

Title: Research Financial Conflict of Interest Relating to PHS Grants, Cooperative Agreements and Contracts	
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Approved by: Administrative Policy Committee, BH System Operations Team, PolicyTech Administrators 02/19/2024	

Discrete Operating Unit/Facility: Banner
 Banner Baywood Medical Center
 Banner Behavioral Health Hospital
 Banner Boswell Medical Center
 Banner Casa Grande Medical Center
 Banner Churchill Community Hospital
 Banner Del E Webb Medical Center
 Banner Desert Medical Center
 Banner Estrella Medical Center
 Banner Fort Collins Medical Center
 Banner Gateway Medical Center
 Banner Goldfield Medical Center
 Banner Heart Hospital
 Banner Ironwood Medical Center
 Banner Lassen Medical Center
 Banner McKee Medical Center
 Banner North Colorado Medical Center
 Banner Ocotillo Medical Center
 Banner Payson Medical Center
 Banner Thunderbird Medical Center
 Banner--University Medical Center Phoenix
 Banner--University Medical Center South
 Banner--University Medical Center Tucson
 East Morgan County Hospital
 Ogallala Community Hospital
 Page Hospital
 Platte County Memorial Hospital
 Sterling Regional Medical Center
 Torrington Community Hospital
 Washakie Medical Center
 Wyoming Medical Center

Banner Corporate
 Banner Health Clinics
 Banner MD Anderson Cancer Center
 Banner Health Network
 Banner Home Care and Hospice
 Banner Plan Administration
 Banner Pharmacy Services
 Banner Surgery Centers
 Banner Urgent Care Centers
 Occupational Health/Employee Services
 Post-Acute Care Services
 Research
 Rural Health Clinics
 University Physicians Health Plans

I. Purpose/Population/Implementation Date:

- A. **Purpose:** The purpose of this conflict of interest policy is to establish standards for the disclosure, review and management of financial conflicts of interest of Investigators in accordance with Title 42 CFR Part 50 Subpart F (titled Promoting Objectivity in Research), Title 45 CFR Part 94 (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation FAR 52.203-16 (Preventing Personal Conflicts of Interest). These federal regulations are collectively referred to as the Financial Conflict of Interest Rules. Banner Health must comply with government regulations when making expenditures with government awards.
- B. **Population:** All Banner Team Members.

II. Definitions:

- A. **Appearance of Bias:** When it appears to a third person, regardless of whether a conflict exists, that an individual's professional judgment or decision-making is influenced.
- B. **Conflict of Interest (COI):** Any activity, commitment or interest of an investigator, including a financial conflict of interest, that could directly and significantly affect the design, conduct or reporting of clinical research.
- C. **Conflict of Interest Committee (COIC)** means the ad hoc committee who will assist in the review of disclosed arrangements and development of management plans when the Conflict of Interest Official (COI Official) identifies a conflict with a specific case. The COIC will also review appeals from Investigators. Members of the COIC will be appointed by the COI Official. The COIC will be composed of at least three (3) voting members selected to serve based on experience and/or expertise in regulatory, compliance, or ethics. At least one (1) voting member should not be part of Banner Research administration or affiliated with the BH facility performing the research. Other voting members may be appointed with qualifications that enhance the disclosure review and conflict management processes.
- D. **Conflict of Interest Management Plan (COI MP):** Formal written plan developed to manage conflicts by mitigating, reducing or eliminating conflicts of interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.
- E. **Conflict of Interest Official (COI Official)** means the Person designated to administer and manage Banner Research's COI program and has the authority to review and resolve COI matters as described in this policy, or to refer the matter to the COIC for resolution.
- F. **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 PHS contract.
- G. **Disclosure** refers to an Investigator's disclosure of Significant Financial Interests to the COI Official.
- H. **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research and/or the negotiation of PHS contracts and the purchase of supplies and services.

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- I. **FCOI Report** means BH's report of a Financial Conflict of Interest to a PHS Awarding Component.
- J. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
- K. **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)).
- L. **Investigator** means the Project Director or Principal Investigator 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.
- M. **Investigator's Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of BH, which may include activities such as Research, Research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- N. **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.
- O. **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 NIH.
- P. **PHS Awarding Component** means the organizational unit of the PHS that funds the Research that is subject to 42 CFR Part 50 Subpart F or 45 CFR Part 94.
- Q. **Project Director (PD) / Principal Investigator (PI)** means a Project Director or Principal Investigator of Research; the PD/PI is included in the definitions of senior/key personnel and Investigator in this policy.
- R. **Public Health Service Act** or PHS Act means the statute codified at 42 U.S.C. 201 et seq.
- S. **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). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority (e.g., a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award). For the purpose of this policy, Research does not include activity which is not funded (or funding is not sought) through a PHS grant, cooperative agreement or contract.
- T. **Senior/Key Personnel** means the PD/PI and any other person identified as senior/key Personnel by BH in the grant application, progress report or any other report submitted to

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the PHS by BH under this policy.

