

THE UNIVERSITY OF TULSA

Financial Conflict of Interest Policy for Research Conducted Under the Public Health Service

- I. Purpose and Scope
- II. Definitions
- III. Training
- IV. Disclosure by Investigators
- V. Disclosure by Subrecipients and Collaborators
- VI. Designated Institutional Official Review
- VII. Managing FCOI
- VIII. Public Access and Retention
- IX. Sanctions
- X. PHS Conflict of Interest Regulations

I. PURPOSE AND SCOPE

This policy implements the 2011 Public Health Services (PHS) regulations on Promoting Objectivity in Research at The University of Tulsa (“Institution”). The PHS regulations are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct and reporting of PHS Research Activities will be free from bias resulting from any Investigator’s Financial Conflicts of Interest.

This policy is applicable to all PHS Research Activities with an award issue date of August 24, 2012 or later, and to proposals for PHS Research Activities submitted to PHS on or after August 24, 2012. PHS Research Activities that are ongoing as of August 24, 2012 will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost extension. This policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are independently responsible for the design, conduct or reporting of a PHS Research Activity.

This policy is applicable to all research activities supported by PHS and by other sponsors and programs that specifically request review consistent with PHS regulations on objectivity on research.

II. DEFINITIONS

For the purposes of this policy, the following terms shall apply:

Designated Institutional Official(s): The Institutional official(s) designated to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator who is planning to participate in or is participating in a PHS Research Activity.

Financial Conflict(s) of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS Research Activity.

Institutional Responsibilities: Investigator's professional responsibilities associated with his/her institutional appointment or position, such as research, research consultation, teaching, and institutional committee responsibilities.

Investigator: Project director or Principal Investigator and any other individual, regardless of title or position, that the Principal Investigator identifies as independently responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, which may include collaborators or consultants. This includes, but is not limited to, Senior/Key Personnel named in a PHS proposal or award.

PHS Research Activity(ies): Any award for which research funding is available from PHS excluding Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) award programs.

Principal Investigator (PI): Investigator (normally an academic appointee) who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

Senior/Key Personnel: A PHS research project director, Principal Investigator, and any other personnel considered essential to work performance and identified as Senior/Key Personnel in the proposal, progress report, or any other report submitted by the Institution.

Significant Financial Interest (SFI): A financial interest that meets the PHS thresholds for reporting (see Article IV.b. below) received by the Investigator (including the Investigator's spouse, domestic partner, and dependent children) that reasonably appears to be related to Investigator's Institutional Responsibilities.

III. TRAINING

Investigators must complete the CITI FCOI training/education program located at www.citiprogram.org:

- A. Before engaging in PHS Research Activities and at least every four years thereafter while receiving PHS research funding, and
- B. Immediately when:
 - 1. This policy, the PHS disclosure form or procedures are modified in any way that affects the requirements of Investigators;
 - 2. Investigator is not in compliance with this policy or has failed to comply with an approved management plan; or
 - 3. Investigator is newly appointed to Institution

IV. DISCLOSURE BY INVESTIGATORS

- A. Investigators shall disclose SFI at the following times:
 - 1. Initial disclosures must be made by all Investigators planning to participate on a proposed PHS Research Activity before the application for funding is submitted.
 - 2. Investigators who are engaged in PHS Research Activities have an ongoing responsibility to update their disclosures throughout the period of PHS support:

- a. Within thirty (30) days of acquiring or discovering any new SFI; and
 - b. At least annually
 3. New Investigators must complete a disclosure of SFI before joining an ongoing PHS Research Activity.
- B. Investigator shall disclose SFI that consist of one or more of the following interests of the Investigator (and those of the Investigator's spouse, domestic partner, or dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibility to Designated Institutional Official:
1. For a publicly traded entity: The value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any interest in the entity as of the date of the 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 interests include stock, stock options, or other ownership interest, as determined by public prices or other reasonable measures of fair market value. *Mutual funds or other investment vehicles such as retirement funds shall not be considered an SFI as long as the Investigator does not directly control the investment decisions made for these investment vehicles.*
 2. For a non-publicly traded entity: 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, domestic partner, or dependent children) hold any equity interest (e.g. stock, stock options, or other ownership interest). *SFI does not include (a) payments made by the Institution, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from Institution; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education.*
 3. Intellectual property rights and interests: Income from each organization that exceeds \$5,000 during the twelve months preceding the disclosure. *SFI does not include royalties received from Institution related to patents or copyrights.*
 4. Travel: Any reimbursed or sponsored travel (i.e., that which is paid on behalf of Investigator and not reimbursed to Investigator so that the exact monetary value may not be readily available), *related to their Institutional Responsibilities in the 12 months prior to the disclosure, but excluding travel that is reimbursed or sponsored by (i) a Federal, state or local government agency, (ii) an institution of higher education, or (iii) an academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education.* Disclosure of this interest will include the purpose and duration of the trip, the identity of the sponsor/organizer, and the travel destination. Designated Institutional Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with PHS Research Activities.

