



<b>TITLE: Research Financial Conflict of Interest Policy</b>			
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<b>Type: Administrative</b>		<b>Author: Katy Gilbert</b>	
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<b>Population (Define): All Employees</b>			
<b>Replaces:</b>			
<b>Approved by: Administrative Policy Committee, Senior Management Team</b>			

**TITLE: Research Financial Conflict of Interest Policy**

**I. Purpose/Expected Outcome:**

- A. The purpose of this conflict of interest policy is to establish standards for the disclosure, review and management of conflicts of interest in research at Banner Health (BH) and prevent the professional and personal interests of Banner Health (BH) Personnel from influencing the performance of their duties on behalf of Banner Research. This policy requires the disclosure of actual or potential conflicts. The policy establishes standards for the disclosure, review and management of conflicts of interest in research at Banner Health (BH) and any of its consolidated subsidiaries (BH and each of its consolidated subsidiaries is referred to as “BH”) in accordance with Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F and Title 45 Code of Federal Regulations Part 94.

**II. Definitions:**

- A. **Conflict of Interest (COI)** means an interest that might affect, or might reasonable appear to affect, the judgment or conduct of any director, officer, committee member or executive manager in an adverse manner.
- B. **Conflict of Interest Committee (COIC)** means the committee who will review and approve management plans when the Administrative or Science Director has a conflict with a specific case, provide advice and guidance to the Administrative and Science Directors as needed, monitor compliance with the management plans, and review appeals from investigators/employee. Members of the COIC include the Banner Research Chief Operating Officer, the Research Regulatory Affairs Senior Manager and the Director of the Office of Grant Strategy Development and Administration.
- C. **Conflict of Interest Official (COIO)** means the Administrative Director who will solicit and review disclosures of significant financial interests to determine whether those interests represent a financial conflict of interest. Should a financial conflict of interest exist, the Administrative Director and the Chief Science Officer will work with the Investigator/employee to develop a management plan to reduce or eliminate the conflict.

- D. **Contractor** means an entity that provides property or services for the direct benefit or use of the Federal Government. BH shall be a contractor where: (1) BH submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or (2) BH assumes the legal obligation to carry out the research required under the contract.
- E. **Disclosure of significant financial interests** means an Investigator's or an employee's disclosure of significant financial interests to Banner Research (see article VIII of this policy).
- F. **FCOI report** means Banner Health's report of a financial conflict of interest to a PHS Awarding Component.
- G. **Financial conflict of interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research and/or the negotiation of contracts and the purchase of supplies and services.
- H. **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.
- I. **HHS** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated including, but not limited to the National Institutes of Health (NIH).
- J. **Investigator** means the principal investigator or project director and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding; which may include, for example, collaborators or consultants. For purposes of the requirements of this policy relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.
- K. **Investigator's Institutional Responsibilities** means an Investigator's or employee's professional responsibilities on behalf of Banner Health, which may include: activities such as purchasing, contracting for services, research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- L. **Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- M. **PHS** means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

- N. **PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50 Subpart F.
- O. **Principal Investigator (PI) / Project Director (PD)** means a Principal Investigator or Project Director of a PHS-funded project; the PI/PD is included in the definitions of senior/key personnel and Investigator in this policy.
- P. **Public Health Service Act** or PHS Act means the statute codified at 42 U.S.C. 201 et seq.
- Q. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- R. **Senior/Key Personnel** means the PI/PD and any other person identified as senior/key personnel by Banner Research in the grant application, progress report or any other report submitted to the PHS by BH under this policy.
- S. **Significant Financial Interest**
1. Financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's/employee's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's or employee's institutional responsibilities:
    - a. With regard to any **publicly traded entity**, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity 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** entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator or employee (or the Investigator's or employee's spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
  2. Significant financial interest also includes occurrences of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator or employee and not reimbursed to the individual so that the exact monetary value may not be readily available), related to an Investigator's or employee's institutional responsibilities. 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.
  3. Significant financial interest does ***not*** include the following types of financial interests: salary, royalties, or other remuneration paid by BH to the Investigator or employee if the individual is currently employed or otherwise appointed by BH, including intellectual property rights assigned to BH and agreements to share in royalties related to such rights; any ownership interest in BH held by the individual if BH is a commercial or for-profit organization; 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.
- T. **Small Business Innovation Research (SBIR) Program** means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For the purposes of 42 CFR Part 50 Subpart F the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

