

 Sheppard Pratt		Policy Number: HS-120.10
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Manual: Sheppard and Enoch Pratt Hospital Administrative Manual		Effective: 11/19/2020
Section: 100 - Health System	Sub-section: 120 - Corporate Compliance	Prepared by: Jennifer Sklar
Title: Research Financial Conflict of Interest Policy		

## I. POLICY

- A. The purpose of this policy is to define the process for identifying, reporting, evaluating, and managing financial relationships that have or may have an impact on the objectivity and integrity of research conducted under the auspices of Sheppard Pratt and its affiliated entities (“Sheppard Pratt Entities”).
- B. All research conducted at Sheppard Pratt and all of its related entities shall be compliant with applicable laws, regulations and these policies and procedures, which includes the requirements that (a) all Covered Individuals disclose all significant financial interests in accordance with this policy, before research begins and immediately when a change in financial interest occurs or is acquired (e.g., through purchase, marriage, or inheritance) and (b) all Covered Individuals with conflicts address those conflicts as determined by the Conflict of Interest Official prior to beginning or resuming research activities.

## II. DEFINITIONS

- A. Covered Individual (CI):
  1. Any employee, contractor or medical staff member of a Sheppard Pratt Entity who has the authority to make independent decisions related to the design, conduct, or reporting of a Sheppard Pratt research project, but not including individuals who perform only incidental or isolated tasks, related to the project. Examples of a CI include a principal investigator, sub-investigator, research nurse, associate, personnel whose resume is provided to a sponsor, personnel listed on study budgets or on an FDA 1572 Form, or individuals who are likely to be authors on publications of research findings;
  2. Members of a Sheppard Pratt research review-related committee (e.g., IRB members, Local Research Review Committee members, Privacy Board members, Data Safety Monitoring Board members for investigator-initiated studies and/or members of other research review committees); or
  3. Staff who negotiate or execute research agreements on behalf of Sheppard Pratt.
- B. Conflict of Interest Official (COI Official): The Director of Research Administration, or his/her designee, will oversee the implementation of, and compliance with, this policy.
- C. Covered Family Member: An individual who is the spouse or dependent child of a CI.
- D. Financial Conflict of Interest in Research Committee (FCOI-R Committee): The persons appointed by the COI Official to provide an appropriate review of disclosed Significant Financial Interest(s) (see definition below), make a determination of its relationship of the CI

to the funded research (reasonable belief of a FCOI) and devise an appropriate management plan for all instances in which a conflict of interest has been determined to exist. The FCOI-R Committee is a subcommittee of the Sheppard Pratt Institutional Review Board.

- E. Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.
- F. Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- G. Institutional Responsibilities: A CI's professional responsibilities on behalf of a Sheppard Pratt Entity including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee membership, and/or service on panels such as the IRB or any other research related review committee or panel as mentioned above.
- H. Investigator or Principal Investigator: An individual who is responsible for the design, conduct or reporting of research or proposals for research, regardless of title or position.
- I. Senior/key personnel (for Public Health Services [PHS] funded studies): The Principal Investigator and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS by Sheppard Pratt.
- J. Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of a CI or Covered Family Member that reasonably appears to be related to the CI's Institutional Responsibilities:
  - 1. Publicly Traded Entity
    - a) The value of stock or other equity interest in a publicly traded company that, in aggregate, exceeds \$5,000 as of the date of disclosure and represents more than a five percent ownership interest in any single entity
    - b) Income from a publicly traded company that, in aggregate, exceeds \$5,000 in the 12 months preceding disclosure (includes salary and payment for other services, e.g. consulting fees, honoraria [payment granted in recognition of a special service or distinguished achievement, such as for a presentation or lecture on behalf of a sponsor or company that may or may not be related to a project], paid authorship)
  - 2. Non-Publicly Traded Entity
    - a) Any stock or other equity/ownership interest of any value
    - b) Income from a private company that, when aggregated, exceeds \$5,000 in the 12 months preceding disclosure (includes salary and payment for other services, e.g. consulting fees, honoraria, paid authorship)
  - 3. Intellectual Property Rights and Interest
    - a) Income related to intellectual property rights or interests that exceeds \$5,000 (e.g., patents, copyrights and royalties from such rights)
  - 4. Travel
    - a) Reimbursed travel that exceeds \$1,500 in the 12 months preceding disclosure related to their institutional responsibilities
    - b) Sponsored travel estimated as exceeding \$1,500 (i.e., that which is paid on behalf of the CI and not reimbursed to the CI so that the exact monetary value may not be readily available) in the 12 months preceding disclosure, related to their institutional responsibilities The following information must be provided for all applicable reimbursed or sponsored travel:

- (1) Purpose of the trip
  - (2) Identity of the sponsor/organizer
  - (3) Destination of the trip
  - (4) Duration of the trip
  - (5) Estimate of the monetary value
5. Gifts
  - a) The value and source of a single gift that exceeds \$250 in value, or multiple gifts from a single entity that in aggregate exceed \$250 in value, received in the 12 months preceding disclosure
6. Fiduciary Positions
  - a) A fiduciary position (e.g. member, officer, director, committee member) held in a for-profit or nonprofit entity in the 12 months preceding disclosure, for which the individual received any form of remuneration or reimbursement for expenses exceeding \$5,000
7. Other
  - a) Any other financial interest that the CI or the COI Official believes conflicts with the CI's ability to protect research subjects
- K. Significant Financial Interest (SFI) does not include:
  1. Salary, royalties, or other remuneration paid by a Sheppard Pratt Entity to the CI if the CI is employed or otherwise appointed by the Sheppard Pratt Entity, including intellectual property rights assigned to the Sheppard Pratt Entity and agreements to share in royalties related to such rights.
  2. The following income from a Federal, state or local government agency, an institution of higher education (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:
    - a) Income from seminars, lectures or teaching engagements sponsored by any of the above or sponsored by public or nonprofit entities
    - b) Income from service on advisory committees or review panels for any of the above
    - c) Travel reimbursed or sponsored by any of the above
  3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the CI does not directly control the investment decisions made in these vehicles.
- L. Financial Conflict of Interest (FCOI): An SFI that could directly and significantly affect the design, conduct, or reporting of research.

### III. SCOPE AND RESPONSIBILITY

- A. This policy applies to all Covered Individuals. In cases where a Sheppard Pratt Entity is the awardee Institution and carries out research through a sub-recipient (e.g., subcontractor or collaborator), the Sheppard Pratt Entity will ensure that the written agreement with the subrecipient establishes whether the sub-recipient will follow this policy or the sub-recipient's own financial conflict of interest policy.

#### IV. PROCEDURE

##### A. Submission of Research Financial Disclosure Information by CI's

1. Annually, the COI Official or designee will provide each CI with a copy of this policy as well as instructions for completion of the Sheppard Pratt research disclosure of financial interests form.
2. All CI's must complete and submit Sheppard Pratt Research Financial Disclosure form as follows: (i) annually, (ii) within 30 days of acquiring or discovering a new SFI, and (iii) at the time of application for any new research project. A new CI is required to complete and submit the form prior to involvement in any research-related activities. The financial interests of a CI, as well as those of a Covered Family Member, are subject to disclosure.

##### B. Review of Financial Disclosure Information and Assessment of Potential FCOI

1. The COI Official will review all disclosure forms that identify a CI with an SFI to determine if the SFI represents a FCOI that requires a management plan as described below.
2. If an SFI is disclosed, the COI Official or designee will obtain any additional information needed to provide an assessment of whether an SFI may be related to research, and if so related, whether the SFI may be an FCOI.

##### C. Management of FCOIs

1. If it is determined by the COI Official, in consultation with the FCOI-R Committee, that an SFI creates an FCOI, the COI Official, in consultation with the FCOI-R Committee, shall assess and determine if a management plan is necessary. If an FCOI exists that would reasonably appear to compromise objectivity of the research a management plan will be proposed to eliminate, minimize, manage, or disclose the SFI. Possible strategies include, but are not limited to:
  - a) Public disclosure of the FCOI when presenting or publishing the research
  - b) Disclosure of FCOI directly to potential research subjects
  - c) Monitoring of research by independent reviewers
  - 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
  - g) Severance of relationships that create financial conflicts
2. The proposed management plan will be shared with the Sheppard Pratt IRB, or the reviewing IRB as appropriate, for impacted research studies. The IRB will have authority to add provisions to the management plan, if deemed necessary for the protection of human subjects and will determine if the management plan is appropriate for a given study.
3. The COI Official grants final approval of the management plan.
4. The management plan will be shared with funding agencies, as appropriate.

5. For studies that are ongoing, when an existing CI discloses a new SFI, within 60 days the review process described above will be initiated. If an FCOI exists, a management plan will be implemented. If necessary, additional interim measures may be implemented to manage the FCOI between the date of disclosure and completion of the review.

#### **D. Reporting of Financial Conflicts of Interest to Sponsoring Agency**

1. Prior to Sheppard Pratt expenditure of any sponsor funds, an FCOI report will be sent to the relevant sponsoring agency. Any subsequent FCOI identified for an ongoing study will be reported within 60 days. Annual FCOI reports on the status of a previously reported FCOI and any changes to the management plan will be sent to the relevant sponsoring agency as required.
2. Prior to Sheppard Pratt expenditure of any funds under a PHS awarded grant and cooperative agreement (42 CFR 50 Subpart F), an FCOI report will be submitted to the NIH through the electronic Research Administration (eRA) Commons FCOI Module for any identified FCOI of each investigator, including FCOI reports for subrecipient investigators as needed. Any subsequent FCOI identified for an ongoing study will be reported within 60 days. Annual FCOI reports on the status of a previously reported FCOI and any changes to the management plan will be also be sent through the eRA.
3. FCOI reports will include information required by federal regulations. These include but are not necessarily limited to the following:
  - a) Project number
  - b) PI
  - c) Name of the Investigator with the FCOI
  - d) Name of the entity with which the Investigator has an FCOI
  - e) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
  - f) Value of the financial interest (\$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 why it was determined that the financial interest conflicts with such research
  - h) A description of the key elements of the management plan, including:
    - (1) Role and principal duties of the conflicted Investigator in the research project
    - (2) Conditions of the management plan
    - (3) How the management plan is designed to safeguard objectivity in the research project
    - (4) Confirmation of the Investigator's agreement to the management plan
    - (5) How the management plan will be monitored to ensure Investigator compliance

(6) Other information as needed (42 CFR 50.605(b)(3) & 45 CFR 94.5(b)(3))

- i) A confirmation of the Investigator's agreement to the management plan will also be included in the report (i.e., a statement that a signed plan is on file at Sheppard Pratt or the Investigator has agreed to and signed the management plan).