5. To the extent permitted by law, all disclosure forms, FCOI management plans, and related information will be confidential. However, Institution may make such information available to an agency funding research of Investigator, to a requestor of information concerning FCOI related to PHS Research Activity or to the primary entity who made the funding available to the Institution if requested or required. If Institution is requested to provide disclosure forms, FCOI management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

V. DISCLOSURE BY SUBRECIPIENTS AND COLLABORATORS

- A. Subcontracts under PHS awards will specify whether the FCOI policy of Institution or that of the subrecipient will apply to the subrecipient's Investigators. If the subrecipient's policy applies, the subrecipient will be required to certify as part of the subcontract that its policy complies with applicable PHS FCOI regulations and the subcontract will specify time period(s) for the subrecipient to report all identified FCOI to Institution. Alternatively, if the subrecipient's Investigators must comply with Institution's FCOI policy, the subcontract will specify time period(s) for the subrecipient to submit all Investigators' disclosures of SFI to Institution. In either case, the time period(s) specified must be prior to the expenditure of funds and within 60 days of any subsequently identified SFI.
- B. Collaborators who share responsibility for the design, conduct, and reporting of research results and who will participate in PHS Research Activities under an independent consulting agreement issued by Institution should be identified as Investigators by the Institution's Principal Investigator and must comply with Institution FCOI policy including the submission of Institution disclosure forms. If, upon review, Institution determines that these SFI could directly and significantly affect the design, conduct or reporting of the research to be performed under the agreement creating a FCOI, these collaborators will be expected to adhere to the mitigation plans put in place to eliminate, reduce or manage the identified conflicts of interest.

VI. REVIEW AND REPORTING

- A. The Director of Research and Sponsored Programs (DRSP) shall serve as primary Designated Institutional Official and shall solicit and review disclosures of SFI from each Investigator who is planning to participate in, or is participating in PHS Research Activities. In the absence of the DRSP, the Vice Provost for Research shall serve as the Designated Institutional Official.
- B. After reviewing the disclosure, Designated Institutional Official will determine whether either (i) the SFI could be affected by the PHS Research Activity; or (ii) the SFI is an entity whose financial interest could be affected by the PHS Research Activity. If so, the SFI is related to PHS Research Activities.
- C. Designated Institutional Official may consult with the Investigator or other Institutional officials in making the determination whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS Research Activity. If so, the SFI is a FCOI.

- D. If it is determined that a potential FCOI exists, Designated Institutional Official will coordinate the development and implementation of an FCOI Management Plan prior to the expenditure of any funds under the PHS Research Activity.
- E. Designated Institutional Official shall provide FCOI reports to PHS regarding all FCOI of all Investigators and subrecipient Investigators prior to the expenditure of funds and within sixty days of any subsequently identified FCOI. In cases where Institution identifies a FCOI and eliminates it prior to the expenditure of funds, Institution shall not submit an FCOI report to PHS.
- F. For any financial conflict of interest previously reported by Institution with regard to an ongoing PHS Research Activity, Institution shall provide to PHS an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS Research Activity. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. Institution shall provide annual FCOI reports to PHS for the duration of the project period (including extensions with or without funds) in the time and manner specified by PHS.

