

BRIDGEPORT HOSPITAL CONFLICT OF INTEREST POLICY APPLICABLE
TO
PUBLIC HEALTH SERVICES PRIME AWARDS AND SUBAWARDS

The federal Public Health Service (PHS) has adopted regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on *Promoting Objectivity in Research*. These regulations describe the actions an individual and an organization must take in order to promote objectivity in research. The regulations apply to all PHS funded grants, which include National Institute of Health (NIH) funded grants, cooperative agreements, and research contracts (but not Phase 1 Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) program grants), and subawards where the originating sponsor is PHS. The regulations require that investigators who submit a proposal for, or who receive PHS research funding, by means of a contract, subrecipient award or otherwise, disclose any significant financial interests related to their institutional responsibilities at Hospital. Under this policy the term investigator(s) include a project director, 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, who may include, for example, collaborators or consultants. The Hospital is responsible for ensuring implementation of this policy, including the completion of the required training by investigators and the requirements of website posting, and may suspend all relevant activities until a financial conflict of interest or any violation of this policy is resolved or other appropriate action implemented. Violation of any part of this policy may constitute cause for disciplinary or other administrative action.

I. Definitions

Institutional responsibilities means an Investigator's professional activities on behalf of Hospital. These include research, research consultation, teaching, clinical care, committee membership, and service on Institutional Review Boards or Data and Safety Monitoring Boards and any other professional activities on behalf of Hospital.

Investigator means the project director (PD) or principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS by an award or a subaward, or proposed for such funding, which may include, for example, collaborators or consultants.

Public Health Service or PHS means the Public Health Service (PHS) of the U.S. Department of Health and Human Services (HHS), and any component of PHS to which the authority of the PHS may be delegated. The components of PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease

Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration, so long as they shall remain components of PHS.

Significant Financial Interest means:

(1) A 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 on behalf of Hospital.

- (i) **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 for the investigator, investigator's spouse and dependent children, 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;
- (ii) **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
- (iii) **With regard to intellectual property rights and interests** (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests.

(2) In addition, for the Investigator only, **any reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator), **related to his/her institutional responsibilities**, must be disclosed to Hospital. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration and any such further information that is deemed necessary by Hospital. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, a U.S. 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) The term *significant financial interest* does not include the following types of financial interests:

- (i) Salary, royalties, or other remuneration paid by Hospital to the Investigator if the Investigator is currently employed or otherwise appointed by Hospital, including intellectual property rights assigned to the Hospital and agreements to share in royalties related to such rights;
- (ii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by an U.S. 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
- (iv) Income from service on advisory committees or review panels for an U.S. 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.

II. Disclosure

Prior to the submission of an application involving Hospital to PHS or to a PHS Grantee for funding, the Principal Investigator, and all other Investigators with a role in the proposed activity, must have disclosed to Hospital's Conflict of Interest Committee (COIC)/designated official an up-to-date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application to PHS or to a PHS Grantee for funding, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the COIC/designated official promptly and prior to participation in the project.

Each Investigator who is participating in research under an award or a subaward where the prime award originates from PHS must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to Hospital, pursuant to this policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a PHS-funded project directly as a PHS Grantee and/or indirectly through a subaward) that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity

interest).

Each Investigator who is participating in research under an award or a subaward where the prime award originates from PHS must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

III. Review by Hospital's COIC/Designated Official

The COIC/designated official will conduct reviews of disclosures. The COIC/designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each research award or subaward funded under a PHS prime award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award or subaward and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award or subaward.

IV. Guidelines for Determining "Relatedness" and Financial Conflict of Interest

The COIC/designated official will determine whether an Investigator's SFI is related to the research under a subaward supported by a PHS prime award and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to the research under the subaward when the COIC/designated official reasonably determines that the SFI: could be affected by the research conducted under the subaward; or is in an entity whose financial interest could be affected by the research. The COIC/designated official may involve the Investigator in the determination of whether a SFI is related to the research supported by the subaward.

A financial conflict of interest exists when the COIC/designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In determining if an Investigator's SFI is related to the research under an award or a subaward supported by a PHS prime award, and if so, whether the relationship creates a FCOI, the COIC/designated official considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the COIC/designated official may also consider the following factors:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such

as where the SFI is a patent, or an interest in a company that has licensed the invention); or

4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that constitutes a significant conflict; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Investigator has a SFI.

V. Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the COIC/designated official will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the COIC/designated official will be guided by the principles discussed in this policy. The COIC/designated official will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c) 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;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g) Severance of relationships that create financial conflicts;
- h) For research projects involving human subjects research, use of a data and safety monitoring board;
- i) Double-blind conditions;
- j) Provisions to conduct the work simultaneously at multiple sites;
- k) Written disclosure of the conflict to all individuals working on the research project;
- l) Annual reports on the research progress to the COIC/designated official.

If the COIC/designated official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The COIC/designated official will keep a record of the disclosure and other relevant information for at least three years. If the COIC/designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on an award or a subaward supported by a PHS prime award will be permitted until the Investigator has complied with the disclosure requirements of this policy and has agreed, in writing, to comply with any plans determined by the COIC/designated official necessary to manage the Conflict of Interest. The COIC/designated official will communicate, in writing, with the PHS Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and that a satisfactory management plan as required by the applicable regulations has been implemented. No expenditures can be incurred until the PHS Grantee has reported the FCOI, if required, to PHS. No report to PHS is required if the financial conflict or interest is eliminated prior to the expenditure of PHS awarded funds. The PHS Grantee should notify Hospital when it may incur expenditures.