#### **E. Monitoring and Compliance**

1. Each CI conducting research under a management plan is responsible for fully and promptly complying with the plan. The management plan will specify who is responsible for monitoring ongoing compliance with the plan.
2. Studies with management plans will be reviewed annually to ensure PI's or Study Team Member's continued compliance to the plan. If deemed necessary by COI Official or designee, the CI with the conflict will be required to update his/her financial status by completing a new FCOI-R disclosure form.
3. If no changes to the management plan is needed after review of study, a letter will be sent to the CI stating the current management plan is still in effect.

#### **F. Corrective Action**

1. If a CI, or a Sheppard Pratt Entity, fails to comply with this policy, they will be referred to the COI Official, who may consult with the FCOI-R Committee and the applicable department director, if any, for noncompliance review and potential reportable event to the IRB.
2. If the COI Official learns of an SFI that was not disclosed or reviewed in a timely manner, the above process for reviewing and managing financial conflicts will be completed within 60 days and reported to the IRB and external agencies as required.
3. If the COI Official learns that (a) an FCOI was not identified or managed in a timely manner or a CI failed to comply with a management plan, a retrospective review will be completed within 120 days of noncompliance determination to determine if the noncompliance caused bias in the design, conduct, or reporting of the research. Based on the results of the retrospective review, an updated FCOI report and/or mitigation report (if bias is found) may be sent to the relevant sponsoring agency, and the IRB as required.
4. The Retrospective Review shall include, but not necessarily be limited to, all of the following key elements:
  - a) Project number
  - b) Project title
  - c) PI
  - 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
  - i) Conclusions of the review

5. Based on the results of the retrospective review, if appropriate, Sheppard Pratt shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Sheppard Pratt will notify and submit a mitigation report to the relevant sponsoring agency, if applicable.
6. 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 Sheppard Pratt'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).
7. Sheppard Pratt Research Administration may decline or withhold funding in all cases in which a CI does not comply with an established conflict of interest management plan. Other consequences may include a letter of reprimand or the removal of a CI from an ongoing project and, in the case of a Sheppard Pratt employee and/or contractor, may include termination of employment or contract.

### **G. Education**

1. All CIs must complete the Sheppard Pratt approved and designated research conflict of interest training module prior to engaging in research at Sheppard Pratt and every 3 years following the initial training. In addition, training may be required when there is a change in institutional policies or there is a case of noncompliance.
2. Other educational activities/resources might include but not limited to:
  - a) Copies of publications or media items;
  - b) Dissemination of new information including laws, regulations, policies or guidance. These materials will be provided through email, relevant meetings, ORA publications, or through other appropriate means as needed.

### **H. Public Accessibility**

1. This policy shall be publicly accessible on the Sheppard Pratt Research page on the Sheppard Pratt website.
  - a) Information regarding current FCOI's of Senior/Key personnel related to PHS funded research will be publicly accessible and will remain accessible for three years from the date the information was most recently updated. If requested, a written response including all the information required under the applicable federal regulation will be provided to the requestor within 5 business days by emailing the Director of Research Administration the required information includes: Investigator's name; Investigator's title and role with respect to the research project; Name of the entity in which the SFI is held; nature of SFI; and approximate dollar value of the SFI \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000- \$100,000 by increments of \$20,000; amounts above \$100,00 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.

**V. DOCUMENTATION**

- A. All Financial Disclosure Forms, records of review and action under this policy, and management plans will be retained for the longer of at least 3 years following:
1. The date of creation; or
  2. The date of termination or completion of a research award contract, or the submission of the final expenditures report, for research identified in a disclosure statement; or
  3. The date of final resolution for any investigation, audit, or similar action involving the records.
- B. This information is confidential and available only to pertinent Sheppard Pratt personnel.

**VI. REFERENCES/AUTHORITY**

- A. FDA: 21 CFR 54.1; 21 CFR 54.2; 21 CFR 54.4; 21 CFR 312.64(d); 21 CFR 812.110(d).  
B. HHS: 42 CFR 50, Subpart F; 45 CFR 94

**References:****Attachments:**

[Sheppard Pratt Financial Disclosure Form](#)

**Revised Dates:**

12/15, 11/20

**Reviewed Dates:**

8/12, 12/15, 11/20

**Signatures:**

Harsh Trivedi: 11/19/20  
Jeffery Grossi: 11/18/20