

TWIN CITIES PBS

FINANCIAL CONFLICT OF INTEREST POLICY

A. General Policy

Twin Cities PBS (“TPT”) requires managers, employees and other collaborators to observe high standards of financial integrity. As employees and representatives of TPT, we have an obligation to identify, evaluate and correct or remove real, apparent and potential conflicts of interest for which there are significant financial interests (“SFI”), as well as comply with all applicable laws and regulations.

B. Scope

This statement of policy and procedures is intended to carry out TPT’s responsibilities under the Public Health Service (“PHS”) Policies on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, 42 CFR Part 50, Subpart F. This Financial Conflict of Interest Policy (“FCOIP” or the “Policy”) is applicable to any person in an Investigator role, as defined in Section C.3. below, who is planning to or is participating in research activity. This Policy is in addition to the Twin Cities PBS Conflict of Interest and Ethics policy which governs TPT’s business decisions and actions of individual employees in conducting TPT business. Any significant variation of this Policy will be approved in advance by General Counsel of TPT.

C. Definitions

1. **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.
2. **Significant Financial Interest (SFI)** exists if the value of remuneration received by the investigator, investigator’s spouse or dependent children that reasonably appear to be related to the investigator’s TPT responsibilities exceeds \$5,000;
 - a) Including:
 - i. Salary or other payments for services (e.g., consulting fees or honoraria) received in the twelve months preceding disclosure;
 - ii. Equity interests (e.g., stocks, stock options or other ownership interests) if the equity interests in a non-publicly traded entity, no matter the amount, constitute an SFI; and
 - iii. Income from intellectual property rights owned by the investigator.
 - b) Excluding:
 - i. Salary or other remuneration from TPT;
 - ii. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, derived from excluded sources;
 - iii. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions; and,
 - iv. Unlicensed intellectual property owned by the investigator that does not generate income. Note that Intellectual property owned by TPT is excluded.
 - c) SFI disclosure also includes travel, specifically, externally funded reimbursed or sponsored travel that would appear to be related to investigator’s TPT responsibilities that is not funded by TPT. Such travel must be disclosed, no matter the amount, except when the expenses are covered by any of the excluded sources.
 - d) Note that the threshold of \$5,000 is applied to the aggregation of a)i and a)ii, or to a)iii.
3. **Investigator** means any principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include employees, contractors, collaborators or consultants.
4. **Investigator’s professional responsibilities on behalf of TPT** means conducting research, submitting patent applications, publication, technical committee membership and teaching as adjunct faculty at an institution of higher education.

5. **An excluded source** means a source of remuneration that is excluded from disclosure. With reference to C.2.b)ii and C.2.c) excluded sources are 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.

D. General Policies and Principals

1. Each such Investigator must:
 - a) **disclose** his or her significant financial interests (SFI) in non-Twin Cities PBS entities that would appear to be related to the investigator's professional responsibilities on behalf of TPT;
 - b) **comply** with an FCOI management plan, if an FCOI is identified; and
 - c) **undergo** FCOI training, at least once every four years.
2. Disclosure of SFI is essential for TPT to determine if an FCOI exists, and in cases of an FCOI determine how it will be managed and reported in full compliance with government regulation. Non-disclosure of SFI or non-compliance with an FCOI management plan may subject the investigator to employment discipline including, without limitation, suspension or termination of employment.
3. Investigators who are planning to or participating in research activity that is either partially or wholly supported by PHS funds must disclose their SFI in a timely fashion, either to a member of the TPT Management Team or the designated TPT FCOI official. The designated TPT FCOI official will determine whether the SFI constitutes an FCOI, based on guidance set by the TPT Management Team. If the SFI is determined to be an FCOI, the TPT Management Team will take actions to discuss and approve the implementation of an FCOI management plan consistent with government regulation and, furthermore, to promptly notify the PHS funding component (e.g., NIH) via an FCOI report.
4. As a part of the FCOI management plan, the TPT Management Team will decide one or more actions depending upon the situation, including requiring certain disclosure in public presentations, investigator role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Investigators with an identified FCOI must comply with the FCOI management plan.

E. Protocol for Handling Financial Conflict of Interest

1. This protocol along with the policy and procedure titled "Financial Conflict of Interest in PHS-Funded Projects" constitute the TPT FCOIP. Capital terms in this protocol shall have the same meaning as set forth in the Financial Conflict of Interest in PHS-Funded Projects policy. This protocol outlines the procedure that will be followed as per regulation (Title 42 CFR 50.601-50.607).
2. This document specifies the FCOI procedures for PHS-funded research that is the step-by-step implementation of the TPT FCOIP.
 - a) Who is required to disclose financial interests?

