

Policy Number: SPA-01	Policy Title: Financial Conflict of Interest (FCOI)	
Section: Sponsored Programs Administration	Responsible Office: Chief Financial Officer	Page 1 of 5
Effective Date: 10 June 2019	Supersedes: SCIR-05	

Purpose:

In accordance with federal requirements for institutions that apply for or receive Research funding from the United States Public Health Service (PHS) awarding components, the purpose of this policy is to ensure objectivity in research such that the design, conduct and reporting of research is free from bias resulting from Financial Conflict of Interest (FCOI).

Definitions:

1. *Exempt Organization* means the Institute or a federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or another research institute that is affiliated with an institution of higher education.
2. *Financial Conflict of Interest (FCOI)* means a Significant Financial Interest (SFI) disclosed by the Covered Individual that could directly and significantly affect the design, conduct, or reporting of Federally Funded Research. Exceptions are Research funded through phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.
3. *Federally Funded Research* means any Research funded by a Public Health Service (PHS) awarding component, such as the National Institutes of Health (NIH), National Science Foundation (NSF), Department of Defense (DOD), Department of Energy (DOE), or other U.S. federal agencies.
4. *Covered Individual* means any person, regardless of title or position, who is responsible for the design, conduct, or reporting of Federally Funded Research or Research that is proposed for federal funding.
5. *Covered Individual's Institutional Responsibilities* means professional activities taking place on behalf of the Institute, including, but not limited to, Research, Research consultation, teaching, institutional committee memberships, and service on committees or panels such as Institutional Review Boards or other monitoring boards.

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6. *Management of an FCOI* means taking action to address the FCOI, including reducing or eliminating the conflict so that the Institute can reasonably expect that the Covered Individual's design, conduct, and reporting of Research will be free from bias.
7. *Management Plan* means a written document approved by the Conflict of Interest (COI) Committee under which a Covered Individual with an identified FCOI must take steps and follow guidelines, conditions, and/or restrictions to reduce or eliminate the conflict.
8. *Research* means a systematic investigation designed to develop or contribute to generalizable knowledge. Research includes any activity for which research funding is available, regardless of the source.
9. *Significant Financial Interest (SFI)* means anything of monetary, or potential monetary, value that was received from an entity in the twelve (12) months preceding the disclosure, whether or not the value is readily ascertainable, belonging to the Covered Individual, his or her spouse, and/or his or her dependent children, alone or in combination, that reasonably appears to be related to the Covered Individual's Institutional Responsibilities.
10. *Small Business Innovation Research (SBIR)* means an award designed to support projects from small businesses having commercial viability.
11. *Small Business Technology Transfer (STTR)* means a program under the SBIR program designed to foster technology innovation through cooperative efforts between small businesses and research institutions.

Policy:

1. **Applicability.** This policy applies to all individuals who fit the definition of Covered Individual.

2. **Mandated Training.** All Covered Individuals must complete a COI training tutorial prior to engaging in Federally Funded Research and at least every four (4) years thereafter. Training is required under the following circumstances:
 - a. The Covered Individual is a new Institute employee;
 - b. Every four (4) years;
 - c. The Institute's FCOI Policy changes in a manner that affects Covered Individual requirements; and
 - d. The Covered Individual is non-compliant with the Institute's FCOI Policy or Management Plan.

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3. Disclosure of Significant Financial Interests (SFIs). In accordance with “Procedures Section 2 (Disclosing SFIs),” Covered Individuals must disclose their (and those of their spouse and/or dependent children) SFIs.

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);
- iii. Income from intellectual property rights owned by the Covered Individual; and
- iv. Travel that is not reimbursed or sponsored by an Exempt Organization.
- v. Financial gains related to human subjects research (e.g. interest in trial outcome due to Intellectual Property or Equity).

b. Excluding

- i. Salary, royalties, stock options or other remuneration from the Institute;
- ii. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels derived from Exempt Organizations;
- iii. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decisions; and
- iv. Unlicensed intellectual property owned by the employee that does not generate income.

