

## FINANCIAL CONFLICT OF INTEREST

### **INTRODUCTION**

Consistent with the principles outlined in Texas Christian University Code of Conduct/Conflict of Interest Disclosure Policy Number 2.070 the Associate Provost for Research, and Office of Sponsored Programs is committed to overseeing the conduct of research in a manner that ensures the integrity of the research process and maintains the public trust and that of sponsors in the integrity and credibility of its faculty, its staff, and its research programs. This commitment requires the university to ensure that research results are not biased by any external commitments and financial interests of persons who are responsible for the design, conduct, reporting, or direct administration of university research. In accordance with Texas Christian University, the Associate Provost of Research and Office of Sponsored Programs, Financial Conflicts of Interest Related to Research Policy 1.0, university research personnel will report their external commitments and financial interests in a timely manner and real and apparent financial conflicts of interest of research personnel will be identified and responsibly managed.

### **Reason for Policy/Purpose**

This document sets forth Texas Christian University's Associate Provost for Research and Office of Sponsored Programs policy on the disclosure, review, management and resolution of Significant Financial Conflicts of Interest and pertains to Principal Investigators and their designated Senior/Key Personnel.

This policy is required by, and is intended to establish compliance with, the US Public Health Service (PHS), National Institutes of Health Regulation (42 CFR Part 50, Subpart F) "Promoting Objectivity in Research." It is also intended to establish compliance with the National Science Foundation (NSF) and other granting agencies' policies on Conflict of Interest.

This policy governing financial conflict of interest applies to all externally funded Research Principal Investigators/Project Director, of Texas Christian University. TCU's Research Integrity Officer (RIO), Dr. Bonnie E. Melhart, is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

### **Applicability**

This policy applies to all persons, including TCU employees, TCU undergraduate, graduate or post-doctoral students, subrecipient personnel, collaborators and consultants, who are involved with externally sponsored programs at TCU **and** meet the definition of "Investigator" or "Senior/Key Personnel" as defined below.

### **DEFINITIONS**

*Research* - means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to society, including the sciences, social sciences, and the humanities. The term encompasses basic and applied research and product development (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

*Sponsored Programs* - include both research and other programs that receive external funding based upon competitive proposals submitted to local, state, and federal agencies and other organizations. Grants and contracts are managed through the Office of Sponsored Programs (OSP).

*Clinical Trial* means any research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

*Conflict of Interest Committee (COI Committee)* means the Institution's committee or individual that advises the Institutional Official on conflict of interest matters. The committee consists of the Unit Head/Dean of the Researcher's/Participant's Area/College, the Research Integrity Officer and other experts as needed. **Deans and Department/Unit Heads** are responsible for compliance with and implementation of this policy within their schools or departments. The head of the responsible unit (or designee) is responsible for collaborating with the Investigator, the Principal Investigator, as applicable, and the in the development, completion, and oversight of management plans within their school, department, center, or institute. Office of Sponsored Programs has sample FCOI Management Plans on its website.

*Family* means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

*Financial Interest* means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

*Financial Interest* does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

*Significant Financial Interest* means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or

- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not reimbursed through the Institution.

*Financial Conflict of Interest* means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of Institutional research.

*Institutional official* means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as Dr. Bonnie E. Melhart, Associate Provost of Research.

*Institutional responsibilities* means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

*Investigator* means any individual who is responsible for the design, conduct, or reporting of PHS/NSF sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

*Management Plans.* Actions taken by the institution to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

Management Plans may include a single element or several elements such as:

- Monitoring of the sponsored program by independent researchers or reviewers, or the FCOI Committee or their designee
- Modifications to the research or program plan
- Appointment of an oversight panel or person to review research/scholarship
- Limitations on the employees' involvement in personnel decisions on behalf of PSU
- Divestiture of Significant Financial Interests and/or
- Other arrangements that manage, reduce, or eliminate a potential Financial Conflict of Interest

*Public Health Service* or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

*National Science Foundation* or *NSF* is divided into the following seven directorates that support science and engineering research and education: Biological Sciences, Computer and Information

Science and Engineering, Engineering, Geosciences, Mathematics and Physical Sciences, Social, Behavioral and Economic Sciences, and Education and Human Resources. Each is headed by an assistant director and each is further subdivided into divisions like materials research, ocean sciences and behavioral and cognitive sciences. Some of the divisions within NSF's Office of the Director also support research and researchers. These include the Office of Polar Programs, the Office of Integrative Activities (covering activities that span many areas), the Office of International Science and Engineering and the Office of Cyberinfrastructure. Other sections of NSF are devoted to financial management, award processing and monitoring, legal affairs, outreach and other functions. The Office of the Inspector General examines the foundation's work and reports to the NSB and Congress.