Investigators planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests ("PHS-funded Investigators").
 - b) SFI disclosure:

PHS-funded Investigators are required to disclose SFIs to either a member of the TPT Management Team or the designated TPT FCOI official, as follows:

 - i. Investigators planning to participate in PHS-funded research are required to disclose all SFIs prior to submission of an application for PHS-funded research.
 - ii. Once the research project has been funded, all PHS-funded Investigators shall submit SFI disclosures within thirty (30) days of acquiring any new or increased SFI.
 - iii. When a new Investigator joins an ongoing PHS-funded project, the Investigator shall submit SFI disclosures within thirty (30) days of joining the project.
 - iv. All PHS-funded Investigators shall submit an updated SFI disclosure annually.

- v. SFI disclosures (except travel) must include the following information:
 - a. Identity of the sponsor/organizer; and
 - b. Nature of SFI (e.g., salary, license income, stock).
 - vi. Externally funded travel also constitutes SFI. PHS-funded Investigators shall submit SFI disclosures for externally funded travel prior to submission of an application for PHS-funded research; and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:
 - a. Purpose,
 - b. Identity of the sponsor/organizer,
 - c. Destination, and
 - d. Duration.
- c) Review of disclosures
- i. All SFI disclosures, including those submitted by a new Investigator who joins an ongoing PHS-funded project, will be reviewed by the designated TPT FCOI official. The review will determine whether an SFI is related to the PHS-funded research and therefore an FCOI. The designated TPT FCOI official may involve the relevant Investigator in the review, and request additional information from the Investigator.
 - ii. When an SFI that was not disclosed by a PHS-funded Investigator in a timely manner is identified, the designated TPT FCOI official will determine if FCOI exists, and will develop and implement a FCOI management plan within sixty (60) days after the identification of the SFI. In addition, the designated TPT FCOI official will conduct a retrospective review of SFIs for the PHS-funded Investigator within one hundred twenty (120) days and document the review.
- d) Management of FCOI
- i. For each disclosure that leads to determination of FCOI, the TPT Management Team will discuss and approve the implementation of a management plan developed by the designated TPT FCOI official. PHS-funded Investigators with an identified FCOI must comply with the management plan. The management plan will include the following elements at a minimum:
 - a. The role and principal duties of the conflicted PHS-funded Investigator in the research project;
 - b. Conditions of the management plan (see examples below);
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the PHS-funded Investigator's agreement to the management plan; and
 - e. How the management plan will be monitored to ensure PHS-funded Investigator compliance.
 - ii. Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:
 - a. Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s));
 - b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to 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 FCOI;
 - d. Modification of the research plan;
 - e. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
 - f. Reduction or elimination of the SFI (e.g., sale of an equity interest); or
 - g. Severance of relationships that create financial conflicts.
- e) Reporting FCOI to PHS Awarding Component (e.g. the NIH)
- i. Based on the FCOI management plan, the designated TPT FCOI official will make sure an initial FCOI report is submitted to the PHS-funding component, for example NIH. The

report will be submitted, for example using eRA Commons for NIH, and consist of all elements required by the regulation.

- ii. The FCOI report will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new Investigators joining an ongoing PHS-funded project.
 - iii. Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.
- f) Training for FCOI: PHS-funded Investigators must undergo training with respect to this Policy and PHS FCOI rules and regulations as follows:
- i. TPT will include an overview of these guidelines in the annual grant training;
 - ii. Prior to participating in PHS-funded research, and/or at least once every four years;
 - iii. When the TPT FCOI policy changes in a manner that affects PHS-funded Investigator disclosure or compliance requirements; and
 - iv. If TPT Management Team determines that a PHS-funded Investigator is not compliant with the FCOI Policy or an FCOI Management Plan.
- g) Sanctions for violation of this Policy
- i. Disclosure of SFI is essential for TPT to implement its FCOIP. If a PHS-funded Investigator fails to comply with this Policy (with regard for instance to the SFI disclosure requirement or implementation of an FCOI management plan), and appears to have biased the PHS-funded research, the TPT Management Team will implement a mitigation plan and require that the Investigator disclose the FCOI in each public presentation of the results of the research, and to remedy previously published presentations with an FCOI disclosure addendum. In addition, the investigator may be subject to employment discipline including, without limitation, suspension or termination of employment.
 - ii. In any case, the PHS-funding agency will be promptly notified.
- h) Retention of records
- Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report.
- i) Subrecipient compliance
- When working with a subrecipient, a written agreement will be put in place to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed, and, (b) in either case, clarify the timeline for disclosure and reporting. Note that the prime awardee is responsible for monitoring the subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified financial conflicts of interest.
- j) Public Accessibility
- i. As required by PHS regulation, the TPT FCOIP is being made accessible on TPT's web site, www.tpt.org.
 - ii. If a PHS-funded Investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will also be posted on the web site, as follows:
 - 1) Include the minimum elements required by the regulation;
 - 2) Update within sixty (60) days of a newly identified FCOI;
 - 3) Update annually; and
 - 4) Remain available for three (3) years.