatDocument.asp?inDoc=/ars/32/01401.htm&Title=32&DocType=ARS) .

i. The form prescribed by the board can be found at: http://www.azmd.gov/PhysicianCenter/PatientNotice.aspx.

b. Where Investigator is subject to the Arizona Board of Osteopathic Examiners In Medicine & Surgery Investigator shall not refer a patient to a diagnostic or treatment facility or prescribe goods and services without disclosing, on a form prescribed by the Board, that the physician has a direct pecuniary interest in the facility, goods or services to which the patient has been referred or prescribed. Investigator shall describe on a form prescribed by the Board a direct financial interest in a prescribed treatment, good or service if the treatment, good or service is available on a competitive basis. The form must be dated and signed by the patient or guardian acknowledging that the patient or guardian has read the form and understands such facts (A.R.S. 32-1854 (33) and (47); see: http://www.azleg.gov/FormatDocument.asp?inDoc=/ars/32/01854.htm&Title=32&DocType=ARS).

i. The form prescribed by the board can be found at: https://www.azdo.gov/Files/Financial%20Interest%20Disclosure%20Form.pdf.

E. Investigator COI Disclosure Form Submission prior to Research

1. An Investigator shall submit a ***COI Disclosure Form*** to the electronic mail address set forth in this policy or as otherwise directed by the COI Official prior to the Research.
   a. Where the Investigator does not have a COI (e.g., a Reportable Significant Financial Interest or Investigator COI) they shall complete the form in a manner which identifies the Research, select/check the appropriate box on the ***COI Disclosure Form*** indicating the absence of such interests, sign and date the form, and submit the form to electronic mail address set forth in this policy or as otherwise directed by the COI Official.

F. Retention of Documentation

1. BH will maintain all documentation noted in this Policy and all other documentation related to COI indefinitely, unless written permission to destroy/dispose of the documentation is obtained from the COI Official. BH will maintain all records as required by applicable law and regulation.

G. Corporate Oversight

1. The BH General Counsel and/or BH Vice President of Ethics & Compliance/Chief Compliance Officer may, through written instruction or directive, vary the application of some or all components of this policy.

V. Procedural Documentation:

A. ***Form: COI Disclosure Form***

VI. Additional Information:

A. Electronic Mail Address for submission of COI Disclosure Form: ResearchConflictofInterestSubmittal@bannerhealth.com

B. Questions with regard to this Policy should be directed as follows:

1. Sue Colvin
   Banner Research Regulatory Affairs Senior Manager / Conflict of Interest Official
   Phone: (602) 839-4583

sue.colvin@bannerhealth.com

VII. References:

A. 21 Code of Federal Regulations (CFR) Part 54
B. 45 CFR Part 46
C. 45 CFR 160
D. 45 CFR 164
E. Association of American Medical Colleges, Task Force on Financial Conflicts of Interest in Clinical Research, Protecting Subjects, Preserving Trust, Promoting Progress (2001)
F. Association of American Medical Colleges, Task Force on Financial Conflicts of Interest in Clinical Research, Protecting Subjects, Preserving Trust, Promoting Progress II (2002)
G. Arizona Revised Statutes, Medicine & Surgery, Arizona Medical Board, Chapter 13, Article 1, Title 32-1401 (27) (ff)

VIII. Other Related Policies/Procedures:

A. ***Policy: Conflict of Interest (#2794)***
B. ***Policy: Research Conflict of Interest Relating to PHS Grants, Cooperative Agreements & Contracts (#13245)***

IX. Keywords and Keyword Phrases:

A. COI
B. COIC
C. Conflict of Interest
D. Conflict of Interest Committee
E. Covered Individual Conflict of Interest
F. Financial Conflict of Interest
G. Institutional Conflict of Interest
H. Institutional Review Board
I. IRB
J. Research
K. Research Conflict of Interest
L. Study Conflict of Interest

X. Appendix:

A. COI Disclosure Form

Banner Health
Research Related Document
Conflict of Interest Disclosure Form
("COI Disclosure Form")

Completion of this form is mandatory for all Investigators prior to the Research and all and all Conflicted Parties, as directed by the BH *Research Conflict of Interest - Disclosure, Review & Management* policy (Policy # 9163).

PART A

Your role on the Research/clinical trial/human subjects Research:

- ☐ Investigator
- ☐ Covered Individual (who is not also the Investigator)
- ☐ Covered Individual reporting an Institutional Conflict of Interest
- ☐ Institutional Review Board Member
- ☐ Other: _____

Your name: Last: _____First:_____ MI:_____

Phone:_____ **Email**: _____

Business Address: _____

Employer Name: _____

Department Name: _____

Research Project Title: _____

_____

Relevant BH/BR/Project Identification Number(s):_____

_____

This submission is for a:

- ☐ New Research project (Deadline to initiate project: _____)
- ☐ Continuation of an existing Research project
- ☐ Update to previous COI Disclosure Form

Describe the Conflict of Interest (COI) (e.g., a Reportable Significant Financial Interest, Investigator COI, Covered Individual COI, Institutional COI, and/or IRB Member COI):

☐ I am an Investigator and I do not have a *Reportable Significant Financial Interest* or an *Investigator COI*.

Attach relevant documents to this form.

My signature below indicates that 1) I have read and understand the BH's *Research Conflict of Interest - Disclosure, Review & Management* policy (Policy # 9163); 2) I have made all required disclosures required by the Policy # 9163; and, 3) I will comply with any conditions or restrictions imposed by BH to manage, reduce or eliminate the COI regarding this Research.

_____ _____

Your Signature Date

PART B:
TO BE COMPLETED BY COI OFFICIAL

Disclosure form received on: _____ *(date)*

Signed :_____
COI Official

Print Name: _____

Date: _____

A copy is to be retained by the COI Official in accordance with BH policy # 9163.