### **CONFLICT OF INTEREST:**

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs faculty about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional official.

#### **1) DISCLOSURE OF FINANCIAL INTERESTS**

All Investigators are required to disclose their outside financial interests to the Institution on an annual and on an ad hoc basis, as described below. The Institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

##### **a) Annual Disclosures**

All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional official or designee by March 1 for the previous calendar year.

##### **b) Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, **within 30 days** of their initial appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year **within thirty (30) days** of discovering or acquiring the Significant Financial Interest.

**c) Travel**

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

**2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL**

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS or NSF-supported research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator is responsible for developing and submitting a proposed management plan, in consultation with the respective Dean or Department/Unit Head and the Institutional Official.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

**3) CLINICAL TRIALS: Please follow the NIH guidelines for clinical trials, and the new requirements for Food and Drug Administration Amendments Act (FDAAA) of 2007 [http://grants.nih.gov/clinicaltrials\\_fdaaa/](http://grants.nih.gov/clinicaltrials_fdaaa/).**

**4) REPORTING TO PHS/NSF**

Should any reported conflict or non-compliance require reporting to PHS/NSF, the Institutional official will report in accordance with PHS/NSF regulations. If the funding for the Research is made available from a prime PHS/NSF-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS/NSF.

**5) INVESTIGATOR NON-COMPLIANCE**

**a) Disciplinary Action**

In the event of an Investigator's failure to comply with this Policy, the Institutional official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

The Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator, and where applicable, the IRB, and will notify the individual of the right to appeal the decision.

#### **b) Retrospective Review**

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional official will update any previously submitted report to the PHS/NSF or the prime PHS/NSF-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS/NSF regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

### **6) TRAINING**

Each Investigator and Senior/Key Personnel must complete training on this Policy through the Collaborative Institutional Training Initiative (CITI) online module prior to engaging in research funded by PHS/NSF-funded grant or contract and at least every 5 years. In addition, training must be completed immediately under the following circumstances:

- TCU FCOI policies change in a manner that affects Investigator requirements.
- An Investigator is new to TCU.
- TCU finds an Investigator noncompliant with the institutional policy or his/her Management Plan.

At the time of training, Investigator and Senior/Key Personnel shall provide acknowledgement that they have read and understand this policy. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is

determined that the Investigator has not complied with this policy or with a management plan related to their activities.

## 7) RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS/NSF or to the prime PHS/NSF awardee.

## 8) CONFIDENTIALITY

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

## 9) PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the Significant Financial Interest is related to the PHS/NSF-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS/NSF policy.

## 10) REGULATORY AUTHORITY

The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the U.S. Federal Government.

U.S. Food and Drug Administration

- [21 CFR Chapter 1, Subchapter A, Part 54, Financial Disclosure by Clinical Investigators](#)

U.S. Department of Education

- [34 CFR Part 74, Subpart C § 74.42, Codes of Conduct](#)

- [34 CFR Part 75, Subpart E § 75.525, Conflict of interest: Participation in a project](#)

U.S. Department of Health and Human Services (Including Public Health Service and National Institutes of Health)

- [42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought.](#)
- [45 CFR Part 94, Responsible Prospective Contractors](#)

National Science Foundation

- [NSF "Investigator Financial Disclosure Policy"](#)
- [NSF "Frequently Asked Questions Concerning the DHHS Objectivity in Research Regulations and the NSF Investigator Financial Disclosure Policy"](#)
- [NSF Proposal and Award Policies and Procedures Guide, January 2011, Part II - Award & Administration Guide, Chapter IV, A. Conflict of Interest Policies](#)
- [NSF Proposal and Award Policies and Procedures Guide, January 2011, Part I - Grant Proposal Guide, Chapter II, C.1.e. Proposal Certifications](#)

TCU shall, for any federal research funding from the PHS/NSF or any other federal funding agency that imposes FCOI requirements:

- Include in the subaward agreement terms that establish whether this policy or that of the subrecipient will apply to the subrecipient's Investigators and provide FCOI reports regarding subrecipient Investigators to the awarding federal funding agency;
- maintain the records of, and related to, FCOI disclosures;
- report conflicting Significant Financial Interest to the awarding component of the funding agency;
- inform the National Science Foundation, Office of the General Counsel if it is unable to satisfactorily manage a Significant Financial Conflict of Interest related to a project funded by NSF;
- report to the NIH the existence of any conflicting Financial Interests and assure that the interest has been managed, reduced, or eliminated in accordance with NIH regulations; and
- maintain records related to Investigator disclosures of Financial Interests and the institution's review of, or response to, such disclosures and all actions under this policy or retrospective review for at least three years from the date of the final expenditure report.