U. Significant Financial Interest (SFI) means:

1. Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator'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 the Investigator's spouse 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 and not reimbursed to the individual so that the exact monetary value may not be readily available), related to an Investigator'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 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; 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.

- V. 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

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Subpart F the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

- W. **Sponsored Projects Office** means the staff in the Banner Research Sponsored Projects who will, among other tasks, help identify all known Banner Research investigators conducting research supported by PHS grant funds, help share policy, obtain reasonable assurance from collaborators with BH to comply with relevant FCOI policy. Provide information to the COI official relevant to PHS funded research projects to assist with review of SFI's to determine whether those interests represent a Financial Conflict of Interest.

III. Policy:

- A. It is BH policy to promote objectivity in Research by establishing standards to ensure the design, conduct, or reporting of Research funded under PHS grants or cooperative agreements (or contracts, as applicable) will not be biased by any FCOI 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 above).
- C. All BH Investigators who participate in PHS sponsored projects must complete conflict of interest training prior to engaging in Research related to any PHS-funded grant and prior to commencing an activity involving PHS funded purchases of supplies, services and/or contracting and at least every four years. The training may have to be taken again immediately under the following circumstances:
1. This policy (or any policy implementing 42 CFR 50, Subpart F and 45 CFR 94) changes in a manner that affects Investigator requirements;
 2. An Investigator is new to BH; or
 3. BH finds an Investigator noncompliant with this policy (or any policy implementing 42 CFR 50, Subpart F and 45 CFR 94) or a management plan directed by this policy.
- D. **Disclosure.** Each Investigator who is planning to participate in the PHS-funded Research or planning to assume direct or indirect responsibility for PHS funded purchases of supplies, services and/or contracts must disclose to the COI Official their Significant Financial Interests no later than the time of application for PHS-funded Research or prior to commencing an activity involving PHS funded purchases of supplies, PHS funded services and/or contracting, and annually thereafter.

IV. Procedure/Interventions:

- A. Significant Financial Interest Disclosures, Evaluation, Management & Certification
1. The COI Official with the assistance of the Sponsored Projects Office will:
 - a) The COI Official will 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, posting this policy on BH's Policy & Procedure database and taking other steps at the COI Official's reasonable discretion;
 - b) The Sponsored Projects Office will obtain reasonable assurance that Investigators carrying out 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, maintaining such

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- documentation with award documentation, and taking other steps at the COI Official's reasonable discretion;
- c) The COI Official or designee will solicit and review financial disclosure statements from each Investigator who is planning to participate in or is participating in Research. The COI Official or designee shall facilitate the following Investigator actions:
 - i. Each Investigator covered by this policy will report all SFIs held by themselves, their spouse and dependent children to the COI Official on an annual basis;
 - ii. The applicable Investigator will complete a PHS Disclosure of Outside Activities and Financial Interests form (disclosure form) prior to the submission of an application for PHS grant or cooperative Research agreement (or contract, as applicable). If an up to date disclosure form is on file at the time of an application, a new disclosure form is not required unless an Investigator needs to report a change.
 - iii. Each Investigator covered by this policy must submit a disclosure form annually **and within thirty (30) days** of discovering or acquiring a new SFI. The annual disclosure form must be submitted even if the Investigator has no SFIs to report.
 - iv. The Sponsored Projects Office may accomplish the obligations of Part IV.A.1.c. by confirming completion of the disclosure form and completing one of the following: (1) obtain the Investigator's written confirmation that the form is current in its description of Investigator's SFIs; or (2) obtain from the Investigator a written description of any changes to the Investigator's SFIs.
 - d) Prior to the BH's expenditure of any funds under a Research project, the COI Official shall, consistent with this policy (and in particular, 42 CFR Part 50.604(f)): review all Investigator disclosures of SFIs; determine whether any SFIs relates to the Research; determine whether a FCOI exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:
 - i. Public disclosure of FCOIs (e.g., when presenting or publishing the Research);
 - ii. For Research projects involving human subjects research, disclosure of FCOI directly to participants;
 - iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI;
 - iv. Modification of the Research plan;
 - v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
 - vi. Reduction or elimination of the Financial Interest (e.g., sale of an equity interest);
OR
 - vii. Severance of relationships that create the FCOI.
 - e) Whenever the COI Official implements a management plan pursuant to this policy, the COI Official or designee shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the Research.
 - f) Whenever, in the course of ongoing Research, an Investigator who is new to participating in the Research discloses a SFI or an existing Investigator discloses a new SFI to BH, the COI Official shall, within sixty (60) days: review the disclosure of the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the SFI, the COI Official may determine that