### III. Policy:

- A. It is BH policy to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under Public Health Service (PHS) grants or cooperative agreements (or contracts, as applicable) will be biased by any conflicting financial interest of an Investigator.
- B. This Policy is applicable where BH applies for PHS grants or cooperative agreements (or contracts, where applicable) for research and to each Investigator who is planning to participate in, or is participating in, such research; provided, that this policy does not apply to SBIR Program Phase I applications (see definitions below)

- C. All Banner Health investigators and employees who participate in sponsored projects must complete training Conflict of Interest Training prior to engaging in research related to any PHS-funded grant and prior to commencing an activity involving purchases of supplies, services and/or contracting at least every four years. The training may have to be taken again immediately under the following circumstances:
1. BH's FCOI policies change in a manner that affects Investigator/employee requirements;
  2. An Investigator/employee is new to Banner Health; or
  3. Banner Health finds an Investigator/employee noncompliant with the FCOI policy or management plan.
- D. **Disclosure** Each investigator/employee who is planning to participate in the PHS-funded research or planning to assume direct or indirect responsibility for purchases of supplies, services and/or contracts must disclose to a Grant Manager or the Director of the Office of Grant Strategy Development and Administration (see article VIII of this policy) his or her significant financial interests as well as those of their spouse/domestic partner and/or dependent children no later than the time of application for PHS-funded research or prior to commencing an activity involving purchases of supplies, services and/or contracting, and annually thereafter. The Significant Financial Interest can be only one of the items listed in the Significant Financial Interest definition. Intellectual property rights and interests such as patents and copyrights, upon receipt of the income related to such rights and interests will also be considered a significant financial interest.

#### **IV. Procedure/Interventions:**

- A. BH Responsibilities Regarding Financial Conflict of Interests of Investigators
1. COI Official & Duties. The Director of the Office of Grant Strategy Development and Administration will:
    - a. Obtain reasonable assurance that each Investigator conducting research at BH is informed of this policy by sending notice of this policy to all known Investigators after the policy's effective date and posting this policy on BH's Policy & Procedure database;
    - b. Obtain reasonable assurance that Investigators carrying out PHS-funded research through subgrantees, contractors, or collaborators with BH comply with this policy or their own policy which is compliant with 42 CFR 50, Subpart F and 45 CFR 94 through a written agreement; and providing such documentation to be maintained with award documentation.
    - c. Shall solicit and review financial disclosure statements from each Investigator who is planning to participate in or is participating in PHS-funded research:
      - i. Each Investigator covered by this policy will report all SFIs held by themselves, their spouse and dependent children to the COI Official;
      - ii. A ***Disclosure of Significant Financial Interest Form*** must be completed and submitted by the applicable Investigator prior to the submission of an application for PHS grant or cooperative research agreement (or contract, as applicable).

- iii. Disclosures will be made by the Investigator completing the ***Disclosure of Significant Financial Interest Form***, and sent to the COI Official for each new award;
2. Certifications in PHS Applications for Funding (or contract proposals, as applicable)
- a. In any application for funding (under PHS grants, cooperative agreements or contracts, as applicable) BH shall certify that:
    - i. it in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
    - ii. Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests;
    - iii. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart;
    - iv. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and
    - v. Shall fully comply with the requirements of 42 CFR 50, Subpart F and 45 CFR 94.
- B. Investigator Responsibilities Regarding Conflicting Interests
- 1. Investigator shall:
    - a. Report all Reportable Significant Financial Interests (SFIs) or the lack thereof held by Investigator (where Investigator has a current award or pending application). Disclosures will be made by completing ***Disclosure of Significant Financial Interest Form*** and submitting to the COI Official for every new submission or when new SFIs are acquired;
    - b. Investigators/employees must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator/employee and not reimbursed to the Investigator/employee so that the exact monetary value may not be readily available), related to their institutional responsibilities. This disclosure requirement 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;
    - c. Any investigator/employee must submit an updated disclosure of significant financial interests annually, as part of the annual progress report, during the period of award. Such disclosure shall include any information that was not disclosed initially to Banner Health in accordance with this policy or in a subsequent disclosure of significant financial interest, and shall include updated information regarding any previously disclosed significant financial interest (i.e., the updated value of a previously disclosed equity interest);
    - d. Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research; and

- e. Comply with the instructions and directives (e.g., training and conflict of interest management plan) of the COI Official with regard to this policy.