An SFI exists if the value of remuneration exceeds \$5000. The threshold of \$5000 is applied to the aggregation of 3.a.i and 3.a.ii and exclusively to 3.a.iii; however, equity interest in a non-publicly traded entity, no matter the amount, constitutes an SFI.

Many scientific journals have implemented policies that require authors to declare competing financial interests in relation to work published in those journals. Such requirements of third parties, including how financial interests are defined, are distinct from the requirements in this policy relating to Federally Funded Research and must not be used as guidance for the information a Covered Individual must disclose under this policy.

4. Compliance and Enforcement. The Institute is required to establish adequate enforcement mechanisms and provide for employee sanctions and/or other administrative action, where appropriate, to address any failure by the Covered Individual to comply with the FCOI Policy or a Management Plan. Violations of this policy may result in progressive

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disciplinary action up to and including dismissal from the Institute.

A Covered Individual is non-compliant and in violation of the FCOI Policy if the Covered Individual fails to:

- a. Complete COI training;
- b. Submit an SFI Disclosure Form at the start of their employment;
- c. Submit an SFI Disclosure Form prior to applying for Federally Funded Research;
- d. Submit an SFI Disclosure Form every April;
- e. Fulfill their ongoing obligation to update SFI Disclosure Forms within thirty (30) days of discovering or acquiring a new SFI;
- f. Provide the Chief Financial Officer written acknowledgement of a Management Plan; or
- g. Provide the Chief Financial Officer and/or COI Committee with requested documentation regarding compliance with a Management Plan.

The Institute (i) may not submit any new grant applications to a federal agency for Research projects, and (ii) may not spend any federal funds in connection with Notices of Award for new or continuing Federally Funded Research projects until all Covered Individuals identified to work on such projects have completed the training and submitted their disclosures as required by COI Regulations and this policy.

5. **Precedence.** Where more stringent requirements and regulations relating to conflict of interest of any funding agency or sponsor conflict with the Institute's FCOI Policy, the requirements and regulations of that funding agency or sponsor will take precedence.
6. **Public Accessibility of the Institute's FCOI Policy.** In accordance with Federal regulations, the Institute's FCOI Policy will be publicly accessible on its website (www.txbiomed.org).

Procedures:

1. **Training.** The Institute provides the required training as a web-based tutorial through the Collaborative Institutional Training Initiative (CITI) Program. The Chief Financial Officer or delegate manages this resource. New employees, first-time CITI users or individuals requesting CITI account affiliation with Texas Biomed can obtain access by sending email to fcoi@txbiomed.org.

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- 2. Disclosing SFIs.** All Covered Individuals must submit a complete, accurate and current SFI Disclosure Form:
- a. At the beginning of their time at the Institute;
 - b. Every April;
 - c. Within thirty (30) days of discovering or acquiring a new SFI; and
 - d. Prior to submission of an application for Federally Funded Research, if update to initial or annual disclosure is needed.

All Covered Individuals will be prompted upon hire and each April thereafter to submit their SFI Disclosure Form. Covered individuals will be sent a link to a portal where they will submit their SFI Disclosure Form. In addition, Covered Individuals have an ongoing obligation to promptly submit an updated SFI Disclosure Form to accurately reflect any significant change in their external activities, SFIs, and internal responsibilities. This form may be submitted at: <https://texasbiomedicalresearchinstitute-psoce.formstack.com/forms/sfi>

Relevant Federal and/or State Statutes:

- a. 42 CFR Part 50 Subpart F (grants) – Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought
- b. 42 CFR Part 94 (contracts) – Responsible Protective Contractors
- c. Public Health Service (PHS) Final Rule on “Objectivity in Research”
- d. NIH Financial Conflict of Interest (FCOI) Tutorial:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

- e. PHS FCOI Frequently Asked Questions:

https://grants.nih.gov/grants/policy/coi/coi_faqs.htm

Relevant Texas Biomed Policies, Procedures and Forms:

- a. Addendum: Protocol for Handling Financial Conflict of Interest

Dates Approved:

1 February 2012 (SCIR-05)
10 June 2019 (SPA-01)