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additional interim measures are necessary with regard to the Investigator's participation in the Research between the date of disclosure and the completion of the COI Official's review.

- g) Whenever the COI Official identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by BH during ongoing Research (e.g., was not timely reviewed or reported by a subrecipient), the COI Official shall, within sixty (60) days: review the SFI; determine whether it is related to the Research; determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.
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 it:
 - i. Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs 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 policy's requirements including those pertaining to disclosure of SFIs;
 - iii. Shall manage FCOIs 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 FCOI; and
 - v. Shall fully comply with the requirements of 42 CFR 50, Subpart F and 45 CFR 94.
- B. Investigator Responsibilities Regarding Financial Interests
- 1. Investigator shall accomplish all of the following:
 - a) Report all SFIs or the lack thereof held by Investigator (where Investigator has a current award or pending application). Disclosures will be made by completing the disclosure form annually (or completing the tasks directed by the COI Official as set forth in Part IV.A.1.c. of this policy) and submitting new SFI disclosures to the COI Official for every new submission or within 30 days from when new SFIs are acquired. Investigators who report receiving remuneration such as consulting fees, honoraria, speaker fees, advisory board fees from an outside entity in excess of \$5,000 **must** submit a copy of associated service(s) agreement to the COI Official.
 - b) Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to Investigator's 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) Investigators must submit an updated disclosure of SFIs annually during the period of award. Such disclosure shall include any information that was not disclosed initially to BH in accordance with this policy or in a subsequent disclosure of SFI, and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

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- d) Each Investigator who is planning to participate in the Research will submit an annual disclosure form and will disclose to the COI Official the Investigator's SFIs no later than the time of application for Research; and 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. Appeal

1. The Investigator may contest the determination of a Financial Conflict of Interest and may appeal any conditions of the management plan to the COIC. The COIC will have final decision-making authority in such cases.

D. Records

1. BH will maintain the online COI Disclosure and other records of all financial disclosures and all actions taken by BH with respect to each FCOI 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 75.361-365](#) for different situations..
 - a) 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 4.7 through 4.706).
2. Records will be maintained by the COI Official and disclosure completion dates will be shared with the Sponsored Projects Office. 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).

E. Federal Agencies and Financial Interest Information

1. The information disclosed by an 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.

F. Reporting

1. Prior to BH'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 SFI found by BH to be conflicting (i.e., a FCOI) and ensure that BH has implemented a management plan in accordance with this policy and the regulations. In cases in which BH identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, BH shall not submit an FCOI report to the PHS Awarding Component.
2. For any SFI that the COI Official identifies as conflicting subsequent to the BH's initial FCOI report during an ongoing Research project (e.g., upon the participation of an Investigator who is new to the Research project), the COI Official shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the FCOI and ensure that BH has implemented a management plan in accordance with this policy. Where such FCOI report involves a SFI 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 COI Official also is required to complete a retrospective review to determine whether any Research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such Research. Additionally, if bias is found, the COI Official is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
3. Any FCOI report required shall include sufficient information to enable the PHS

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Awarding Component to understand the nature and extent of the FCOI, 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) PD/PI or contact PD/PI if a multiple PD/PI model is used
 - c) Name of the Investigator with the FCOI
 - d) Name of the entity with which the Investigator has a FCOI
 - e) Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
 - f) Value of the 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
 - g) A description of how the Financial Interest relates to the Research and the basis for the Institution's determination that the Financial Interest conflicts with such Research
 - 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
 - vi. Other information as needed.
4. For any FCOI previously reported by BH with regard to an ongoing Research project, BH shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the Research project. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI 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.

