

 Sheppard Pratt HEALTH SYSTEM		Policy Number: HS-120.10
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Manual: Sheppard and Enoch Pratt Hospital Administrative Manual		Effective: 1/4/2016
Section: 100 - Health System	Sub-section: 120 - Corporate Compliance	Prepared by: Donna Corbett
Title: Sheppard Pratt Conflict of Interest Policy for Public Health Service-Funded Research		

POLICY:

The purpose of this Policy is to promote objectivity in biomedical and behavioral research through a combination of disclosure of significant financial interests and increased review to determine when such financial interests may create an actual or apparent threat to the objectivity of the research. The Policy is specifically intended to comply with the requirements applicable to research conducted with funding from the United States Public Health Service, including the National Institutes of Health (all “PHS”).

PURPOSE:

This Policy applies to all research where any part of the funding (by grant, contract, cooperative agreement or contract) is received from the PHS, and whether Sheppard Pratt is a direct or subcontracting recipient of the funding. This Policy applies to all persons who meet the definition of *Investigator* set forth below, if they are participating in, or planning to participate in, such research.

DEFINITIONS:

Conflict of Interest Disclosure Form means a form available on the Sheppard Pratt website at www.sheppardpratt.org, intended for the disclosure of the information required by the Regulations and this Policy.

Conflict of Interest Officer means the person who is designated as such by the Board of Trustees of Sheppard Pratt Health System, Inc. The Conflict of Interest Officer shall be a person who has no research responsibilities.

Disclosure of significant financial interests means an Investigator’s disclosure of significant financial interests to Sheppard Pratt’s Conflict of Interest Officer on a Conflict of Interest Disclosure Form.

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.

FCOI report means Sheppard Pratt’s report of a financial conflict of interest to a PHS awarding component.

Financial interest means anything of monetary value, whether or not the value is readily

ascertainable.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of Sheppard Pratt, which may include for example: 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.

Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for any part of the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, senior/key personnel, collaborators or consultants, post-doctoral associates or residents.

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.

PHS means the Public Health Service 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).

Regulations means 42 CFR Part 50 and 45 CFR Part 94.

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 Policy, the term includes any such activity for which research funding is available from PHS 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.

Senior/key personnel means a PHS principal investigator, co-investigator, or project director and any other person who contributes to the scientific development or execution of a project in a substantive measurable way, and/or who is included in a grant application or subcontract, progress report, or any other report submitted on behalf of Sheppard Pratt, whether or not the person receives salary or compensation under the grant or contract.

Sheppard Pratt means Sheppard Pratt Health System, Inc., Sheppard Pratt Physicians, P.A., and Sheppard and Enoch Pratt Foundation, Inc.

Significant financial interest means a financial interest consisting of anything of monetary value or potential monetary value held by the Investigator (or by the Investigator's spouse and dependent children) that reasonably or apparently appears to be related to the Investigator's

institutional responsibilities, fitting one or more of the following categories:

- (1) 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 off air market value;
- (2) 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
- (3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (4) 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 their institutional responsibilities; provided, however, that this definition does not include travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. In the event of such travel, the disclosure shall include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration and the actual or the estimated monetary value.

The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by Sheppard Pratt to the Investigator if the Investigator is currently employed or otherwise appointed by Sheppard Pratt, including intellectual property rights assigned to Sheppard Pratt 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 Investigator 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, 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

PROCEDURE:

Responsibilities of Sheppard Pratt:

Acting under the oversight of the Conflict of Interest Officer, Sheppard Pratt shall implement this Policy in accordance with the requirements of the Regulations. Its duties include the following:

1. To make this Policy and information regarding any identified FCOI's available on a publicly accessible website, and to respond to any written requests regarding this Policy or identified FCOI's within five (5) business days of receipt of the request. The information regarding FCOI's shall include, at a minimum, the Investigator's name; the name of the research project, the Investigator's title and role with respect to 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 using dollar 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. The information provided on the publicly accessible website shall be updated at least annually, and within sixty days of the receipt or identification of information concerning any FCOI that was not previously disclosed, or upon the disclosure of FCOI of any financial interest of senior/key personnel new to the PHS-funded research project. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the identification of a new FCOI. Posted information shall remain available for at least three years from the date that the information was most recently updated.
2. To inform each Investigator of the Policy, the Investigator's responsibilities regarding disclosure of significant financial interests, and of the Regulations.
3. To provide access to appropriate training materials regarding the Policy and the Regulations, to require each Investigator to complete training regarding the Policy and the Regulations prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately if Sheppard Pratt revises the Policy in any manner that affects the requirements of Investigators, or an Investigator is new to Sheppard Pratt, or if it is determined that an Investigator is not in compliance with the Policy or with a management plan, and to require each Investigator to submit training completion documentation.
4. If Sheppard Pratt carries out any PHS-funded research through a subrecipient (*e.g.*, subcontractors or consortium members), to take reasonable steps to ensure that any subrecipient Investigator complies with this Policy and the Regulations by incorporating as part of a written agreement with the subrecipient terms that establish whether this Policy or a financial conflicts of interest policy of the subrecipient conforming with the Regulations will apply to the subrecipient's Investigators.
5. To designate a Conflicts of Interest Officer to solicit and review disclosures of significant

financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

6. To require that
 - (a) each Investigator who is planning to participate in PHS-funded research disclose to the Sheppard Pratt Conflicts of Interest Officer on a Conflict of Interest Disclosure Form provided by Sheppard Pratt 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;
 - (b) each Investigator who is participating in the PHS-funded research submit an updated disclosure of significant financial interests at least annually, during the period of the award or contract. Such disclosure shall include any information that was not disclosed previously to Sheppard Pratt as well as updated information regarding any previously disclosed significant financial interest (*e.g.*, the updated value of a previously disclosed equity interest);
 - (c) each Investigator who is participating in the PHS-funded research submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (*e.g.*, through purchase, marriage, or inheritance, or in the event of certain reimbursed or sponsored travel) a new significant financial interest.
7. To provide guidelines for the Conflicts of Interest Officer to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest.
8. To take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to the Regulations. Whenever a management plan is implemented, Investigator compliance with the management plan shall be monitored on an ongoing basis until the completion of the PHS-funded research project.
9. To provide initial and ongoing FCOI reports to the PHS as required pursuant to the Regulations.
10. To maintain records relating to all Investigator disclosures of financial interests and Sheppard Pratt's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a financial conflict of interest) and all actions under the 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.
11. To establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

12. To certify, in each application for PHS funding that Sheppard Pratt (i) 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; (ii) shall promote and enforce Investigator compliance with the requirements of the Regulations pertaining to disclosure of significant financial interests; (iii) shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS consistent with the Regulations; (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 Sheppard Pratt's determination of a financial conflict of interest; and (v) shall fully comply with the requirements of the Regulations.

Responsibilities of the Investigator:

Any Investigator involved in any application for PHS-funded research or in any PHS-funded research shall have the following duties and responsibilities:

1. Prior to the submission of an application for PHS-funded research, or, if not involved in the submission of the application, prior to the initiation of any PHS-funded research:
 - (a) To review this Policy and understand the responsibilities regarding disclosure of significant financial interests;
 - (b) To complete training regarding the Policy and the Regulations prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under certain circumstances;
 - (c) To disclose to the Sheppard Pratt Conflict of Interest Officer on a Conflict of Interest Disclosure Form provided by Sheppard Pratt the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) that the Investigator determines to be reasonably related or apparently related to the PHS-funded or proposed research or to the Investigator's Institutional responsibilities.

No PHS-funded research may be commenced, and no PHS research funds may be expended until all of the foregoing requirements have been satisfied.

2. During the course of participating in any PHS-funded research:
 - (a) To submit to the Sheppard Pratt Conflict of Interest Officer on a Conflict of Interest Disclosure Form an updated disclosure of significant financial interests at least annually during the period of the award or contract. Unless otherwise agreed, all annual updates shall be due on the April 1 following the initial disclosure, and annually on that date thereafter. Such update disclosure shall include any information that was not disclosed previously to Sheppard Pratt that the Investigator determines to be reasonably related or apparently related to the proposed research or to the Investigator's Institutional responsibilities, as well as updated information regarding any previously disclosed significant financial interest (*e.g.*, the updated value of a previously disclosed equity interest);

(b) To submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (*e.g.*, through purchase, marriage, or inheritance, or in the event of certain reimbursed or sponsored travel) a new significant financial interest.

3. At all times:

- (a) To cooperate with the Conflict of Interest Officer in the determination of whether a significant financial interest is related to the PHS-funded research and whether it constitutes an FCOI;
- (b) To cooperate with the Conflict of Interest Officer and the Sheppard Pratt IRB in their effort to establish and implement a management plan in the event that it is determined that a FCOI exists. **When it is determined that a FCOI exists, no PHS -funded research may be commenced, and no PHS research funds may be expended until the Investigator has agreed in writing to a management plan developed by the Conflict of Interest Officer and the Sheppard Pratt IRB;**
- (c) To cooperate with the Conflict of Interest Officer in the retrospective review of any FCOI which was not identified and managed in a timely manner;
- (d) To cooperate with the Conflict of Interest Officer in development of any mitigation report to be submitted to the PHS.

Responsibilities of the Conflict of Interest Officer:

In addition to providing general oversight of Sheppard Pratt's implementation of the Policy, the Conflict of Interest Officer shall;

1. Solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research;
2. Review all Investigator disclosures of significant financial interests prior to the expenditure of any funds under a PHS-funded research project, and all new or updated Investigator disclosures within thirty (30) days to determine whether any significant financial interests relate to PHS-funded research; and to determine whether a financial conflict of interest exists. An Investigator's significant financial interest is related to PHS-funded research when the Conflict of Interest Officer reasonably determines that the significant financial interest: could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. The Conflict of Interest Officer may involve the Investigator in the Conflict of Interest Officer's determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Conflict of Interest Officer reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. In the event that the Conflict of Interest Officer determines that a FCOI exists, the Conflict of Interest Officer promptly shall notify the Investigator and the Sheppard Pratt IRB.
3. In cases where it is determined that a financial conflict of interest exists, in collaboration with the Sheppard Pratt IRB, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict

of interest include, but are not limited to, (i) public disclosure of financial conflicts of interest (*e.g.*, when presenting or publishing the research); (ii) for research projects involving human subjects research, disclosure of financial conflicts of interest 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 financial conflict of interest; (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 financial conflicts.