C. Enforcement

1. Failure to comply with this policy may subject the Investigator to possible sanctions, which may include but are not limited to:
  - a. Formal warning;
  - b. Formal & documented Investigator-education
  - c. Letter to the Investigator's personnel file;
  - d. Suspension of certain research privileges;
  - e. Corrective action, up to and including termination of employment;
  - f. Notification to actual or potential funding agencies (which may also otherwise be required under this policy);
  - g. For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
  - h. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
  - i. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
  - j. Modification of the research plan;
  - k. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research or purchasing duties;
  - l. Reduction or elimination of the financial conflict of interest (e.g., sale of an equity interest); or
  - m. Severance of relationships that create the financial conflict.

- D. Appeal - The Investigator/employee may contest the determination of a financial conflict of interest and may appeal any conditions of the management plan to the conflict of Interest Committee. The COIC will have final decision-making authority in such cases.

E. Records

1. BH will maintain the ***Disclosure of Significant Financial Interest Form*** and other records of all financial disclosures and all actions taken by BH with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations [see <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl> (2012 version, refer to most current version)] For contracts, such retention shall be for three years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, Subpart 4.7 [see <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=a5710c655adb5ea980a81e47679821a8&rgn=div5&view=text&node=45:1.0.1.1.52&idno=45>. See 4.7 through 4.705-3 (2012 version, refer to most current version)st]. Records will be maintained by the COI Official. All disclosures and related

documentation are considered, within BH, to be confidential to the extent permitted by applicable law but see Article IV.E (below).

**F. Federal Agencies and RSFI Information**

1. The information disclosed by Investigator may be released to the funding agency representatives. HHS has asserted (in 42 CFR 50 Subpart F and 45 CFR Part 94) that HHS will maintain the confidentiality of all records of financial interests to the extent permitted by law.

**G. Reporting**

1. Prior to Banner Health's expenditure of any funds under a PHS-funded research project, BH shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's/employee's significant financial interest found by BH to be conflicting and ensure that BH has implemented a management plan in accordance with this policy and the regulations. In cases in which BH identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, BH shall not submit an FCOI report to the PHS Awarding Component.
2. Any FCOI report required shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of BH's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:
  - a. Project number;
  - b. PI/PD or Contact PI/PD if a multiple PI/PD model is used;
  - c. Name of the Investigator with the financial conflict of interest;
  - d. Name of the entity with which the Investigator has a financial conflict of interest;
  - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
  - f. Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
  - g. A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
  - h. A description of the key elements of BH's management plan, including:
    - i. Role and principal duties of the conflicted Investigator in the research project;
    - ii. Conditions of the management plan;
    - iii. How the management plan is designed to safeguard objectivity in the research project;
    - iv. Confirmation of the Investigator's agreement to the management plan;
    - v. How the management plan will be monitored to ensure Investigator compliance; and
    - vi. Other information as needed.

3. For any financial conflict of interest previously reported by BH with regard to an ongoing PHS-funded research project, BH shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. BH shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.
4. *New Personnel:* For any significant financial interest that BH identifies as conflicting subsequent to BH's initial FCOI report (e.g., upon the participation of an Investigator/employee who is new to the research project), BH shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest. BH will implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, of interest. Depending on the nature of the significant financial interest, BH may determine that additional interim measures are necessary with regard to the Investigator's/employee's participation in the PHS-funded research project and/or purchasing activities between the date that the financial conflict of interest or the Investigator's /employee's noncompliance is determined and the completion of BH's retrospective review.
5. *Untimely disclosure:* If BH identifies a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed or managed by BH (e.g., was not timely reviewed or reported by a subrecipient), the designated official shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so: implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.
6. BH is responsible for ensuring any subrecipient's compliance with the regulations and reporting identified financial conflicts of interests for subrecipient Investigators to the PHS awarding agency<sup>1</sup>. BH must incorporate as part of a written agreement with subrecipient terms that establish whether the Financial Conflict of Interest policy of BH or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or financial conflict of interest reporting requirements. BH is responsible for monitoring subrecipient's compliance with the financial conflict of interest regulations, management plans, and for reporting all identified financial conflicts of interest to the NIH prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

#### **H. Noncompliance and Retrospective Review**

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<sup>1</sup> §50.604(c) (1) – (2)

1. Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator/employee to disclose a significant financial interest that is determined by BH to constitute a financial conflict of interest; failure by BH to review or manage such a financial conflict of interest; or failure by the Investigator/employee to comply with a financial conflict of interest management plan, BH shall, within 120 days of BH's determination of noncompliance, complete a retrospective review of the Investigator's/employee's activities and the PHS-funded research project and/or purchasing responsibilities to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Such retrospective review shall be completed by the Conflict of Interest Committee.
2. BH's documentation of the retrospective review shall include, but not necessarily be limited to, all of the following key elements:
  - a. Project number;
  - b. Project title;
  - c. PI/PD or contact PI/PD if a multiple PI/PD model is used;
  - d. Name of the Investigator/employee with the FCOI;
  - e. Name of the entity with which the Investigator/employee has a financial conflict of interest;
  - f. Reason(s) for the retrospective review;
  - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  - h. Findings of the review;
  - i. Conclusions of the review; and
  - j. Management plan.
3. Based on the results of the retrospective review, if appropriate, BH shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, BH is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and BH's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, BH will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, BH may determine that additional interim measures are necessary with regard to the Investigator's/employee's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's /employee's noncompliance is determined and the completion of BH's retrospective review.