The COIC/designated official will keep a record of Investigator disclosures of financial interests and the COIC/designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and final payment made and in accordance with the terms and conditions of the award or subaward and relevant PHS Regulations.

VI. Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of any funds under a PHS award or a subaward funded by a PHS prime award, Hospital will ensure public accessibility, via a publicly accessible Web site or by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- (i) The Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by Hospital in the award or subaward application, progress report or any other report submitted to PHS or the PHS Grantee;
- (ii) Hospital has determined that the Significant Financial Interest is related to the research funded through an award or a subaward; and
- (iii) Hospital has determined that the Significant Financial Interest is a financial conflict of interest.

The information that Hospital will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the Significant Financial Interest is held;
- (iv) The nature of the Significant Financial Interest; and
- (v) The approximate dollar value of the Significant Financial Interest in the following ranges: \$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.

If Hospital uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the PHS-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the PHS-funded research project, if it is determined by the COIC/designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.

If Hospital responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of the Hospital's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the Significant Financial Interests of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via Hospital's publicly accessible Web site for at least three years from the date that the information was most recently updated.

VII. Reporting of Financial Conflicts of Interest Under a Subaward

Prior to the expenditure of any funds under a subaward funded by a PHS prime award, Hospital will provide to the PHS Grantee a FCOI report compliant with PHS regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. Hospital cannot incur expenditures until it has received notification to do so from the PHS Grantee.

While the subaward is ongoing (including any extensions with or without funds), Hospital will provide to the PHS Grantee an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Hospital will provide to the PHS Grantee, within forty five days, an FCOI report regarding the financial conflict of interest and ensure that Hospital has implemented a management plan and the Investigator has agreed to the relevant management plan.

VIII. Training Requirements

Each Investigator must receive a copy of this policy and complete training on *Hospital Conflict of Interest Policy Applicable to Public Health Services Prime Award(s) and Subawards* prior to engaging in research related to any PHS-funded subaward and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- 1) Hospital revises this policy, or procedures related to this policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);

- 2) An Investigator is new to Hospital research under an award or subaward issued under a PHS prime award (training is to be completed prior to his/her participation in the research); or
- 3) Hospital finds that an Investigator is not in compliance with this policy or a management plan issued under this policy (training is to be completed within 30 days in the manner specified by the COIC/designated official).

In fulfillment of the training requirement, Hospital requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>, or some subsequently Hospital-approved training, in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training and supply a copy to COIC/designated official for audit purposes.

IX. Reporting to PHS

The COIC/designated official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

X. Subrecipient Requirements

Hospital shall as part of a written subrecipient agreement with a subrecipient under a PHS prime award, establish whether the financial conflicts of interest policy of Hospital or that of the subrecipient will apply to the subrecipient's investigator(s). If the subrecipient relies on its conflicts of interest policy, the subrecipient shall certify as part of the subrecipient agreement, that its policy complies with 42 CFR Part 50 and 45 CFR Part 94, as appropriate. In either case, the subrecipient agreement will include time periods to meet the disclosure and/or Financial Conflict of Interest reporting requirements of Hospital to PHS.

XI. Failure to Comply with Hospital's Conflict of Interest Policy Applicable to Public Health Service Funded Subaward

When a FCOI is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because a FCOI was not timely reviewed or reported by a subrecipient or by Hospital; or because an investigator failed to comply with a management plan; then Hospital will within 120 days:

- a) Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
- b) Document the retrospective review consistent with the regulations;
- c) Document Hospital's determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research; and
- d) Notify the PHS Grantee in writing.

If bias is found, Hospital shall notify the PHS Grantee promptly and submit a mitigation report to the PHS Grantee that shall address the following:

- Impact of the bias on the research project and
- Hospital's plan of action or actions taken to eliminate or mitigate the effect of the bias.

If Hospital is the PHS Grantee, Hospital shall promptly notify PHS, by notice to the component of PHS that is the source of the award, of the corrective action taken or to be taken and take such other action as may be required.

Hospital shall submit FCOI reports to a PHS Grantee, in accordance with the regulation and terms and conditions of the subaward agreement. Depending on the nature of the Financial Conflict of Interest, Hospital may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of Hospital's independent retrospective review.

XII. Clinical Research

If the HHS or PHS determines that one of its funded clinical research projects 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 Financial Conflict of Interest that was not managed or reported by Hospital, shall require the Investigator 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.

XIII. Failure to Comply with This Policy

No expenditures of funds on a PHS award or subaward supported by a PHS prime award will be permitted unless the Investigator has complied with the Disclosure requirements of this policy and has agreed, in writing, to comply with any COIC/designated official-approved FCOI management plan.

Any failure by an individual to adhere to this policy may be cause for disciplinary action, including, in severe cases, termination, and termination of the award or subaward.

XIV. Other Applicable Policies

If Hospital should maintain a policy on financial conflicts of interest that includes standards that are more stringent (e.g., that require a more extensive disclosure of financial interests) than the standards established by 42 CFR Part 50 Subpart F and 45 CFR Part 94, the Hospital shall adhere to its policy and provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with Hospital's own standards and the timeframe prescribed by the federal regulations. Otherwise, Hospital shall apply a financial conflict of interest policy that meets the regulations.

XV. Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required.

XVI. Public Accessibility

A copy of this Policy shall be maintained on Hospital's publicly accessible website unless it lacks or ceases to maintain a presence on a currently available website. Should it lack or cease to maintain a presence on a currently available website, Institution shall make its written policy available to any requestor within five business days of a request and available on its website within 30 calendar days of acquiring a website.

XVII. Regulatory Authority

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