G. Subrecipients

1. If the BH carries out the Research through a subrecipient (e.g., subcontractors or consortium members), BH (awardee Institution) shall (via the Sponsored Projects Office):
 - a) Incorporate as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of BH (i.e., the policy implementing 42 CFR 50, Subpart F and 45 CFR 94) or that of the subrecipient will apply to the subrecipient's Investigators.
 - i. If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR 50, Subpart F and 45 CFR 94. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of BH for disclosing SFIs (to BH) that are directly related to the subrecipient's work for BH.
 - ii. Additionally, if the subrecipient's Investigators must comply with subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOIs to BH. Such time period(s) shall be sufficient to enable BH to provide timely FCOI reports, as necessary, to the PHS

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as required by this policy.

- iii. If the subrecipient's Investigators must comply with BH's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to BH. Such time period(s) shall be sufficient to enable BH to comply timely with its review, management, and reporting obligations under this policy.
- iv. Provide FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators consistent with this policy, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

H. Noncompliance and Retrospective Review

1. Whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by BH to constitute a FCOI; failure by BH to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, BH shall, within 120 days of BH's determination of noncompliance, complete a retrospective review of the Investigator's activities and the Research project and/or purchasing responsibilities to determine whether any 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 COI Official and approved by the COIC.
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) PD/PI or contact PD/PI if a multiple PD/PI model is used
 - d) Name of the Investigator with the FCOI
 - e) Name of the entity with which the Investigator has a FCOI
 - 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
 - j) Management plan
3. Based on the results of the retrospective review, if appropriate, the COI Official shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the COI Official 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, the COI Official will submit FCOI reports annually. Depending on the nature of the FCOI, the COI Official may determine that additional interim measures are necessary with regard to the Investigator's participation in the Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of BH's retrospective review.

I. Remedies

1. The COI Official will establish adequate enforcement mechanisms and provide for

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Investigator sanctions or other administrative actions to ensure Investigator compliance as appropriate, including such mechanisms, sanctions, and actions set forth in this policy.

2. If the failure of an Investigator to comply with BH's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the Research, the COI Official 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 FCOI. BH is required to submit, or permit on-site review of, all records pertinent to compliance with this policy.
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 with a FCOI that was not managed or reported by BH as required by the regulations, BH shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.
5. Sanctions: If the COI Official determines that an Investigator has violated this Policy, including any failure to make a required SFI Disclosure or comply with a requirement of a COI management plan, the COI Official will notify the COIC. 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) Notification to the Chief Clinical Officer
 - d) Letter to the Investigator's personnel file
 - e) Suspension of Research privileges
 - f) Corrective action, up to and including termination of employment
 - g) Notification to actual or potential funding agencies (which may also otherwise be required under this policy)

J. Public Accessibility

1. BH will post this policy on its publicly available website. Prior to BH's expenditure of any funds under a Research project, BH shall ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any SFI disclosed to BH that meets all of the following three criteria: (1) The SFI was disclosed and is still held by the Senior/Key personnel as defined by this policy; (2) BH determines that the SFI is related to the Research; and (3) BH determines that the SFI is a FCOI. (2) BH determines that the SFI is related to the Research; and (3) BH determines that the SFI is a FCOI.
2. The information shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to BH and/or the Research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (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

Title: Research Financial Conflict of Interest Relating to PHS Grants, Cooperative Agreements and Contracts

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 FCOI, which should be requested subsequently by the requestor.

3. Information concerning the SFIs of an individual subject to this Article IV.J. shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

V. Procedural Documentation:

A. Form: PHS Disclosure of Outside Activities and Financial Interests

1. Posted by COI Official

VI. Additional Information:

- A. Electronic mail address for the COI Official:
BHResearchCompliance@bannerhealth.com
- B. Questions with regard to this Policy should be directed to the Sponsored Projects Office: BHGrants@bannerhealth.com.
- C. Title 42 CFR Part 50, Subpart F, "[Responsibilities of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought](#)"
- D. Title 45 CFR Part 94, "[Responsible Prospective Contractor](#)"
- E. Additional federal guidance on FCOI can be found at:
<https://grants.nih.gov/grants/policy/coi/index.htm>

VII. References:

- A. 42 Code of Federal Regulations (CFR) Part 50, Subpart F Promoting Objectivity in Research
- B. 45 CFR Part 94 Responsible Prospective Contractors
- C. C. 45 CFR 75.112 Conflict of Interest, 45 CFR 75.361-370 Record Retention and Access

VIII. Other Related Policies/Procedures:

- A. **Policy: Conflict of Interest (#2794)**
- B. **Policy: Research Conflict of Interest – Disclosure, Review & Management (#9163)**

IX. Keywords and Keyword Phrases:

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

X. Appendix:

- A. N/A