## **I. Remedies**

1. BH will establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator and employee compliance as appropriate, including such mechanisms, sanctions, and actions set forth in this policy.
2. If the failure of an Investigator/employee to comply with BH's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, BH shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.
3. The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and BH's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in BH's determination of a financial conflict of interest. BH is required to submit, or permit on-site review of, all records pertinent to compliance with this subpart.
4. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator/employee with a financial conflict of interest that was not managed or reported by BH as required by the regulations, BH shall require the Investigator/employee involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

**J. Public Accessibility**

1. BH will post its financial conflict of interest policy on its publically available website. Prior to BH's expenditure of any funds under a PHS-funded research project, BH shall ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to BH that meets the following three criteria: (1)The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy; (2) BH determines that the significant financial interest is related to the PHS-funded research; and (3) BH determines that the significant financial interest is a financial conflict of interest.
2. The information shall include, at a minimum, the following: the Investigator's/employee's name; the Investigator's/employee's title and role with respect to BH and/or the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. BH will note in its written response that the information provided is current as of the date of the correspondence and

is subject to updates, on at least an annual basis and within 60 days of BH's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

3. Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests for at least three years from the date that the information was most recently updated.

#### **K. Maintenance of Records**

1. BH will maintain records relating to all Investigator and employee disclosures of financial interests and BH's review of, and response to, such disclosures (whether or not a disclosure resulted in BH's determination of a financial conflict of interest) and all actions under BH's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.
2. BH will certify, in each application for funding to which the regulations apply, that BH (1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS; (2) Shall promote and enforce Investigator and employee compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests; (3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with the regulations; (4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator or employee disclosure of financial interests and BH's review of, and response to, such disclosure, whether or not the disclosure resulted in BH's determination of a financial conflict of interest; and (5) Shall fully comply with the requirements of 42 CFR 50, Subpart F and 45 CFR 94.

#### **V. Procedural Documentation:**

- A. *Form: Disclosure of Significant Financial Interest Form*

#### **VI. Additional Information:**

- A. Electronic mail address for submission of Disclosure of Significant Financial Interest Form: [Kathryn.Gilbert@bannerhealth.com](mailto:Kathryn.Gilbert@bannerhealth.com).
- B. Questions with regard to this Policy should be directed to [Kathryn.Gilbert@bannerhealth.com](mailto:Kathryn.Gilbert@bannerhealth.com).
- C. Title 42 CFR Part 50, Subpart F, "Responsibilities of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought" can be found at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f67ea01984581d3934103b5074c05500&rgn=div5&view=text&node=42:1.0.1.4.22&idno=42#42:1.0.1.4.22.6> or <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f67ea01984581d3934103b5074c05500&rgn=div5&view=text&node=42:1.0.1.4.22&idno=42> (see Subpart F)

- D. Title 45 CFR Part 94, “Responsible Prospective Contractor” can be found at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title45/45cfr94\\_main\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl)
- E. Additional Guidance from the U.S. Department of Health and Human Services, National Institutes of Health can be found at: <http://grants.nih.gov/grants/policy/coi/>

## **VII. References:**

- A. 42 Code of Federal Regulations (CFR) Part 50, Subpart F
- B. 45 CFR Part 94
- C. 45 CFR 74.53(b)

## **VIII. Other Related Policies/Procedures:**

- A. *Policy: Conflict of Interest*
- B. *Policy: Research Conflict of Interest – Disclosure, Review & Management*

## **IX. Keywords and Keyword Phrases:**

- A. COI
- B. Conflict of Interest
- C. Financial Conflict of Interest
- D. Research
- E. Research Conflict of Interest
- F. Study Conflict of Interest
- G. Public Health Service
- H. Public Health Service Grants
- I. Public Health Service Cooperative Agreements
- J. Public Health Service Contracts

## **X. Appendix:**

- A. *Disclosure of Significant Financial Interest Form*