VII. MANAGING FCOI

- A. Designated Institutional Official(s) will coordinate the development of any FCOI management plan that may be required by this policy. Such coordination will involve, at a minimum, consultation with the Investigator found to have the potential FCOI and other Institutional officials, as necessary. Management plans will be structured to ensure that the disclosed SFI will not affect the design, conduct, or reporting of the PHS Research Activities and will address, at a minimum, the following:
 - 1. Role and principal duties of the conflicted Investigator in the PHS Research Activities;
 - 2. Conditions of the management plan;
 - 3. How the management plan is designed to safeguard objectivity in the PHS Research Activities;
 - 4. Confirmation of Investigator's agreement to the management plan; and
 - 5. How the management plan will be monitored to ensure investigator compliance.
- B. Examples of conditions or restrictions that might be imposed to manage a potential FCOI include, but are not limited to:
 - 1. Public disclosure of financial conflicts of interest (e.g. when presenting or publishing the research);
 - 2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - 3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the potential FCOI;
 - 4. Modification of the research plan;
 - 5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - 6. Reduction or elimination of the financial interests (e.g., sale of an equity interest); or
 - 7. Severance of relationships that create financial conflicts.

- C. Whenever Institution implements a management plan, Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS Research Activity.
- D. Whenever, in the course of an ongoing PHS Research Activity, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to Institution, Designated Institutional Official shall, within sixty days: review the disclosure of the SFI; determine whether it is related to PHS Research Activity; determine whether a FCOI; 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 FCOI. Depending on the nature of the SFI, an Institution may determine that additional interim measures are necessary with regard to Investigator's participation in the PHS Research Activity between the date of disclosure and the completion of Institution's review.
- E. Whenever Institution identifies a SFI that was not disclosed timely by Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS Research Activity (e.g., was not timely reviewed or reported by a subrecipient), Designated Institutional Official shall, within sixty days: review the SFI; determine whether it is related to PHS Research Activity; determine whether a FCOI 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 FCOI going forward.
- F. Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by Investigator to disclose a SFI that is determined by Institution to constitute a FCOI; failure by Institution to review or manage such a FCOI; or failure by Investigator to comply with a FCOI management plan, Institution shall, within 120 days of Institution's determination of noncompliance, complete a retrospective review of Investigator's activities and the PHS Research Activity to determine whether any PHS Research Activity, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Institution is required to document the retrospective review in accordance with PHS requirements.
- G. Based on the results of the retrospective review, if appropriate, Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Institution will promptly notify the PHS and submit a mitigation report that, at a minimum, documents the key elements of the retrospective review, describes the impact of the bias in the PHS Research Activity, and outlines Institution's plans to eliminate or mitigate the effect of the bias. Thereafter, Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, Institution may determine that additional interim measures are necessary with regard to Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or Investigator's noncompliance is determined and the completion of Institution's retrospective review.

XI. PUBLIC ACCESS AND RETENTION

- A. Institution shall maintain an up-to-date, written, enforced policy on FCOI. Such policy shall be available on the Office of Research and Sponsored Programs website.

- B. Institution is required to respond within five (5) business days to any request for information about SFIs held by Investigators when Institution has determined that the disclosed SFIs are related to PHS Research Activity and constitute FCOIs. Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within sixty (60) days of Institution's identification of a new FCOI, which may subsequently requested by the requestor.
- C. Information concerning the SFI's shall remain available for responses to written requests for three (3) years from the date that the information was most recently updated.
- D. Records of financial disclosures, Designated Institutional Official's determination, and Institution action regarding management of a FCOI will be retained for at least three (3) years beyond the date of submission of the PHS Research Activity's final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

XII. SANCTIONS

- A. Institution anticipates that Investigators will comply fully and promptly with this FCOI policy. In the event of Investigator's failure to comply with this policy, Institution may suspend all relevant activities including suspension of an ongoing research project or take other disciplinary action until the matter is resolved.
- B. Failure by Investigator to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline pursuant to The University of Tulsa Statement on Academic Freedom, Responsibility and Tenure and/or other applicable employee or student disciplinary policies.
- C. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause.
- D. Agreements with subrecipient organizations may be terminated for cause if that organization fails to comply with its obligations under PHS regulations.
- E. Institution will file required reports to the federal sponsor of any violations of federal regulations and Institution policy.

XIII. PHS CONFLICT OF INTEREST REGULATIONS

42 CFR 50 Part F.

<http://grants.nih.gov/grants/policy/coi/index.htm>