

Sheppard Pratt
Public Health Service Funded Research
Financial Disclosure Form Instructions

Explanation: At the time that a proposal for research to be funded by the United States Public Health Service, including the National Institutes of Health, (“PHS-funded research”) is submitted, Federal Regulations at 42 CFR Part 50 and 45 CFR Part 94 (the ”Regulations”) and the **Sheppard Pratt Conflict of Interest Policy for Public Health Service-Funded Research** (the “Policy”), available at www.sheppardpratt.org (click Research/IRB), require that any individual with responsibility for design, conduct, or reporting of a project (an "Investigator") must disclose Significant Financial Interests of themselves, their spouse, and dependent child(ren) where that financial interest actually or apparently may be: 1) affected by the research being conducted or, 2) in any organization that would reasonably appear to be affected by or benefit from the research being conducted. The disclosure requirement also applies to certain reimbursed or sponsored travel related to the Investigator’s institutional responsibilities. The disclosure requirement also applies in the event of any relevant change in a Significant Financial Interest, and the disclosure requirement requires at least annual updates of the disclosure. The disclosure requirement applies to grants, contracts and awards where Sheppard Pratt or the Investigator is the direct recipient and to grants, contracts and awards where Sheppard Pratt or the Investigator is a subrecipient.

NOTE: This Disclosure Form is for use only with respect to PHS-funded research, and does not fulfill any other disclosure requirement. Please submit this Disclosure Form to the Sheppard Pratt Conflict of Interest Officer at 6501 North Charles Street, Baltimore, MD 21204.

For purposes of this Disclosure Form, the following definition applies:

Significant Financial Interest (SFI) 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 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 of fair 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.

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.

Significant financial interests must be disclosed if the work performed in a PHS-funded project would appear to affect the Investigator's significant financial interest, *for example*, if

- Results of project being carried out by Investigator would be relevant to development, manufacturing, or improvement of product or service of entity in which Investigator has a SFI.
- Investigator has significant financial interest in an entity, which might manufacture or commercialize drug, device, procedure, or any other product used in the project or that will predictably result from the project.
- Investigator receives consulting income from a single entity that exceeded \$5,000 during the prior twelve months; and the financial interests of that entity, or the Investigator's significant financial interest related to consulting for that entity, would reasonably appear to be affected by the research to be conducted.
- Investigator is the beneficiary of travel reimbursed or provided by an entity to which the outcome of the PHS-funded research would be relevant to research being conducted by the entity or to development, manufacturing or services provided by the entity.
- The entity where the significant financial interests lie is proposed as a subcontractor, consortium member, supplier of goods, lessor, or otherwise involved with the PHS-funded project.

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THIS SUBMITTAL is for a: New Disclosure Updated Disclosure

Investigator's Name: _____

Principal Investigator Name (if different from Investigator): _____

Proposal/Project Title: _____

Project Number: _____

Proposal Type (please check one):

Public Health Service (PHS), including National Institutes of Health (NIH), etc.

Subaward from a PHS (including NIH, etc.) prime awardee

All Investigators **must answer the following question:**

Do you, your spouse, or dependent child(ren) have any significant financial interest(s) (i) that would reasonably appear to be affected by the research for which funding is sought or, (ii) that is/are in entities whose financial interests would reasonably appear to be affected by the research?

NO

YES

If you answered NO, please sign this form (on the last page) and submit.

If you answered YES, please answer the following questions (attach a separate sheet if needed), sign and submit.

Please complete one separate set of all questions for each Entity in which you have a significant financial interest.

Name of Entity: _____

Principal Business of Entity: _____

1. If you, your spouse, or dependent child(ren) hold a position of management with this Entity, state the position title, describe the responsibilities of the position, and explain any relationship to this research project.

2. If you, your spouse, or dependent child(ren) have equity interest in excess of \$5,000 or 5% ownership in Entity, state the value, type of equity (stock, securities, etc.), and percentage of ownership.

3. If you, your spouse, or dependent child(ren) have received income in excess of \$5,000 from the Entity in the past 12 months, describe the nature of the income and explain any relationship to this research project.

4. Have you, your spouse, or dependent child(ren) been the beneficiary of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator, spouse or child and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to your institutional responsibilities, not including 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.

_____ No _____ Yes

If "Yes" please complete the following:

The purpose of the trip: _____

The identity of the sponsor/organizer: _____

The destination: _____

The duration: _____

The actual or, if unknown, the estimated monetary value: _____

Any relationship between the travel and the research project: _____

5. Have you, your spouse, or dependent child(ren) assigned to the Entity rights to a pending application or issued patent to an invention(s), license rights, or copyright for software?

_____ No _____ Yes

If YES, have you, your spouse or dependent child(ren) received any income as a result of this assignment?

_____ No _____ Yes If yes, amount in the past 12 months: _____

6. If this research project proposal includes or may include the Entity as a subcontractor, consortium member, supplier of goods, lessor or otherwise involved in the project, explain and describe.

7. If the Entity might manufacture or commercialize any drug, vaccine, device, product, procedure, or process that is associated with or that will predictably result from the research project, explain and describe.

8. If the Entity reasonably could be expected to be directly and significantly *affected* by the design, conduct, or reporting of the research project, explain and describe.

9. Is it reasonable to anticipate that your financial interest could be directly and significantly *affected* by the design, conduct, or reporting of the research project?

___ No: Explain.

___ Yes: Explain.

10. Please provide any additional comments and information which you believe may be relevant to a determination as to whether your significant financial interest constitutes a conflict of interest with your role in the research project. Attach a separate sheet if necessary.

Certification by individual filing disclosure

___ I certify that neither I, my spouse, nor my dependent child(ren) have any significant financial interest(s) that (i) would reasonably appear to be affected by the research project, or, (ii) are in entities whose financial interests would be reasonably likely to be affected by the research project.

Or

___ I certify that this is a complete disclosure of all financial interests related to this Entity.

Signature: _____

Date: _____

Please note that the information provided on this form, in accordance with the requirements of the Regulations and the Policy, may be posted on the Sheppard Pratt publicly-accessible website, and may otherwise be made available to the public. This form will be retained for three (3) years after termination of the sponsored project or until resolution of any action by the sponsor, whichever is longer.