4. Whenever a significant financial interest is identified that was not disclosed timely by an Investigator, or, for whatever reason, was not previously reviewed by the Conflict of Interest Officer during an ongoing PHS-funded research project (*e.g.*, was not timely reviewed or reported by a subrecipient), within sixty (60) 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, on at least 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.
5. Complete within 120 days of the determination of noncompliance, with the assistance of the Sheppard Pratt IRB, a retrospective review of the Investigator's activities and the PHS-funded research project 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 whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Conflict of Interest Officer to constitute a financial conflict of interest; failure by the Conflict of Interest Officer to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan. 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 (Program Director/Principal Investigator) 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 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; and (i) Conclusions of the review. If the retrospective review determines that 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 during the period of the determination of noncompliance, the retrospective review shall be accompanied by a mitigation plan to address any such issues. The mitigation plan must include, at a minimum, a description of the impact of the bias on the research project and the plan of action or actions to be taken to eliminate or mitigate the effect of the bias;
6. Promptly determine, while any retrospective review is in process, whether any additional interim measures are necessary with regard to the Investigator's participation in the PHS-

funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the retrospective review;

7. Provide, in conjunction with the Finance Office Grants Manager, initial, annual, and ongoing FCOI reports to the PHS as required pursuant to the Regulations (42 CFR Part 50.605(b) and 45 CFR Part 94.5(b)), including but not limited to updates of previously submitted FCOI reports in the event that a FCOI is subsequently identified, either as a result of an updated Disclosure Form or a retrospective review, specifying the actions that will be taken to manage the financial conflict of interest going forward. Annual reports shall be required for any FCOI previously reported by Sheppard Pratt with regard to an ongoing PHS-funded research project, and the annual report shall address the status of the FCOI 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;
8. Notify the PHS promptly if bias is found in a retrospective review and, with the assistance of the Sheppard Pratt IRB and in conjunction with the Finance Office Grants Manager, submit a mitigation report to the PHS. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and the 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);
9. Take such actions as are necessary to manage financial conflicts of interest of an Investigator who is a subrecipient of a PHS-funded grant, contract, or award to Sheppard Pratt or a Sheppard Pratt Investigator, or to assure that a subrecipient has in place and will abide by a Policy conforming to the Regulations.

Responsibilities of the Sheppard Pratt IRB:

The Sheppard Pratt IRB shall assist the Conflict of Interest Officer in each of the following:

1. The development of a management plan in any instance where the Conflict of Interest Officer determines that there is a FCOI;
2. The monitoring on an ongoing basis of any management plan implemented with respect to a FCOI involving PHS-funded research;
3. The conduct of any required retrospective review of an Investigator's activities and the PHS-funded research project 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 whenever a financial conflict of interest is not identified or managed in a timely manner;
4. The development of a mitigation plan in any instance where as a result of a retrospective review it is determined as a result of a FCOI, that PHS-funded research was biased in the design, conduct, or reporting of such research;
5. No member of the Sheppard Pratt IRB shall participate in numbers 1 – 4 above if the IRB member has any personal involvement of any kind in the research that is subject to the FCOI.

No member of the Sheppard Pratt IRB shall participate in any of the foregoing activities if he or she has a significant financial interest in the project to which the activities pertain.

Sanctions:

The failure of an Investigator to complete and file a truthful Conflict of Interest Disclosure Form as required by this Policy, or to comply with the conditions or restrictions imposed in the resolution, management, or elimination of financial conflicts of interest pursuant to this Policy constitutes a violation of this Policy and may violate federal law. In such cases, the Investigator will be subject to appropriate sanctions and disciplinary action consistent with Sheppard Pratt personnel policies. In addition, Sheppard Pratt may require that the Investigator participate in additional education regarding the Policy, file more frequent Conflict of Interest Disclosure Forms, suspend the research project, halt the expenditure of research funds, suspend technology transfer activity, or take such other action as is necessary to prevent the continued violation of this Policy.

Appeals:

Any Investigator may appeal any decision made by the Conflict of Interest Officer by an appeal in writing to the President/CEO of Sheppard Pratt, delivered within fifteen (15) days of the action from which the appeal is taken.

References:

Attachments:

[Public Health Service Funded Research Financial Disclosure Form Instructions](#)
[Public Health Service Funded Research Financial Disclosure Form](#)

Revision Dates:

12/15

Reviewed Dates:

8/12, 12/15

Signatures: